

Table 1025: Listing of all adverse events during treatment - Safety

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
1	Acne	Skin and subcutaneous tissue disorders	2014-08-19	2014-09-17	No	1. recovered/resolved	1	not related	not assessable	No
1	Pneumonitis	Respiratory, thoracic and mediastinal disorders	2015-07-29	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
1	Dizziness	Nervous system disorders	2014-07-22	2014-08-18	No	2. recovering/resolving	2	not related	not assessable	No
1	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-07-29	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
1	Neutropenia	Blood and lymphatic system disorders	2014-07-14	2014-07-21	No	1. recovered/resolved	2	related	not related	No
1	Osteonecrosis of jaw	Musculoskeletal and connective tissue disorders	2015-03-05	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
1	Dizziness	Nervous system disorders	2014-08-19	2014-10-14	No	1. recovered/resolved	1	not related	not related	No
1	Animal bite	Injury, poisoning and procedural complications	2015-04-22	2015-05-26	No	1. recovered/resolved	1	not related	not related	No
1	Leukopenia	Blood and lymphatic system disorders	2014-09-17	2014-10-14	No	1. recovered/resolved	1	related	not assessable	No
1	Pulpitis dental	Infections and infestations	2014-12-29	2014-12-29	No	1. recovered/resolved	2	not related	not related	No
1	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-07-07	2015-07-09	No	1. recovered/resolved	2	related	not related	No
1	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2015-06-24	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
1	C-reactive protein increased	Investigations	2014-10-15	2014-12-10	No	1. recovered/resolved	1	not related	not assessable	No
1	C-reactive protein increased	Investigations	2015-04-02	2015-05-26	No	1. recovered/resolved	1	not related	not related	No
1	Type 2 diabetes mellitus	Metabolism and nutrition disorders	2014-06-30	2014-07-21	No	1. recovered/resolved	3	not related	not related	No
1	Neutropenia	Blood and lymphatic system disorders	2015-01-23	2015-02-05	No	1. recovered/resolved	3	related	not related	No
1	Hyperglycaemia	Metabolism and nutrition disorders	2014-07-14	2014-07-18	No	1. recovered/resolved	3	not related	not assessable	Yes
1	Pneumonitis	Respiratory, thoracic and mediastinal disorders	2015-07-07	2015-08-18	No	1. recovered/resolved	2	related	not related	No
1	Leukopenia	Blood and lymphatic system disorders	2014-07-22	2014-08-18	No	1. recovered/resolved	1	related	not assessable	No
1	Leukopenia	Blood and lymphatic system disorders	2015-04-02	2015-05-26	No	1. recovered/resolved	1	related	related	No
1	Diarrhoea	Gastrointestinal disorders	2015-01-15	2015-01-15	No	1. recovered/resolved	2	not related	not related	No
1	Polyneuropathy	Nervous system disorders	2015-03-05	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
1	Nasopharyngitis	Infections and infestations	2015-02-04	2015-03-04	No	1. recovered/resolved	2	not related	not related	No
1	Localised infection	Infections and infestations	2015-01-15	2015-03-04	No	1. recovered/resolved	2	not related	not related	No
2	Sinusitis	Infections and infestations	2014-10-28	2014-11-04	No	1. recovered/resolved	2	not related	not related	Yes
2	Bronchitis	Infections and infestations	2014-10-28	2014-11-04	No	1. recovered/resolved	2	not related	not related	Yes
2	Nasopharyngitis	Infections and infestations	2014-08-15	2014-09-29	No	3. not recovered/ not resolved	2	not related	not related	No
2	Leukopenia	Blood and lymphatic system disorders	2014-09-12	NA	Yes	1. recovered/resolved	1	related	not related	No
2	Neutropenia	Blood and lymphatic system disorders	2015-01-09	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
2	Insomnia	Psychiatric disorders	2014-08-15	2014-10-05	No	3. not recovered/ not resolved	2	unlikely	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
2	Chronic sinusitis	Infections and infestations	2014-12-09	2014-12-18	No	1. recovered/resolved	2	unlikely	unlikely	Yes
2	Anaemia	Blood and lymphatic system disorders	2014-08-15	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
2	Insomnia	Psychiatric disorders	2014-10-06	2015-02-23	No	1. recovered/resolved	3	unlikely	not assessable	No
2	Respiratory tract infection	Infections and infestations	2014-08-30	2014-09-06	No	1. recovered/resolved	2	possible	possible	Yes
2	Mood altered	Psychiatric disorders	2014-10-06	2014-10-13	No	1. recovered/resolved	3	unlikely	not assessable	No
2	Neutropenia	Blood and lymphatic system disorders	2014-10-14	2014-12-17	No	1. recovered/resolved	2	related	not related	No
2	Night sweats	Skin and subcutaneous tissue disorders	2014-10-06	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
2	Acute sinusitis	Infections and infestations	2014-12-09	2014-12-18	No	1. recovered/resolved	2	unlikely	unlikely	Yes
2	Constipation	Gastrointestinal disorders	2014-08-05	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
2	Polyneuropathy	Nervous system disorders	2014-09-12	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
2	Headache	Nervous system disorders	2014-07-25	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
2	Bronchitis	Infections and infestations	2014-12-09	2014-12-18	No	1. recovered/resolved	2	unlikely	unlikely	Yes
2	Restlessness	Psychiatric disorders	2014-09-08	2014-09-09	No	1. recovered/resolved	3	not related	not related	No
2	Bone pain	Musculoskeletal and connective tissue disorders	2014-10-06	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
2	Palpitations	Cardiac disorders	2014-07-21	2014-07-22	No	1. recovered/resolved	2	not related	not related	No
3	Leukopenia	Blood and lymphatic system disorders	2014-11-19	2014-12-17	No	3. not recovered/ not resolved	2	related	related	No
3	Neutropenia	Blood and lymphatic system disorders	2014-11-19	2014-12-17	No	3. not recovered/ not resolved	2	related	related	No
3	Fatigue	General disorders and administration site conditions	2014-07-29	2015-01-14	No	3. not recovered/ not resolved	1	related	not related	No
3	Leukopenia	Blood and lymphatic system disorders	2014-12-18	2015-01-14	No	1. recovered/resolved	1	related	not related	No
3	Post herpetic neuralgia	Nervous system disorders	2014-12-12	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
3	Anaemia	Blood and lymphatic system disorders	2014-10-22	2014-11-18	No	1. recovered/resolved	1	not related	not related	No
3	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-22	2014-12-17	No	1. recovered/resolved	1	related	related	No
3	Neutropenia	Blood and lymphatic system disorders	2014-12-18	2015-01-14	No	1. recovered/resolved	1	related	not related	No
3	Fatigue	General disorders and administration site conditions	2015-01-15	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
3	Neutropenia	Blood and lymphatic system disorders	2014-09-24	2014-10-21	No	1. recovered/resolved	1	related	not related	No
3	Vision blurred	Eye disorders	2014-09-04	2014-09-23	No	1. recovered/resolved	1	not related	not related	No
3	Leukopenia	Blood and lymphatic system disorders	2014-07-31	2014-09-03	No	1. recovered/resolved	1	related	not related	No
3	Upper respiratory tract infection	Infections and infestations	2014-11-28	2014-12-07	No	1. recovered/resolved	2	related	not related	No
3	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2014-11-19	2015-02-01	No	1. recovered/resolved	2	related	not related	No
3	Neutropenia	Blood and lymphatic system disorders	2014-07-31	2014-09-03	No	1. recovered/resolved	1	related	not related	No

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ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
3	Herpes zoster	Infections and infestations	2014-12-04	2014-12-11	No	1. recovered/resolved	2	not related	not related	No
3	Leukopenia	Blood and lymphatic system disorders	2014-09-24	2014-10-21	No	1. recovered/resolved	1	related	not related	No
3	Anaemia	Blood and lymphatic system disorders	2014-12-18	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
3	Anaemia	Blood and lymphatic system disorders	2014-09-04	2014-09-23	No	1. recovered/resolved	1	not related	not related	No
4	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-17	NA	Yes	3. not recovered/ not resolved	4	related	not related	No
4	Infection	Infections and infestations	2014-10-27	2014-11-16	No	1. recovered/resolved	2	related	not assessable	No
4	Psychiatric symptom	Psychiatric disorders	2014-07-05	2014-07-06	No	1. recovered/resolved	3	not related	not assessable	No
4	Distractibility	Psychiatric disorders	2014-08-27	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
4	Herpes simplex	Infections and infestations	2014-10-27	2014-11-16	No	1. recovered/resolved	2	not related	not assessable	No
4	Dyspepsia	Gastrointestinal disorders	2014-08-27	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
4	Oral herpes	Infections and infestations	2014-07-11	2014-07-29	No	1. recovered/resolved	1	not related	not assessable	No
4	Anaemia	Blood and lymphatic system disorders	2014-12-19	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
4	Fatigue	General disorders and administration site conditions	2014-07-08	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
4	Leukopenia	Blood and lymphatic system disorders	2014-11-17	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
4	Nausea	Gastrointestinal disorders	2014-07-08	2014-07-10	No	3. not recovered/ not resolved	2	related	not related	No
4	Neutropenia	Blood and lymphatic system disorders	2014-08-27	2014-09-23	No	3. not recovered/ not resolved	2	related	not related	No
4	Anaemia	Blood and lymphatic system disorders	2014-07-30	2014-08-26	No	3. not recovered/ not resolved	1	not related	not related	No
4	Neutropenia	Blood and lymphatic system disorders	2014-07-14	2014-07-29	No	1. recovered/resolved	3	related	not assessable	No
4	Thrombocytopenia	Blood and lymphatic system disorders	2014-09-24	2014-10-21	No	3. not recovered/ not resolved	2	related	not related	No
4	Anaemia	Blood and lymphatic system disorders	2014-08-27	2014-10-21	No	3. not recovered/ not resolved	2	not related	not related	No
4	Dizziness	Nervous system disorders	2014-08-27	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
4	Nausea	Gastrointestinal disorders	2014-07-11	2014-07-29	No	1. recovered/resolved	1	probable	not assessable	No
4	Dysgeusia	Nervous system disorders	2014-07-11	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
4	Leukopenia	Blood and lymphatic system disorders	2014-08-27	2014-10-21	No	1. recovered/resolved	2	related	not related	No
4	Anaemia	Blood and lymphatic system disorders	2014-11-17	2014-12-18	No	3. not recovered/ not resolved	3	related	not related	No
4	Leukopenia	Blood and lymphatic system disorders	2014-07-30	2014-08-26	No	3. not recovered/ not resolved	1	related	not related	No
4	Oedema peripheral	General disorders and administration site conditions	2014-08-27	2014-09-23	No	1. recovered/resolved	1	not related	not assessable	No
4	Neutropenia	Blood and lymphatic system disorders	2014-09-24	2014-10-21	No	1. recovered/resolved	3	related	not related	No
4	Anaemia	Blood and lymphatic system disorders	2014-10-22	2014-11-16	No	3. not recovered/ not resolved	1	not related	not related	No
4	Polyneuropathy	Nervous system disorders	2014-08-27	2014-09-23	No	1. recovered/resolved	1	not related	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
4	Neutropenia	Blood and lymphatic system disorders	2014-11-17	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
4	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-22	2014-11-17	No	3. not recovered/ not resolved	3	related	not related	No
5	Nausea	Gastrointestinal disorders	2014-07-26	2014-08-24	No	1. recovered/resolved	2	related	not related	No
5	Anaemia	Blood and lymphatic system disorders	2014-11-20	2015-01-18	No	3. not recovered/ not resolved	2	related	related	No
5	Abdominal pain	Gastrointestinal disorders	2014-10-06	2014-10-20	No	1. recovered/resolved	2	related	not related	No
5	Insomnia	Psychiatric disorders	2014-08-25	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-09-17	2014-10-05	No	1. recovered/resolved	1	not related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2015-01-19	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
5	Anaemia	Blood and lymphatic system disorders	2014-08-18	2014-09-16	No	3. not recovered/ not resolved	3	not related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-12-11	2014-12-17	No	1. recovered/resolved	4	related	related	No
5	Weight decreased	Investigations	2014-12-18	2015-01-04	No	3. not recovered/ not resolved	1	not related	not related	No
5	Anaemia	Blood and lymphatic system disorders	2014-10-21	2014-11-19	No	3. not recovered/ not resolved	3	not related	not related	No
5	Leukopenia	Blood and lymphatic system disorders	2014-09-17	2014-10-20	No	1. recovered/resolved	1	not related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-21	2014-11-05	No	3. not recovered/ not resolved	2	not related	not related	No
5	Myalgia	Musculoskeletal and connective tissue disorders	2014-08-25	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
5	Dizziness	Nervous system disorders	2014-07-26	2014-10-20	No	1. recovered/resolved	2	related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-10-06	2014-10-20	No	2. recovering/resolving	3	related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-10-06	2014-10-20	No	2. recovering/resolving	3	related	not related	No
5	Epistaxis	Respiratory, thoracic and mediastinal disorders	2014-12-08	NA	Yes	3. not recovered/ not resolved	2	related	related	No
5	Abdominal pain	Gastrointestinal disorders	2014-07-26	2014-08-17	No	3. not recovered/ not resolved	3	related	not related	No
5	Asthenia	General disorders and administration site conditions	2014-11-20	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
5	Visual impairment	Eye disorders	2014-08-25	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
5	Asthenia	General disorders and administration site conditions	2014-09-07	2014-11-19	No	3. not recovered/ not resolved	2	related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-06	2014-11-09	No	3. not recovered/ not resolved	3	not related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-23	2014-12-28	No	3. not recovered/ not resolved	3	not related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-08-04	2014-08-17	No	3. not recovered/ not resolved	4	not related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-09-08	2014-10-20	No	3. not recovered/ not resolved	3	not related	not related	No
5	Weight decreased	Investigations	2015-01-05	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
5	Muscle spasms	Musculoskeletal and connective tissue disorders	2014-10-06	2014-10-20	No	1. recovered/resolved	2	related	not related	No
5	Anaemia	Blood and lymphatic system disorders	2015-01-19	NA	Yes	3. not recovered/ not resolved	3	not related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
5	Diarrhoea	Gastrointestinal disorders	2015-01-02	2015-01-05	No	1. recovered/resolved	2	not related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-10	2014-12-22	No	3. not recovered/ not resolved	4	not related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-29	NA	Yes	3. not recovered/ not resolved	4	not related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-08-18	2014-09-16	No	3. not recovered/ not resolved	3	not related	not related	No
5	Anaemia	Blood and lymphatic system disorders	2014-09-17	2014-10-20	No	3. not recovered/ not resolved	2	not related	not related	No
5	Thrombocytopenia	Blood and lymphatic system disorders	2014-08-18	2014-09-07	No	3. not recovered/ not resolved	1	not related	not related	No
5	Hyperhidrosis	Skin and subcutaneous tissue disorders	2014-09-19	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
5	Abdominal pain upper	Gastrointestinal disorders	2014-08-18	2014-08-24	No	1. recovered/resolved	3	not related	not assessable	No
5	Neutropenia	Blood and lymphatic system disorders	2014-11-24	2014-12-04	No	3. not recovered/ not resolved	4	related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-12-29	2015-01-04	No	1. recovered/resolved	4	related	related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-10-12	2014-11-19	No	1. recovered/resolved	1	related	not related	No
5	Neutropenia	Blood and lymphatic system disorders	2014-08-04	2014-08-17	No	2. recovering/resolving	4	related	not related	No
5	Nausea	Gastrointestinal disorders	2014-10-21	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
5	Fatigue	General disorders and administration site conditions	2014-11-10	NA	Yes	3. not recovered/ not resolved	3	not related	not related	No
5	Bone pain	Musculoskeletal and connective tissue disorders	2014-08-18	2014-10-20	No	1. recovered/resolved	2	not related	not related	No
6	Upper respiratory tract infection	Respiratory, thoracic and mediastinal disorders	2015-03-19	2015-03-23	No	1. recovered/resolved	2	possible	possible	No
6	Pain in extremity	Musculoskeletal and connective tissue disorders	2014-11-15	2014-12-15	No	1. recovered/resolved	1	unlikely	unlikely	No
6	Leukopenia	Blood and lymphatic system disorders	2014-08-18	2014-08-25	No	1. recovered/resolved	1	probable	NA	No
6	White blood cell count decreased	Investigations	2014-10-30	2014-11-03	No	1. recovered/resolved	1	probable	NA	No
6	White blood cell count decreased	Investigations	2015-05-19	2015-05-21	No	2. recovering/resolving	2	probable	probable	No
6	Neutrophil count decreased	Investigations	2014-11-27	2014-12-08	No	1. recovered/resolved	1	possible	possible	No
6	Paraesthesia	Nervous system disorders	2015-01-13	2015-01-15	No	1. recovered/resolved	1	possible	possible	No
6	Neutrophil count decreased	Investigations	2015-05-12	2015-05-21	No	2. recovering/resolving	3	probable	probable	No
6	Flatulence	Gastrointestinal disorders	2014-10-15	2016-02-29	No	3. not recovered/ not resolved	1	possible	NA	No
6	White blood cell count decreased	Investigations	2015-04-15	2015-04-20	No	1. recovered/resolved	3	probable	probable	No
6	White blood cell count decreased	Investigations	2014-12-15	2015-01-22	No	3. not recovered/ not resolved	1	possible	possible	No
6	Muscle spasms	Musculoskeletal and connective tissue disorders	2014-08-15	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
6	Headache	Nervous system disorders	2015-01-15	2015-01-15	No	1. recovered/resolved	2	possible	possible	No
6	Blood thyroid stimulating hormone increased	Investigations	2015-01-22	2015-03-19	No	1. recovered/resolved	1	unlikely	unlikely	No
6	Glossodynia	Gastrointestinal disorders	2014-08-15	2014-10-15	No	1. recovered/resolved	1	possible	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
6	White blood cell count decreased	Investigations	2015-01-22	2015-02-09	No	2. recovering/resolving	2	possible	possible	No
6	Lip infection	Infections and infestations	2015-01-15	2015-02-15	No	1. recovered/resolved	1	possible	possible	No
6	Lymphocyte count decreased	Investigations	2015-03-23	2015-04-15	No	3. not recovered/ not resolved	1	possible	possible	No
6	Neutrophil count decreased	Investigations	2015-02-19	2015-02-23	No	3. not recovered/ not resolved	2	possible	possible	No
6	White blood cell count decreased	Investigations	2015-09-07	2016-02-29	No	3. not recovered/ not resolved	1	probable	NA	No
6	Lymphocyte count decreased	Investigations	2015-02-19	2015-03-09	No	1. recovered/resolved	2	possible	possible	No
6	Paraesthesia oral	Gastrointestinal disorders	2015-01-13	2015-01-15	No	1. recovered/resolved	1	possible	possible	No
6	White blood cell count decreased	Investigations	2014-10-02	2014-10-06	No	3. not recovered/ not resolved	1	probable	NA	No
6	Nasopharyngitis	Infections and infestations	2015-02-15	2015-03-15	No	1. recovered/resolved	1	possible	possible	No
6	Nasopharyngitis	Infections and infestations	2014-10-15	2014-11-15	No	1. recovered/resolved	2	possible	NA	No
6	White blood cell count decreased	Investigations	2015-02-23	2015-03-03	No	1. recovered/resolved	1	possible	possible	No
6	White blood cell count decreased	Investigations	2015-02-09	2015-02-19	No	3. not recovered/ not resolved	1	possible	possible	No
6	Nasopharyngitis	Infections and infestations	2014-11-15	2014-12-02	No	1. recovered/resolved	1	possible	possible	No
6	Neutrophil count decreased	Investigations	2015-04-15	2015-04-20	No	1. recovered/resolved	4	probable	probable	No
6	Pain in extremity	Musculoskeletal and connective tissue disorders	2015-08-24	2016-02-29	No	3. not recovered/ not resolved	1	unlikely	NA	No
6	Platelet count decreased	Investigations	2014-08-25	2014-09-05	No	1. recovered/resolved	2	probable	NA	No
6	Inflammation	General disorders and administration site conditions	2015-08-13	2016-02-29	No	3. not recovered/ not resolved	1	unlikely	NA	No
6	White blood cell count decreased	Investigations	2015-03-19	2015-04-15	No	3. not recovered/ not resolved	2	probable	probable	No
6	Lymphocyte count decreased	Investigations	2015-04-15	2015-04-20	No	1. recovered/resolved	3	probable	probable	No
6	Neutrophil count decreased	Investigations	2014-09-29	2014-10-02	No	1. recovered/resolved	3	probable	NA	No
6	Neutrophil count decreased	Investigations	2014-12-30	2015-01-12	No	1. recovered/resolved	2	possible	possible	No
6	Neutrophil count decreased	Investigations	2015-09-08	2016-02-29	No	3. not recovered/ not resolved	3	probable	NA	No
6	White blood cell count decreased	Investigations	2014-12-08	2014-12-15	No	2. recovering/resolving	2	possible	possible	No
6	Neutrophil count decreased	Investigations	2015-03-23	2015-04-15	No	3. not recovered/ not resolved	3	probable	possible	No
6	Lymphocyte count decreased	Investigations	2015-03-19	2015-03-23	No	2. recovering/resolving	2	possible	possible	No
6	Fatigue	General disorders and administration site conditions	2015-01-15	2015-01-15	No	2. recovering/resolving	3	possible	possible	No
6	Arthralgia	Musculoskeletal and connective tissue disorders	2014-12-15	NA	Yes	3. not recovered/ not resolved	1	unlikely	unlikely	No
6	Fatigue	General disorders and administration site conditions	2014-09-15	2014-12-02	No	1. recovered/resolved	1	possible	possible	No
6	Hypokalaemia	Metabolism and nutrition disorders	2014-10-30	2014-11-06	No	1. recovered/resolved	1	possible	NA	No
6	Constipation	Gastrointestinal disorders	2014-09-15	2016-02-29	No	3. not recovered/ not resolved	2	possible	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
6	Neutrophil count decreased	Investigations	2014-11-24	2014-11-27	No	2. recovering/resolving	3	possible	possible	No
6	Lymphocyte count decreased	Investigations	2014-12-30	2015-01-22	No	3. not recovered/ not resolved	1	possible	possible	No
6	White blood cell count decreased	Investigations	2014-10-06	2014-10-30	No	2. recovering/resolving	2	probable	NA	No
6	Cough	Respiratory, thoracic and mediastinal disorders	2014-11-06	2014-11-15	No	1. recovered/resolved	1	unlikely	possible	No
6	White blood cell count decreased	Investigations	2015-02-19	2015-02-23	No	2. recovering/resolving	2	possible	possible	No
6	Night sweats	Skin and subcutaneous tissue disorders	2014-11-06	2015-06-17	No	1. recovered/resolved	1	possible	possible	No
6	Neutrophil count decreased	Investigations	2014-10-30	2014-11-03	No	1. recovered/resolved	2	probable	NA	No
6	Platelet count decreased	Investigations	2015-04-15	2015-04-20	No	2. recovering/resolving	2	probable	probable	No
6	Dyspepsia	Gastrointestinal disorders	2014-12-15	2016-02-29	No	3. not recovered/ not resolved	1	possible	possible	No
6	Leukopenia	Blood and lymphatic system disorders	2014-09-05	2014-09-08	No	1. recovered/resolved	2	probable	NA	No
6	Sensation of foreign body	General disorders and administration site conditions	2014-12-15	2014-12-15	No	1. recovered/resolved	1	unlikely	possible	No
6	Lymphocyte count decreased	Investigations	2015-01-22	2015-01-27	No	1. recovered/resolved	2	possible	possible	No
6	White blood cell count decreased	Investigations	2014-11-10	2014-11-27	No	1. recovered/resolved	1	possible	possible	No
6	Cough	Respiratory, thoracic and mediastinal disorders	2015-06-17	2015-07-16	No	1. recovered/resolved	1	possible	NA	No
6	Neutrophil count decreased	Investigations	2014-09-05	2014-09-08	No	1. recovered/resolved	3	probable	NA	No
6	Neutrophil count decreased	Investigations	2014-09-08	2014-09-15	No	1. recovered/resolved	2	possible	NA	No
6	Fatigue	General disorders and administration site conditions	2015-02-15	2016-02-29	No	3. not recovered/ not resolved	3	possible	possible	No
6	Fatigue	General disorders and administration site conditions	2015-01-27	2015-02-15	No	1. recovered/resolved	1	possible	possible	No
6	Blood urea increased	Investigations	2014-10-02	2015-06-17	No	1. recovered/resolved	1	possible	NA	No
6	Neutrophil count decreased	Investigations	2015-02-23	2015-03-09	No	1. recovered/resolved	3	possible	possible	No
6	Neutrophil count decreased	Investigations	2015-03-19	2015-03-23	No	3. not recovered/ not resolved	1	possible	possible	No
6	Abdominal discomfort	Gastrointestinal disorders	2014-08-15	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
6	Neutrophil count decreased	Investigations	2015-05-21	2015-06-17	No	1. recovered/resolved	2	probable	NA	No
6	Diarrhoea	Gastrointestinal disorders	2015-08-13	2016-02-29	No	3. not recovered/ not resolved	1	unlikely	NA	No
6	Leukopenia	Blood and lymphatic system disorders	2014-09-29	2014-10-02	No	1. recovered/resolved	2	probable	NA	No
6	Paraesthesia	Nervous system disorders	2015-08-24	2016-02-29	No	3. not recovered/ not resolved	1	possible	NA	No
6	White blood cell count decreased	Investigations	2015-05-21	2015-06-17	No	1. recovered/resolved	1	probable	probable	No
6	Neutrophil count decreased	Investigations	2014-10-02	2014-10-06	No	1. recovered/resolved	1	probable	not related	No
6	Neutrophil count decreased	Investigations	2015-01-22	2015-02-09	No	1. recovered/resolved	3	possible	possible	No
7	Head discomfort	Nervous system disorders	2015-02-15	2015-04-15	No	1. recovered/resolved	1	unlikely	unlikely	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
7	Nausea	Gastrointestinal disorders	2014-11-03	2014-11-07	No	1. recovered/resolved	3	unlikely	probable	No
7	Diarrhoea	Gastrointestinal disorders	2014-11-04	2014-11-07	No	1. recovered/resolved	2	unlikely	probable	No
7	Neutrophil count decreased	Investigations	2015-10-01	2015-10-29	No	3. not recovered/ not resolved	1	probable	NA	No
7	Fatigue	General disorders and administration site conditions	2014-11-03	2014-11-07	No	1. recovered/resolved	3	unlikely	probable	No
7	Leukopenia	Blood and lymphatic system disorders	2014-08-29	2014-09-08	No	1. recovered/resolved	1	probable	NA	No
7	Diarrhoea	Gastrointestinal disorders	2015-05-26	2015-05-26	No	1. recovered/resolved	1	unlikely	unlikely	No
7	Diarrhoea	Gastrointestinal disorders	2015-02-15	2015-04-15	No	1. recovered/resolved	1	unlikely	unlikely	No
7	White blood cell count decreased	Investigations	2014-12-01	2014-12-15	No	1. recovered/resolved	1	probable	possible	No
7	Pain	General disorders and administration site conditions	2014-10-23	2014-11-15	No	1. recovered/resolved	3	unlikely	NA	No
7	Anaemia	Blood and lymphatic system disorders	2014-11-17	2015-02-18	No	3. not recovered/ not resolved	1	possible	possible	No
7	Neutropenia	Blood and lymphatic system disorders	2014-11-26	2014-12-15	No	2. recovering/resolving	2	possible	possible	No
7	Blood urea increased	Investigations	2015-07-03	2015-08-04	No	1. recovered/resolved	1	possible	NA	No
7	Renal pain	Renal and urinary disorders	2014-11-03	2014-11-07	No	1. recovered/resolved	3	unlikely	possible	No
7	Anaemia	Blood and lymphatic system disorders	2015-09-30	NA	Yes	NA	1	possible	NA	No
7	Neutrophil count decreased	Investigations	2015-09-30	2015-10-01	No	2. recovering/resolving	2	probable	NA	No
7	Neuralgia	Nervous system disorders	2014-08-15	2014-11-15	No	1. recovered/resolved	3	unlikely	NA	No
7	Neutrophil count decreased	Investigations	2015-06-03	2015-07-02	No	3. not recovered/ not resolved	1	possible	possible	No
7	White blood cell count decreased	Investigations	2015-01-21	2015-01-27	No	1. recovered/resolved	1	probable	possible	No
7	Neutrophil count decreased	Investigations	2015-10-29	NA	NA	NA	2	probable	NA	No
7	Agitation	Psychiatric disorders	2015-02-15	2015-04-15	No	1. recovered/resolved	1	unlikely	unlikely	No
7	Limb discomfort	Musculoskeletal and connective tissue disorders	2015-10-29	NA	NA	NA	1	unlikely	NA	No
7	Blood urea increased	Investigations	2015-02-18	2015-04-14	No	1. recovered/resolved	1	possible	possible	No
7	Neutrophil count decreased	Investigations	2015-07-03	2015-08-03	No	2. recovering/resolving	3	probable	NA	No
7	Neutrophil count decreased	Investigations	2015-08-03	2015-08-04	No	1. recovered/resolved	1	probable	NA	No
7	Hypertension	Vascular disorders	2015-06-03	2015-06-22	No	1. recovered/resolved	3	possible	possible	No
7	Hyperkalaemia	Metabolism and nutrition disorders	2015-01-21	2015-02-09	No	1. recovered/resolved	1	possible	possible	No
7	Nasopharyngitis	Infections and infestations	2015-02-23	NA	No	1. recovered/resolved	1	possible	possible	No
7	Urinary tract infection	Infections and infestations	2015-10-29	NA	NA	NA	1	possible	NA	No
7	Hyperkalaemia	Metabolism and nutrition disorders	2015-08-04	2015-09-02	No	1. recovered/resolved	1	possible	NA	No
7	Anaemia	Blood and lymphatic system disorders	2015-02-18	2015-03-09	No	2. recovering/resolving	2	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
7	White blood cell count decreased	Investigations	2014-12-29	2014-12-30	No	1. recovered/resolved	1	probable	possible	No
7	Incontinence	Renal and urinary disorders	2015-02-15	2015-04-15	No	1. recovered/resolved	1	unlikely	unlikely	No
7	Anaemia	Blood and lymphatic system disorders	2015-03-23	2015-04-08	No	2. recovering/resolving	2	possible	possible	No
7	Blood urea increased	Investigations	2014-10-27	2014-11-26	No	1. recovered/resolved	1	possible	NA	No
7	Dyspepsia	Gastrointestinal disorders	2015-02-15	2015-04-15	No	1. recovered/resolved	1	unlikely	unlikely	No
7	Decreased appetite	Metabolism and nutrition disorders	2014-11-15	2014-12-30	No	1. recovered/resolved	1	unlikely	possible	No
7	Neutrophil count decreased	Investigations	2015-07-02	2015-07-03	No	3. not recovered/ not resolved	2	probable	NA	No
7	Anaemia	Blood and lymphatic system disorders	2015-04-08	2015-09-02	No	1. recovered/resolved	1	possible	possible	No
7	Gamma-glutamyltransferase increased	Investigations	2014-11-10	2014-11-17	No	1. recovered/resolved	1	possible	possible	No
7	Neutrophil count decreased	Investigations	2015-05-07	2015-05-11	No	1. recovered/resolved	3	possible	possible	No
7	Oedema	General disorders and administration site conditions	2015-02-15	2015-04-15	No	1. recovered/resolved	1	unlikely	unlikely	No
7	Neck pain	Musculoskeletal and connective tissue disorders	2014-09-15	2014-11-15	No	1. recovered/resolved	1	unlikely	NA	No
7	Swelling face	Skin and subcutaneous tissue disorders	2014-12-15	2014-12-15	No	1. recovered/resolved	2	possible	possible	No
7	Anaemia	Blood and lymphatic system disorders	2014-10-23	2014-11-10	No	1. recovered/resolved	1	possible	NA	No
7	Weight fluctuation	Metabolism and nutrition disorders	2014-10-15	2014-10-15	No	1. recovered/resolved	1	unlikely	NA	No
7	Hyperkalaemia	Metabolism and nutrition disorders	2015-05-07	2015-06-03	No	1. recovered/resolved	1	possible	possible	No
7	Anaemia	Blood and lymphatic system disorders	2014-09-15	2014-09-26	No	1. recovered/resolved	1	possible	NA	No
7	Blood urea increased	Investigations	2015-02-18	2015-04-14	No	1. recovered/resolved	1	possible	possible	No
7	Nasopharyngitis	Infections and infestations	2014-10-15	2014-10-15	No	1. recovered/resolved	1	possible	NA	No
7	Abdominal pain upper	Gastrointestinal disorders	2015-09-25	NA	NA	NA	1	possible	NA	No
7	Proteinuria	Renal and urinary disorders	2015-04-14	NA	Yes	NA	2	unlikely	unlikely	No
7	White blood cell count decreased	Investigations	2015-04-08	2015-04-13	No	1. recovered/resolved	1	probable	possible	No
7	Neutropenia	Blood and lymphatic system disorders	2014-12-15	2014-12-30	No	1. recovered/resolved	1	possible	possible	No
7	White blood cell count decreased	Investigations	2015-07-02	2015-08-04	No	1. recovered/resolved	1	probable	NA	No
7	White blood cell count decreased	Investigations	2015-05-11	2015-06-03	No	1. recovered/resolved	1	probable	possible	No
7	White blood cell count decreased	Investigations	2015-09-30	NA	Yes	NA	1	possible	NA	No
7	Palpitations	Cardiac disorders	2015-02-15	2015-04-14	No	1. recovered/resolved	1	possible	unlikely	No
7	Fatigue	General disorders and administration site conditions	2015-09-29	NA	NA	NA	1	possible	NA	No
7	Neutrophil count decreased	Investigations	2015-04-08	2015-04-13	No	1. recovered/resolved	2	possible	possible	No
7	White blood cell count decreased	Investigations	2015-05-07	2015-05-11	No	2. recovering/resolving	2	probable	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
7	Abdominal pain upper	Gastrointestinal disorders	2015-05-26	2015-05-26	No	1. recovered/resolved	1	unlikely	unlikely	No
7	Paraesthesia	Nervous system disorders	2015-10-29	NA	NA	NA	1	possible	NA	No
8	Leukopenia	Blood and lymphatic system disorders	2015-06-05	2015-07-02	No	1. recovered/resolved	2	related	related	No
8	C-reactive protein increased	Investigations	2015-04-08	2015-06-04	No	1. recovered/resolved	2	not related	not related	No
8	Pneumocystis jirovecii pneumonia	Infections and infestations	2015-02-01	2015-02-25	No	1. recovered/resolved	3	possible	possible	Yes
8	Asthenia	General disorders and administration site conditions	2015-03-13	2015-05-05	No	1. recovered/resolved	2	not related	not related	No
8	C-reactive protein increased	Investigations	2014-10-29	2014-11-25	No	1. recovered/resolved	1	not related	not related	No
8	Infection	Infections and infestations	2015-04-01	2015-05-05	No	1. recovered/resolved	2	related	related	No
8	Erythema	Skin and subcutaneous tissue disorders	2015-06-05	2015-07-30	No	1. recovered/resolved	1	not related	not related	No
8	Nasopharyngitis	Infections and infestations	2014-10-04	2014-10-17	No	1. recovered/resolved	1	not related	not related	No
8	Polyneuropathy	Nervous system disorders	2015-03-13	2015-05-05	No	1. recovered/resolved	1	not related	not related	No
8	Mucosal inflammation	General disorders and administration site conditions	2015-06-05	2015-07-02	No	1. recovered/resolved	1	related	related	No
8	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2015-04-08	2015-05-05	No	1. recovered/resolved	2	not related	not related	No
8	Neutropenia	Blood and lymphatic system disorders	2014-12-29	2015-03-12	No	1. recovered/resolved	3	related	not related	No
8	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2014-10-01	2014-11-26	No	3. not recovered/ not resolved	1	not related	not related	No
8	Acute myocardial infarction	Cardiac disorders	2014-12-21	2014-12-23	No	1. recovered/resolved	4	unlikely	unlikely	Yes
8	Nasopharyngitis	Infections and infestations	2015-12-18	2016-01-14	No	1. recovered/resolved	1	not related	not assessable	No
8	C-reactive protein increased	Investigations	2015-01-12	2015-01-18	No	1. recovered/resolved	1	not related	not related	No
8	Hypotonia	Nervous system disorders	2015-01-22	2015-03-12	No	1. recovered/resolved	1	related	not related	No
8	Leukopenia	Blood and lymphatic system disorders	2014-12-29	2015-03-12	No	1. recovered/resolved	3	related	not related	No
8	Cataract	Eye disorders	2014-11-27	2015-12-18	No	1. recovered/resolved	2	not related	not related	No
8	Muscle spasms	Musculoskeletal and connective tissue disorders	2015-10-27	2015-11-19	No	1. recovered/resolved	2	related	not related	No
8	Leukopenia	Blood and lymphatic system disorders	2014-10-29	2014-11-25	No	2. recovering/resolving	2	related	not related	No
8	Fatigue	General disorders and administration site conditions	2014-10-20	2014-10-28	No	1. recovered/resolved	1	related	not related	No
8	Polyneuropathy	Nervous system disorders	2015-07-31	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
8	Infection	Infections and infestations	2014-11-17	2014-11-27	No	1. recovered/resolved	2	related	not related	No
8	Hypotonia	Nervous system disorders	2014-12-29	2015-01-16	No	3. not recovered/ not resolved	3	related	not related	No
8	Bronchitis	Infections and infestations	2014-12-22	2014-12-28	No	1. recovered/resolved	2	related	related	No
8	Polyneuropathy	Nervous system disorders	2014-10-01	2014-11-26	No	1. recovered/resolved	1	not related	not related	No
8	Insomnia	Psychiatric disorders	2014-10-01	2015-07-03	No	1. recovered/resolved	2	not related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
8	Cataract	Eye disorders	2015-05-07	2015-05-07	No	1. recovered/resolved	2	not related	not related	No
8	Bronchial disorder	Respiratory, thoracic and mediastinal disorders	2014-10-18	2014-11-26	No	1. recovered/resolved	1	not related	not related	No
8	Anaemia	Blood and lymphatic system disorders	2014-11-26	2015-01-20	No	2. recovering/resolving	2	related	related	No
9	Neutrophil count decreased	Investigations	2014-10-21	2014-11-10	No	1. recovered/resolved	3	possible	possible	No
9	Oedema peripheral	General disorders and administration site conditions	2014-09-15	NA	Yes	NA	2	possible	NA	No
9	Neutrophil count decreased	Investigations	2014-11-18	2014-11-25	No	3. not recovered/ not resolved	1	possible	possible	No
9	Anaemia	Blood and lymphatic system disorders	2014-12-04	2014-12-11	No	1. recovered/resolved	2	possible	possible	No
9	Anaemia	Blood and lymphatic system disorders	2015-01-19	2015-01-29	No	2. recovering/resolving	3	possible	possible	No
9	Neutrophil count decreased	Investigations	2014-12-24	2015-01-01	No	1. recovered/resolved	2	possible	possible	No
9	White blood cell count decreased	Investigations	2014-10-21	2014-10-28	No	3. not recovered/ not resolved	1	possible	possible	No
9	Neutrophil count decreased	Investigations	2014-09-24	2014-10-06	No	1. recovered/resolved	3	probable	NA	No
9	Lymphocyte count decreased	Investigations	2014-10-01	2014-11-03	No	3. not recovered/ not resolved	2	possible	NA	No
9	Platelet count decreased	Investigations	2014-09-10	2014-10-13	No	1. recovered/resolved	1	probable	NA	No
9	White blood cell count decreased	Investigations	2014-10-30	2014-11-10	No	1. recovered/resolved	3	possible	possible	No
9	Neutrophil count decreased	Investigations	2014-11-25	2014-12-04	No	1. recovered/resolved	3	possible	possible	No
9	Chills	General disorders and administration site conditions	2014-11-19	2014-11-20	No	1. recovered/resolved	1	possible	possible	No
9	White blood cell count decreased	Investigations	2015-01-01	2015-01-29	No	1. recovered/resolved	2	possible	possible	No
9	Respiratory tract infection	Infections and infestations	2014-10-14	2014-11-15	No	1. recovered/resolved	1	possible	NA	No
9	Lymphocyte count decreased	Investigations	2014-12-04	2014-12-09	No	2. recovering/resolving	2	possible	possible	No
9	White blood cell count decreased	Investigations	2014-10-01	2014-10-06	No	1. recovered/resolved	3	probable	NA	No
9	Lymphocyte count decreased	Investigations	2014-12-09	2014-12-11	No	3. not recovered/ not resolved	1	possible	possible	No
9	Cough	Respiratory, thoracic and mediastinal disorders	2014-10-14	2014-11-15	No	1. recovered/resolved	1	possible	NA	No
9	Body temperature increased	Investigations	2014-09-15	NA	Yes	1. recovered/resolved	1	possible	NA	No
9	Lymphocyte count decreased	Investigations	2014-11-03	2014-11-25	No	1. recovered/resolved	3	possible	possible	No
9	Pneumonia	Infections and infestations	2015-01-01	2015-01-20	No	1. recovered/resolved	3	possible	possible	Yes
9	Platelet count decreased	Investigations	2014-10-21	2014-12-09	No	1. recovered/resolved	1	possible	possible	No
9	Anaemia	Blood and lymphatic system disorders	2014-12-24	2015-01-19	No	3. not recovered/ not resolved	2	possible	possible	No
9	Rib fracture	Injury, poisoning and procedural complications	2015-01-15	NA	Yes	3. not recovered/ not resolved	3	unlikely	unlikely	No
9	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2014-09-15	NA	Yes	NA	1	possible	NA	No
9	Neutrophil count decreased	Investigations	2014-09-10	2014-09-17	No	1. recovered/resolved	3	probable	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
9	Lymphocyte count decreased	Investigations	2014-12-11	2015-01-01	No	2. recovering/resolving	4	possible	possible	No
9	Neutrophil count decreased	Investigations	2015-01-19	2015-01-29	No	1. recovered/resolved	1	unlikely	unlikely	No
9	Blood lactate dehydrogenase increased	Investigations	2014-12-11	2015-01-28	No	1. recovered/resolved	1	possible	possible	No
9	Tremor	Nervous system disorders	2014-10-15	NA	Yes	3. not recovered/ not resolved	3	possible	unlikely	No
9	Disease progression	General disorders and administration site conditions	2015-01-27	NA	Yes	3. not recovered/ not resolved	3	not related	not related	Yes
9	Platelet count decreased	Investigations	2015-01-01	NA	Yes	2. recovering/resolving	2	possible	possible	No
9	Angular cheilitis	Infections and infestations	2014-09-15	2014-12-15	No	1. recovered/resolved	1	possible	NA	No
9	White blood cell count decreased	Investigations	2014-12-17	2014-12-24	No	1. recovered/resolved	1	possible	possible	No
9	Hyperkalaemia	Metabolism and nutrition disorders	2014-12-11	2014-12-24	No	1. recovered/resolved	1	possible	possible	No
9	Anaemia	Blood and lymphatic system disorders	2014-10-06	2014-11-18	No	2. recovering/resolving	2	possible	NA	No
9	White blood cell count decreased	Investigations	2014-11-18	2014-12-04	No	1. recovered/resolved	2	possible	possible	No
9	Anaemia	Blood and lymphatic system disorders	2014-09-24	2014-10-01	No	1. recovered/resolved	2	possible	NA	No
9	Fatigue	General disorders and administration site conditions	2014-09-15	NA	Yes	3. not recovered/ not resolved	2	possible	NA	No
9	Lymphocyte count decreased	Investigations	2015-01-01	2015-01-19	No	2. recovering/resolving	3	possible	possible	No
9	White blood cell count decreased	Investigations	2014-10-28	2014-10-30	No	3. not recovered/ not resolved	2	possible	possible	No
10	Fatigue	General disorders and administration site conditions	2014-09-23	NA	NA	NA	1	unlikely	NA	No
10	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2014-09-23	NA	NA	NA	1	unlikely	NA	No
10	Fatigue	General disorders and administration site conditions	2014-09-16	2014-09-23	No	3. not recovered/ not resolved	1	unlikely	NA	No
10	Fatigue	General disorders and administration site conditions	2014-09-23	NA	NA	NA	2	unlikely	NA	No
10	Neutrophil count decreased	Investigations	2014-09-30	2014-10-02	No	1. recovered/resolved	2	probable	NA	No
10	Platelet count decreased	Investigations	2014-09-23	NA	Yes	NA	3	possible	NA	No
10	White blood cell count decreased	Investigations	2014-09-17	2014-10-02	No	2. recovering/resolving	3	probable	NA	No
10	Neutrophil count decreased	Investigations	2014-09-10	2014-09-17	No	3. not recovered/ not resolved	1	probable	NA	No
10	Anaemia	Blood and lymphatic system disorders	2014-09-10	NA	Yes	NA	2	possible	NA	No
10	Platelet count decreased	Investigations	2014-09-10	2014-09-23	No	3. not recovered/ not resolved	2	possible	NA	No
10	Flank pain	Musculoskeletal and connective tissue disorders	2014-09-16	NA	NA	NA	2	unlikely	NA	No
10	Weight decreased	Investigations	2014-09-23	NA	NA	NA	2	unlikely	NA	No
10	Neutrophil count decreased	Investigations	2014-09-17	2014-09-30	No	2. recovering/resolving	3	probable	NA	No
11	Anaemia	Blood and lymphatic system disorders	2014-09-30	2014-10-02	No	1. recovered/resolved	3	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-10-28	2014-10-29	No	1. recovered/resolved	3	possible	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-11	2014-11-14	No	1. recovered/resolved	4	possible	not related	No
11	Lymphopenia	Blood and lymphatic system disorders	2014-10-27	2014-10-28	No	1. recovered/resolved	3	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-10	2014-12-17	No	1. recovered/resolved	3	possible	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-09-19	2014-09-22	No	1. recovered/resolved	3	possible	not related	No
11	Lymphopenia	Blood and lymphatic system disorders	2014-11-11	2014-11-14	No	1. recovered/resolved	3	possible	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-12-21	2015-01-05	No	1. recovered/resolved	3	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-22	2014-11-24	No	1. recovered/resolved	3	not related	not related	No
11	Back pain	Musculoskeletal and connective tissue disorders	2014-10-24	2014-10-31	No	1. recovered/resolved	3	not related	not related	Yes
11	Leukopenia	Blood and lymphatic system disorders	2014-10-27	2014-10-30	No	1. recovered/resolved	3	possible	not related	No
11	Leukopenia	Blood and lymphatic system disorders	2014-12-12	2014-12-13	No	1. recovered/resolved	3	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2015-01-07	2015-01-16	No	1. recovered/resolved	3	not related	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-09-16	2014-09-30	No	1. recovered/resolved	2	possible	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-09-25	2014-09-30	No	1. recovered/resolved	3	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-11-20	2014-11-22	No	1. recovered/resolved	3	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-22	2014-10-28	No	1. recovered/resolved	2	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-10-28	2014-10-29	No	1. recovered/resolved	3	possible	not related	No
11	Chest pain	General disorders and administration site conditions	2014-10-31	2015-01-24	No	3. not recovered/ not resolved	2	not related	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-10-29	2014-10-30	No	1. recovered/resolved	2	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-24	2014-12-10	No	1. recovered/resolved	2	possible	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-11-11	2014-11-14	No	1. recovered/resolved	4	possible	not related	No
11	Back pain	Musculoskeletal and connective tissue disorders	2015-01-07	2015-01-24	No	3. not recovered/ not resolved	3	unlikely	not related	Yes
11	Anaemia	Blood and lymphatic system disorders	2015-01-05	2015-01-07	No	1. recovered/resolved	2	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-14	2014-11-20	No	1. recovered/resolved	3	not related	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-10-22	2014-10-28	No	1. recovered/resolved	2	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-11-03	2014-11-11	No	1. recovered/resolved	2	possible	not related	No
11	Hangover	General disorders and administration site conditions	2015-01-07	2015-01-24	No	3. not recovered/ not resolved	3	unlikely	not related	Yes
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-17	2014-12-21	No	1. recovered/resolved	2	possible	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-10-27	2014-10-29	No	1. recovered/resolved	3	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-28	2014-11-11	No	1. recovered/resolved	3	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-12-06	2014-12-12	No	1. recovered/resolved	2	possible	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
11	Back pain	Musculoskeletal and connective tissue disorders	2014-11-17	2014-11-24	No	1. recovered/resolved	3	not related	not related	Yes
11	Anaemia	Blood and lymphatic system disorders	2015-01-07	2015-01-09	No	1. recovered/resolved	3	not related	not related	No
11	Leukopenia	Blood and lymphatic system disorders	2014-09-19	2014-09-25	No	1. recovered/resolved	3	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-11-14	2014-11-20	No	1. recovered/resolved	2	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-20	2014-11-22	No	1. recovered/resolved	2	not related	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-12-10	2014-12-21	No	1. recovered/resolved	4	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-03	2014-12-10	No	1. recovered/resolved	2	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2014-09-12	2014-10-10	No	1. recovered/resolved	3	possible	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-09-22	2014-09-25	No	1. recovered/resolved	4	possible	not related	No
11	Leukopenia	Blood and lymphatic system disorders	2014-12-15	2014-12-17	No	1. recovered/resolved	3	possible	not related	No
11	Leukopenia	Blood and lymphatic system disorders	2014-11-17	2014-11-20	No	1. recovered/resolved	3	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2015-01-16	2015-01-24	No	1. recovered/resolved	3	not related	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2014-11-14	2014-11-24	No	1. recovered/resolved	3	possible	not related	No
11	Hangover	General disorders and administration site conditions	2014-12-03	2014-12-22	No	1. recovered/resolved	3	not related	not related	Yes
11	Neutropenia	Blood and lymphatic system disorders	2014-12-21	2015-01-05	No	1. recovered/resolved	3	possible	not related	No
11	Neutropenia	Blood and lymphatic system disorders	2015-01-07	2015-01-08	No	1. recovered/resolved	3	possible	not related	No
11	Anaemia	Blood and lymphatic system disorders	2014-12-12	2015-01-05	No	1. recovered/resolved	3	possible	not related	No
11	Thrombocytopenia	Blood and lymphatic system disorders	2015-01-16	2015-01-24	No	1. recovered/resolved	4	not related	not related	No
11	Anaemia	Blood and lymphatic system disorders	2015-01-09	2015-01-16	No	1. recovered/resolved	2	possible	not related	No
12	White blood cell count decreased	Investigations	2014-10-07	2014-10-21	No	1. recovered/resolved	1	probable	NA	No
12	Neutrophil count decreased	Investigations	2015-01-26	2015-02-02	No	1. recovered/resolved	4	probable	probable	No
12	Spinal pain	Musculoskeletal and connective tissue disorders	2014-10-08	NA	Yes	3. not recovered/ not resolved	2	unlikely	NA	No
12	White blood cell count decreased	Investigations	2014-11-25	2014-11-27	No	1. recovered/resolved	1	probable	probable	No
12	Anaemia	Blood and lymphatic system disorders	2014-10-21	2014-12-16	No	3. not recovered/ not resolved	1	possible	NA	No
12	White blood cell count decreased	Investigations	2015-03-25	2015-04-02	No	1. recovered/resolved	1	probable	probable	No
12	Anaemia	Blood and lymphatic system disorders	2015-04-02	NA	Yes	3. not recovered/ not resolved	2	possible	possible	No
12	Hyperalbuminaemia	Metabolism and nutrition disorders	2014-12-09	NA	Yes	3. not recovered/ not resolved	1	unlikely	unlikely	No
12	White blood cell count decreased	Investigations	2015-02-11	2015-03-18	No	1. recovered/resolved	1	probable	probable	No
12	White blood cell count decreased	Investigations	2015-01-26	2015-02-02	No	1. recovered/resolved	3	probable	probable	No
12	Chest pain	General disorders and administration site conditions	2014-10-08	NA	Yes	3. not recovered/ not resolved	2	unlikely	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
12	Bone pain	Musculoskeletal and connective tissue disorders	2014-11-17	NA	Yes	3. not recovered/ not resolved	1	unlikely	unlikely	No
12	Neutrophil count decreased	Investigations	2015-03-30	2015-04-02	No	2. recovering/resolving	2	probable	probable	No
12	Hyponatraemia	Metabolism and nutrition disorders	2014-10-28	2014-11-11	No	1. recovered/resolved	1	possible	NA	No
12	Bronchitis	Infections and infestations	2015-01-26	2015-02-03	No	1. recovered/resolved	3	unlikely	unlikely	Yes
12	Neutrophil count decreased	Investigations	2015-01-19	2015-01-23	No	3. not recovered/ not resolved	1	probable	probable	No
12	White blood cell count decreased	Investigations	2014-12-30	2015-01-07	No	2. recovering/resolving	2	probable	probable	No
12	Anaemia	Blood and lymphatic system disorders	2014-10-07	2014-10-08	No	1. recovered/resolved	1	possible	NA	No
12	Neutrophil count decreased	Investigations	2015-04-02	NA	Yes	3. not recovered/ not resolved	1	probable	probable	No
12	Fatigue	General disorders and administration site conditions	2014-11-11	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
12	Vision blurred	Eye disorders	2015-03-05	2015-03-25	No	1. recovered/resolved	1	not related	not related	No
12	Neutrophil count decreased	Investigations	2014-10-13	2014-10-21	No	1. recovered/resolved	2	probable	NA	No
12	Post herpetic neuralgia	Nervous system disorders	2015-03-25	2015-03-15	No	1. recovered/resolved	2	unlikely	unlikely	No
12	Constipation	Gastrointestinal disorders	2015-03-05	NA	NA	NA	1	not related	not related	No
12	Neutrophil count decreased	Investigations	2015-03-25	2015-03-30	No	2. recovering/resolving	3	probable	probable	No
12	Weight decreased	Investigations	2014-11-24	NA	Yes	3. not recovered/ not resolved	1	unlikely	unlikely	No
12	N-terminal pro-hormone brain natriuretic peptide increased	Investigations	2014-12-09	NA	NA	NA	1	possible	possible	No
12	Neutrophil count decreased	Investigations	2015-01-23	2015-01-26	No	3. not recovered/ not resolved	3	probable	probable	No
12	Fatigue	General disorders and administration site conditions	2014-12-09	NA	Yes	3. not recovered/ not resolved	1	unlikely	unlikely	No
12	Neutrophil count decreased	Investigations	2014-12-02	2014-12-08	No	1. recovered/resolved	2	probable	probable	No
12	Febrile neutropenia	Blood and lymphatic system disorders	2015-01-26	2015-02-03	No	1. recovered/resolved	3	unlikely	unlikely	Yes
12	Laryngitis	Infections and infestations	2014-11-24	NA	No	1. recovered/resolved	2	unlikely	unlikely	No
12	Night sweats	Skin and subcutaneous tissue disorders	2014-11-24	NA	NA	NA	1	unlikely	unlikely	No
12	Blood creatinine increased	Investigations	2014-12-30	2015-01-07	No	1. recovered/resolved	1	possible	possible	No
12	Asthenia	General disorders and administration site conditions	2014-11-11	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
12	Neuropathy peripheral	Nervous system disorders	2014-10-08	2015-03-05	No	1. recovered/resolved	1	possible	NA	No
12	Blood creatinine increased	Investigations	2015-01-19	2015-02-11	No	1. recovered/resolved	1	possible	possible	No
12	Chills	General disorders and administration site conditions	2014-10-24	2014-10-15	No	1. recovered/resolved	1	unlikely	NA	No
12	White blood cell count decreased	Investigations	2015-01-12	2015-01-20	No	3. not recovered/ not resolved	1	probable	probable	No
12	Nocturia	Renal and urinary disorders	2014-10-15	NA	Yes	NA	1	possible	NA	No
12	White blood cell count decreased	Investigations	2014-09-23	2014-09-30	No	1. recovered/resolved	1	probable	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
12	Anaemia	Blood and lymphatic system disorders	2014-12-16	2015-02-02	No	3. not recovered/ not resolved	2	possible	possible	No
12	Skin disorder	Skin and subcutaneous tissue disorders	2014-10-08	NA	NA	NA	1	possible	NA	No
12	Nausea	Gastrointestinal disorders	2015-03-05	NA	NA	NA	1	unlikely	unlikely	No
12	Hyponatraemia	Metabolism and nutrition disorders	2015-01-26	2015-02-02	No	1. recovered/resolved	1	possible	possible	No
12	Anaemia	Blood and lymphatic system disorders	2015-03-04	2015-04-02	No	3. not recovered/ not resolved	1	possible	possible	No
12	Neutrophil count decreased	Investigations	2015-01-05	2015-01-07	No	2. recovering/resolving	3	probable	probable	No
12	Oedema peripheral	General disorders and administration site conditions	2014-10-15	2015-03-25	No	1. recovered/resolved	1	possible	NA	No
12	White blood cell count decreased	Investigations	2015-01-20	2015-01-26	No	3. not recovered/ not resolved	2	probable	probable	No
12	Decreased appetite	Metabolism and nutrition disorders	2014-12-09	NA	NA	NA	1	unlikely	unlikely	No
12	Neutrophil count decreased	Investigations	2015-01-07	2015-01-19	No	2. recovering/resolving	2	probable	probable	No
12	White blood cell count decreased	Investigations	2014-12-02	2014-12-08	No	1. recovered/resolved	1	probable	probable	No
12	Anaemia	Blood and lymphatic system disorders	2015-02-11	2015-03-04	No	2. recovering/resolving	2	possible	possible	No
12	Anaemia	Blood and lymphatic system disorders	2015-02-02	2015-02-11	No	2. recovering/resolving	3	possible	possible	No
13	Neutrophil count decreased	Investigations	2014-10-02	2014-11-03	No	3. not recovered/ not resolved	3	possible	NA	No
13	Anaemia	Blood and lymphatic system disorders	2014-09-26	2014-09-30	No	2. recovering/resolving	2	possible	NA	No
13	Platelet count decreased	Investigations	2014-09-15	2014-10-10	No	1. recovered/resolved	1	possible	NA	No
13	Neutrophil count decreased	Investigations	2014-11-10	2014-11-17	No	2. recovering/resolving	3	possible	possible	No
13	White blood cell count decreased	Investigations	2014-11-10	2014-12-12	No	2. recovering/resolving	2	probable	probable	No
13	Neutrophil count decreased	Investigations	2014-11-05	2014-11-10	No	1. recovered/resolved	4	possible	NA	No
13	Platelet count decreased	Investigations	2014-12-15	NA	Yes	3. not recovered/ not resolved	1	possible	possible	No
13	White blood cell count decreased	Investigations	2014-09-19	2014-10-13	No	2. recovering/resolving	3	probable	NA	No
13	Anaemia	Blood and lymphatic system disorders	2014-09-19	2014-09-26	No	3. not recovered/ not resolved	1	possible	NA	No
13	Platelet count decreased	Investigations	2014-12-12	2014-12-15	No	2. recovering/resolving	3	possible	possible	No
13	Neutrophil count decreased	Investigations	2014-09-26	2014-10-02	No	2. recovering/resolving	4	possible	NA	No
13	Platelet count decreased	Investigations	2014-12-01	2014-12-08	No	3. not recovered/ not resolved	1	possible	possible	No
13	White blood cell count decreased	Investigations	2014-12-12	NA	Yes	3. not recovered/ not resolved	1	probable	probable	No
13	Platelet count decreased	Investigations	2014-10-27	2014-11-17	No	1. recovered/resolved	1	possible	NA	No
13	Hyperkalaemia	Metabolism and nutrition disorders	2014-10-10	2014-10-13	No	1. recovered/resolved	3	possible	NA	No
13	Neutrophil count decreased	Investigations	2014-11-03	2014-11-05	No	3. not recovered/ not resolved	3	possible	NA	No
13	Fall	Injury, poisoning and procedural complications	2014-12-11	2014-12-12	No	2. recovering/resolving	1	unlikely	unlikely	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
13	Neutrophil count decreased	Investigations	2014-09-19	2014-09-26	No	3. not recovered/ not resolved	2	possible	NA	No
13	White blood cell count decreased	Investigations	2014-11-03	2014-11-10	No	2. recovering/resolving	3	probable	NA	No
13	Platelet count decreased	Investigations	2014-12-08	2014-12-12	No	2. recovering/resolving	4	possible	possible	No
13	Neutrophil count decreased	Investigations	2014-09-15	2014-09-19	No	3. not recovered/ not resolved	1	possible	NA	No
13	Anaemia	Blood and lymphatic system disorders	2014-09-30	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
14	Abdominal pain upper	Gastrointestinal disorders	2015-01-10	2015-01-29	No	4. recovered/ resolved with sequel	2	not related	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2014-12-04	2014-12-10	No	1. recovered/resolved	3	related	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2016-04-14	2016-04-26	No	1. recovered/resolved	3	possible	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2016-06-01	2016-07-05	No	1. recovered/resolved	3	possible	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2015-04-16	2016-04-21	No	1. recovered/resolved	4	possible	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2014-09-22	2014-09-25	No	1. recovered/resolved	2	related	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2014-12-17	2014-12-21	No	1. recovered/resolved	3	related	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2016-02-18	2016-03-13	No	1. recovered/resolved	3	possible	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2015-04-16	2015-04-21	No	1. recovered/resolved	3	possible	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2016-04-19	2016-04-25	No	1. recovered/resolved	4	possible	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2014-12-04	2014-12-10	No	1. recovered/resolved	2	related	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2014-09-22	2014-10-01	No	1. recovered/resolved	3	probable	not related	No
14	Platelet count decreased	Investigations	2014-09-26	2014-10-01	No	1. recovered/resolved	3	related	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2014-11-17	2014-11-20	No	1. recovered/resolved	1	related	not related	No
14	Oral herpes	Infections and infestations	2015-05-07	2015-05-18	No	1. recovered/resolved	1	possible	not related	No
14	Dizziness	Nervous system disorders	2014-09-22	2014-10-02	No	1. recovered/resolved	1	unlikely	not related	No
14	Dizziness	Nervous system disorders	2014-11-11	2014-11-21	No	1. recovered/resolved	1	not related	not related	No
14	Fatigue	General disorders and administration site conditions	2014-12-17	2014-12-30	No	1. recovered/resolved	1	probable	not related	No
14	Bronchitis	Infections and infestations	2016-04-14	2016-04-19	No	1. recovered/resolved	3	probable	not related	Yes
14	Leukopenia	Blood and lymphatic system disorders	2014-10-23	2014-11-16	No	1. recovered/resolved	2	related	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2015-11-19	2016-01-10	No	1. recovered/resolved	3	possible	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2016-04-14	2016-04-25	No	1. recovered/resolved	3	possible	not related	No
14	Fatigue	General disorders and administration site conditions	2015-01-13	2015-01-29	No	3. not recovered/ not resolved	2	probable	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2014-09-26	2014-10-01	No	1. recovered/resolved	4	related	not related	No
14	Alanine aminotransferase increased	Investigations	2014-09-22	2016-09-04	No	1. recovered/resolved	2	probable	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
14	Nasopharyngitis	Infections and infestations	2016-07-05	2017-07-27	No	1. recovered/resolved	2	unlikely	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2014-12-17	2014-12-21	No	1. recovered/resolved	3	related	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2015-04-16	2015-04-21	No	1. recovered/resolved	3	possible	not related	No
14	Nasopharyngitis	Infections and infestations	2014-12-19	2014-12-30	No	1. recovered/resolved	1	possible	possible	No
14	Abdominal pain	Gastrointestinal disorders	2016-02-18	2016-03-14	No	1. recovered/resolved	1	not related	not related	No
14	Eyelid oedema	Eye disorders	2014-10-10	2014-10-13	No	1. recovered/resolved	1	not related	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2014-10-23	2014-11-06	No	1. recovered/resolved	3	related	not related	No
14	Abdominal pain	Gastrointestinal disorders	2015-03-03	2015-05-07	No	1. recovered/resolved	2	not related	not related	No
14	Pain in extremity	Musculoskeletal and connective tissue disorders	2014-10-02	2014-10-06	No	1. recovered/resolved	2	not related	not related	No
14	Nasopharyngitis	Infections and infestations	2014-10-20	2014-11-03	No	1. recovered/resolved	1	possible	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2015-01-29	2015-02-05	No	1. recovered/resolved	1	related	not related	No
14	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2014-12-11	2014-12-30	No	1. recovered/resolved	1	unlikely	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2014-10-02	2014-10-12	No	1. recovered/resolved	2	related	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2015-06-09	2015-07-06	No	1. recovered/resolved	3	possible	not related	No
14	Gamma-glutamyltransferase increased	Investigations	2014-11-03	2016-07-05	No	1. recovered/resolved	2	probable	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2014-10-02	2014-10-12	No	1. recovered/resolved	2	probable	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2014-11-07	2014-11-20	No	1. recovered/resolved	2	related	not related	No
14	Neutropenia	Blood and lymphatic system disorders	2015-03-03	2015-03-10	No	1. recovered/resolved	3	possible	not related	No
14	Nasopharyngitis	Infections and infestations	2015-07-05	2015-07-15	No	1. recovered/resolved	2	not related	not related	No
14	Nasopharyngitis	Infections and infestations	2016-01-11	2016-01-21	No	1. recovered/resolved	1	possible	not related	No
14	Hyperhidrosis	Skin and subcutaneous tissue disorders	2014-12-17	2017-08-17	No	1. recovered/resolved	2	possible	not related	No
14	Leukopenia	Blood and lymphatic system disorders	2014-09-15	2014-09-21	No	1. recovered/resolved	1	probable	not related	No
15	Dehydration	Metabolism and nutrition disorders	2014-10-05	2014-10-15	No	1. recovered/resolved	3	not related	probable	Yes
15	Blood creatinine increased	Investigations	2014-11-20	2014-11-24	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Pneumonia	Infections and infestations	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Acute kidney injury	Renal and urinary disorders	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Renal failure	Renal and urinary disorders	2014-11-28	2014-12-12	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Pleural effusion	Respiratory, thoracic and mediastinal disorders	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Renal hypertension	Renal and urinary disorders	2014-12-18	2014-12-31	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Pneumonia	Infections and infestations	2014-10-27	2014-11-10	No	4. recovered/ resolved with sequel	3	not related	not related	Yes

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
15	Renal failure	Renal and urinary disorders	2014-12-18	2014-12-31	No	4. recovered/ resolved with se-qual	3	not related	not related	Yes
15	Dehydration	Metabolism and nutrition disorders	2014-10-27	2014-11-10	No	4. recovered/ resolved with se-qual	3	not related	not related	Yes
15	Pneumonia	Infections and infestations	2014-10-05	2014-10-15	No	1. recovered/resolved	3	not related	probable	Yes
16	Polyneuropathy	Nervous system disorders	2014-12-03	2015-01-18	No	3. not recovered/ not resolved	2	related	not related	No
16	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-08	2014-11-04	No	1. recovered/resolved	1	related	not related	No
16	Back pain	Musculoskeletal and connective tissue disorders	2014-12-15	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
16	Asthenia	General disorders and administration site conditions	2014-11-01	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
16	Leukopenia	Blood and lymphatic system disorders	2014-10-08	2014-11-04	No	1. recovered/resolved	2	related	not related	No
16	Leukopenia	Blood and lymphatic system disorders	2014-12-03	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
16	Nasopharyngitis	Infections and infestations	2014-10-08	2015-10-22	No	1. recovered/resolved	2	not related	not related	No
16	Anaemia	Blood and lymphatic system disorders	2014-10-08	2014-11-04	No	3. not recovered/ not resolved	2	not related	not related	No
16	Polyneuropathy	Nervous system disorders	2015-01-19	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
16	Neutropenia	Blood and lymphatic system disorders	2014-10-08	2014-11-04	No	1. recovered/resolved	2	related	not related	No
16	Diarrhoea	Gastrointestinal disorders	2015-01-12	2015-01-14	No	1. recovered/resolved	3	not related	not related	No
16	Burning sensa- tion	Nervous system disorders	2014-10-23	2014-12-02	No	3. not recovered/ not resolved	1	related	not related	No
16	Anaemia	Blood and lymphatic system disorders	2014-11-05	NA	Yes	3. not recovered/ not resolved	3	related	not related	No
16	Muscle spasms	Musculoskeletal and connective tissue disorders	2014-10-08	2014-10-22	No	3. not recovered/ not resolved	2	related	not related	No
16	Burning sensa- tion	Nervous system disorders	2014-10-20	2014-10-22	No	1. recovered/resolved	3	related	not related	No
16	Neutropenia	Blood and lymphatic system disorders	2014-12-03	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
16	Burning sensa- tion	Nervous system disorders	2014-12-03	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
16	Muscle spasms	Musculoskeletal and connective tissue disorders	2014-10-23	2014-11-04	No	1. recovered/resolved	3	related	not related	No
16	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-03	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
16	Epistaxis	Respiratory, thoracic and mediastinal disorders	2014-11-21	2014-11-22	No	1. recovered/resolved	3	not related	not related	No
17	Nasopharyngitis	Infections and infestations	2014-11-11	2014-12-15	No	1. recovered/resolved	2	not related	not related	No
17	Abdominal dis- tension	Gastrointestinal disorders	2014-09-30	2016-12-02	No	1. recovered/resolved	1	not related	not related	No
17	Muscle spasms	Musculoskeletal and connective tissue disorders	2014-10-07	2016-12-02	No	1. recovered/resolved	1	possible	not related	No
17	Neutropenia	Blood and lymphatic system disorders	2015-02-10	2015-02-23	No	1. recovered/resolved	3	possible	not related	No
18	Nasopharyngitis	Infections and infestations	2014-12-29	2015-01-16	No	1. recovered/resolved	2	possible	not related	No
18	Neutrophil count decreased	Investigations	2014-12-29	2015-01-16	No	1. recovered/resolved	2	probable	not related	No
18	White blood cell count decreased	Investigations	2015-01-09	2015-01-16	No	1. recovered/resolved	2	probable	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
18	Urinary tract infection	Infections and infestations	2014-12-29	2015-01-02	No	1. recovered/resolved	2	unlikely	not related	No
18	Neutrophil count decreased	Investigations	2014-11-10	2014-11-14	No	1. recovered/resolved	1	probable	not related	No
18	Platelet count decreased	Investigations	2015-01-29	NA	Yes	3. not recovered/ not resolved	2	probable	possible	No
18	Platelet count decreased	Investigations	2014-09-22	2014-09-29	No	3. not recovered/ not resolved	1	probable	not related	No
18	Hypocalcaemia	Metabolism and nutrition disorders	2015-01-16	2015-01-29	No	1. recovered/resolved	1	possible	not related	No
18	Neutrophil count decreased	Investigations	2014-10-13	2014-10-17	No	1. recovered/resolved	1	probable	not related	No
18	Hypocalcaemia	Metabolism and nutrition disorders	2014-12-12	2014-12-29	No	1. recovered/resolved	2	possible	not related	No
18	Platelet count decreased	Investigations	2014-09-29	2014-10-13	No	2. recovering/resolving	2	probable	not related	No
18	Anaemia	Blood and lymphatic system disorders	2014-09-29	2014-10-17	No	2. recovering/resolving	2	probable	not related	No
18	Neutrophil count decreased	Investigations	2015-01-29	NA	Yes	3. not recovered/ not resolved	3	probable	possible	No
18	Fall	Injury, poisoning and procedural complications	2014-11-18	2014-11-18	No	1. recovered/resolved	2	possible	not related	No
18	Myalgia	Musculoskeletal and connective tissue disorders	2014-12-12	NA	No	1. recovered/resolved	1	not related	not related	No
18	Platelet count decreased	Investigations	2014-10-13	2014-10-17	No	1. recovered/resolved	1	probable	not related	No
18	White blood cell count decreased	Investigations	2014-11-03	2014-11-14	No	1. recovered/resolved	2	probable	not related	No
18	White blood cell count decreased	Investigations	2015-01-02	2015-01-09	No	3. not recovered/ not resolved	1	probable	not related	No
18	Syncope	Nervous system disorders	2014-10-17	2014-10-17	No	1. recovered/resolved	3	possible	not related	No
18	Nasopharyngitis	Infections and infestations	2014-11-14	NA	Yes	3. not recovered/ not resolved	1	possible	not related	No
18	Mucosal infection	Infections and infestations	2015-01-02	2015-01-09	No	1. recovered/resolved	2	possible	not related	No
18	Traumatic haematoma	Injury, poisoning and procedural complications	2014-11-18	NA	No	1. recovered/resolved	1	not related	not related	No
18	Anaemia	Blood and lymphatic system disorders	2014-11-14	NA	Yes	3. not recovered/ not resolved	2	probable	not related	No
18	Anaemia	Blood and lymphatic system disorders	2014-11-03	2014-11-10	No	2. recovering/resolving	2	probable	not related	No
18	White blood cell count decreased	Investigations	2014-10-06	2014-10-17	No	1. recovered/resolved	2	probable	not related	No
18	Aphthous ulcer	Gastrointestinal disorders	2015-01-02	NA	No	1. recovered/resolved	1	unlikely	unlikely	No
18	Platelet count decreased	Investigations	2014-12-29	2015-01-16	No	1. recovered/resolved	1	probable	not related	No
19	Pneumonia	Infections and infestations	2014-11-25	2014-12-04	No	1. recovered/resolved	2	related	related	Yes
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-20	2014-11-25	No	1. recovered/resolved	4	related	related	No
19	C-reactive protein increased	Investigations	2014-10-06	2014-12-16	No	3. not recovered/ not resolved	4	related	related	No
19	Pollakiuria	Renal and urinary disorders	2014-11-20	2014-12-16	No	3. not recovered/ not resolved	1	not related	not related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-25	2014-11-26	No	1. recovered/resolved	2	related	related	No
19	Anaemia	Blood and lymphatic system disorders	2014-11-03	2014-11-10	No	1. recovered/resolved	3	related	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
19	Leukopenia	Blood and lymphatic system disorders	2014-11-26	2014-11-27	No	1. recovered/resolved	3	related	related	No
19	General physical health deterioration	General disorders and administration site conditions	2014-10-13	2014-11-13	No	3. not recovered/ not resolved	2	not related	not related	No
19	Nausea	Gastrointestinal disorders	2014-10-13	2014-11-01	No	3. not recovered/ not resolved	1	possible	not related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-04	2014-12-07	No	1. recovered/resolved	4	related	related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-28	2014-11-30	No	1. recovered/resolved	4	related	related	No
19	Nausea	Gastrointestinal disorders	2014-10-02	2014-10-05	No	1. recovered/resolved	1	not related	not related	No
19	Leukopenia	Blood and lymphatic system disorders	2014-12-07	2014-12-16	No	3. not recovered/ not resolved	4	related	related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-10	2014-12-16	No	3. not recovered/ not resolved	4	related	related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-26	2014-11-27	No	1. recovered/resolved	3	related	related	No
19	Bone pain	Musculoskeletal and connective tissue disorders	2014-10-09	2014-12-16	No	3. not recovered/ not resolved	2	unlikely	not related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-30	2014-12-01	No	1. recovered/resolved	3	related	related	No
19	Leukopenia	Blood and lymphatic system disorders	2014-11-03	2014-11-10	No	1. recovered/resolved	3	related	not related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-06	2014-10-20	No	1. recovered/resolved	3	related	not assessable	No
19	Leukopenia	Blood and lymphatic system disorders	2014-10-27	2014-11-03	No	1. recovered/resolved	2	related	not assessable	No
19	Leukopenia	Blood and lymphatic system disorders	2014-11-27	2014-11-30	No	1. recovered/resolved	4	related	related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-01	2014-12-02	No	1. recovered/resolved	4	related	related	No
19	Leukopenia	Blood and lymphatic system disorders	2014-11-20	2014-11-25	No	1. recovered/resolved	4	related	related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-06	2014-10-20	No	1. recovered/resolved	3	related	not related	No
19	Anaemia	Blood and lymphatic system disorders	2014-12-10	2014-12-16	No	3. not recovered/ not resolved	3	related	related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-02	2014-12-03	No	1. recovered/resolved	3	related	related	No
19	Disease progression	General disorders and administration site conditions	2014-12-07	2014-12-16	No	5. fatal	5	not related	not related	Yes
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-10	2014-11-13	No	1. recovered/resolved	4	related	not related	No
19	Thrombocytopenia	Blood and lymphatic system disorders	2014-10-20	2014-11-03	No	4. recovered/ resolved with sequel	4	related	related	No
19	Hypoaesthesia	Nervous system disorders	2014-10-06	2014-12-16	No	3. not recovered/ not resolved	1	not related	not related	No
19	Leukopenia	Blood and lymphatic system disorders	2014-11-12	2014-11-20	No	1. recovered/resolved	2	related	related	No
19	Neutropenia	Blood and lymphatic system disorders	2014-10-20	2014-10-27	No	1. recovered/resolved	3	related	not related	No
19	Leukopenia	Blood and lymphatic system disorders	2014-12-01	2014-12-06	No	3. not recovered/ not resolved	3	related	related	No
19	Skin exfoliation	Skin and subcutaneous tissue disorders	2014-10-13	2014-10-25	No	3. not recovered/ not resolved	1	related	not related	No
19	Anaemia	Blood and lymphatic system disorders	2014-11-24	2014-11-26	No	1. recovered/resolved	3	related	related	No
19	Aphthous ulcer	Gastrointestinal disorders	2014-10-11	NA	Yes	3. not recovered/ not resolved	1	related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
19	Leukopenia	Blood and lymphatic system disorders	2014-10-20	2014-10-27	No	1. recovered/resolved	3	related	not assessable	No
20	Circulatory collapse	Vascular disorders	2014-12-29	2014-12-30	No	3. not recovered/ not resolved	3	not related	not related	No
20	Fatigue	General disorders and administration site conditions	2015-04-08	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
20	Neutropenia	Blood and lymphatic system disorders	2015-04-08	2015-05-28	No	3. not recovered/ not resolved	2	related	related	No
20	Leukopenia	Blood and lymphatic system disorders	2015-02-02	2015-03-01	No	3. not recovered/ not resolved	1	related	not related	No
20	Pneumonia	Infections and infestations	2015-10-05	2015-10-23	No	1. recovered/resolved	3	possible	possible	Yes
20	Nausea	Gastrointestinal disorders	2014-12-29	2015-02-01	No	1. recovered/resolved	2	not related	not related	No
20	Thrombocytopenia	Blood and lymphatic system disorders	2014-11-05	2014-12-02	No	2. recovering/resolving	2	related	not related	No
20	Upper respiratory tract infection	Infections and infestations	2015-01-02	2015-02-01	No	1. recovered/resolved	2	related	not related	No
20	Thrombocytopenia	Blood and lymphatic system disorders	2015-05-04	NA	Yes	3. not recovered/ not resolved	1	not related	related	No
20	Dizziness	Nervous system disorders	2014-12-29	2014-12-30	No	3. not recovered/ not resolved	3	not related	not related	No
20	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2014-12-03	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
20	Dizziness	Nervous system disorders	2015-02-02	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
20	Thrombocytopenia	Blood and lymphatic system disorders	2014-12-03	2015-02-01	No	3. not recovered/ not resolved	1	related	not related	No
20	Polyneuropathy	Nervous system disorders	2014-11-05	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
20	Neutropenia	Blood and lymphatic system disorders	2014-12-03	2015-01-04	No	3. not recovered/ not resolved	2	related	not related	No
20	Diarrhoea	Gastrointestinal disorders	2015-10-27	2015-11-04	No	1. recovered/resolved	2	unlikely	not related	Yes
20	Thrombocytopenia	Blood and lymphatic system disorders	2015-02-02	2015-03-01	No	2. recovering/resolving	2	related	related	No
20	Thrombocytopenia	Blood and lymphatic system disorders	2015-03-02	2015-04-07	No	1. recovered/resolved	3	related	related	No
20	Dizziness	Nervous system disorders	2014-12-30	2015-02-01	No	3. not recovered/ not resolved	1	not related	not related	No
20	Dementia	Nervous system disorders	2015-11-12	NA	Yes	2. recovering/resolving	2	not related	not related	No
20	Asthenia	General disorders and administration site conditions	2015-08-24	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
20	Neutropenia	Blood and lymphatic system disorders	2015-05-29	NA	Yes	3. not recovered/ not resolved	3	related	related	No
20	Gait disturbance	General disorders and administration site conditions	2015-09-21	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
20	Upper respiratory tract infection	Infections and infestations	2015-06-15	2015-06-19	No	1. recovered/resolved	2	related	related	No
20	Leukopenia	Blood and lymphatic system disorders	2015-07-27	NA	Yes	3. not recovered/ not resolved	3	related	related	No
20	Upper respiratory tract infection	Infections and infestations	2015-02-26	2015-03-05	No	1. recovered/resolved	2	related	not related	No
20	Leukopenia	Blood and lymphatic system disorders	2015-03-02	2015-07-26	No	3. not recovered/ not resolved	2	related	related	No
20	Emotional distress	Psychiatric disorders	2014-12-03	2015-01-04	No	1. recovered/resolved	1	not related	not related	No
20	Memory impairment	Nervous system disorders	2015-01-05	NA	Yes	3. not recovered/ not resolved	2	related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
20	General physical health deterioration	General disorders and administration site conditions	2015-09-21	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
20	Rash	Skin and subcutaneous tissue disorders	2015-05-17	2015-05-17	No	1. recovered/resolved	2	not related	not related	No
20	Neutropenia	Blood and lymphatic system disorders	2015-02-02	2015-03-01	No	1. recovered/resolved	3	related	not related	No
20	Asthenia	General disorders and administration site conditions	2014-11-05	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
20	Anaemia	Blood and lymphatic system disorders	2014-12-03	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
20	Leukopenia	Blood and lymphatic system disorders	2014-12-03	2015-01-04	No	1. recovered/resolved	1	related	not related	No
21	Platelet count decreased	Investigations	2014-10-27	2014-11-09	No	1. recovered/resolved	3	probable	not related	No
21	Neutropenia	Blood and lymphatic system disorders	2014-12-15	2014-12-22	No	1. recovered/resolved	3	possible	possible	No
21	General physical health deterioration	General disorders and administration site conditions	2014-12-15	2014-12-22	No	1. recovered/resolved	2	possible	not related	No
21	Oedema peripheral	General disorders and administration site conditions	2015-03-03	2015-03-17	No	1. recovered/resolved	2	unlikely	possible	No
21	Leukopenia	Blood and lymphatic system disorders	2015-02-03	2015-02-08	No	1. recovered/resolved	3	possible	possible	No
21	Bronchitis	Infections and infestations	2015-07-10	2015-07-16	No	1. recovered/resolved	2	possible	unlikely	No
21	Neutropenia	Blood and lymphatic system disorders	2015-02-09	2015-02-12	No	1. recovered/resolved	3	possible	possible	No
21	Neutropenia	Blood and lymphatic system disorders	2015-02-03	2015-02-08	No	1. recovered/resolved	4	possible	possible	No
22	White blood cell count decreased	Investigations	2014-11-06	2014-11-14	No	3. not recovered/ not resolved	1	probable	NA	No
22	Cough	Respiratory, thoracic and mediastinal disorders	2015-04-23	NA	No	1. recovered/resolved	1	possible	NA	No
22	Lymphocyte count decreased	Investigations	2014-10-31	2014-11-21	No	2. recovering/resolving	3	probable	NA	No
22	White blood cell count decreased	Investigations	2015-09-16	2015-10-09	No	3. not recovered/ not resolved	1	probable	NA	No
22	Sciatica	Nervous system disorders	2015-02-15	2015-02-15	No	1. recovered/resolved	NA	unlikely	not related	No
22	Platelet count decreased	Investigations	2015-01-30	2015-02-04	No	1. recovered/resolved	1	probable	not related	No
22	Hypertension	Vascular disorders	2016-07-26	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-08-28	2015-09-04	No	3. not recovered/ not resolved	2	probable	NA	No
22	Platelet count decreased	Investigations	2014-11-14	2014-11-21	No	3. not recovered/ not resolved	2	probable	NA	No
22	Lymphocyte count decreased	Investigations	2016-03-10	2016-04-08	No	2. recovering/resolving	3	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-05-15	2015-05-22	No	3. not recovered/ not resolved	2	probable	NA	No
22	Neutrophil count decreased	Investigations	2014-12-22	2014-12-30	No	3. not recovered/ not resolved	1	probable	NA	No
22	Lymphocyte count decreased	Investigations	2014-12-04	2014-12-22	No	2. recovering/resolving	3	probable	NA	No
22	Lymphocyte count decreased	Investigations	2015-04-23	2015-05-15	No	2. recovering/resolving	3	probable	NA	No
22	White blood cell count decreased	Investigations	2014-10-31	2014-11-06	No	3. not recovered/ not resolved	2	probable	NA	No
22	Lymphocyte count decreased	Investigations	2016-05-06	NA	Yes	3. not recovered/ not resolved	3	probable	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
22	White blood cell count decreased	Investigations	2015-08-21	NA	Yes	3. not recovered/ not resolved	1	probable	NA	No
22	Fatigue	General disorders and administration site conditions	2014-11-15	NA	No	NA	1	possible	NA	No
22	Platelet count decreased	Investigations	2014-11-21	2014-11-28	No	1. recovered/resolved	1	probable	NA	No
22	Tremor	Nervous system disorders	2016-03-10	NA	NA	NA	1	unlikely	NA	No
22	Lymphocyte count decreased	Investigations	2015-03-23	2015-04-23	No	2. recovering/resolving	4	probable	NA	No
22	Platelet count decreased	Investigations	2015-05-15	2015-08-28	No	1. recovered/resolved	1	possible	NA	No
22	Pain in extremity	Musculoskeletal and connective tissue disorders	2016-07-26	NA	Yes	3. not recovered/ not resolved	1	unlikely	NA	No
22	White blood cell count decreased	Investigations	2016-06-28	NA	Yes	3. not recovered/ not resolved	2	probable	NA	No
22	Upper respiratory tract infection	Respiratory, thoracic and mediastinal disorders	2015-10-08	2015-12-17	No	1. recovered/resolved	2	possible	NA	No
22	Neutrophil count decreased	Investigations	2015-03-13	2015-03-23	No	1. recovered/resolved	2	probable	NA	No
22	White blood cell count decreased	Investigations	2014-12-19	2014-12-22	No	3. not recovered/ not resolved	3	probable	NA	No
22	White blood cell count decreased	Investigations	2015-04-10	2015-04-23	No	1. recovered/resolved	3	probable	NA	No
22	Neutrophil count decreased	Investigations	2014-11-14	2014-11-28	No	3. not recovered/ not resolved	3	probable	NA	No
22	Paraesthesia	Nervous system disorders	2014-11-15	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-12-17	2016-02-11	No	3. not recovered/ not resolved	3	probable	NA	No
22	Neutrophil count decreased	Investigations	2014-11-28	2014-12-04	No	1. recovered/resolved	1	probable	NA	No
22	Influenza like illness	General disorders and administration site conditions	2014-12-15	2015-02-04	No	1. recovered/resolved	1	unlikely	NA	No
22	Neutrophil count decreased	Investigations	2015-05-22	2015-05-27	No	1. recovered/resolved	1	probable	NA	No
22	Neutrophil count decreased	Investigations	2016-06-28	2016-07-26	No	1. recovered/resolved	2	probable	NA	No
22	Platelet count decreased	Investigations	2015-11-19	NA	Yes	3. not recovered/ not resolved	1	probable	NA	No
22	Lymphocyte count decreased	Investigations	2015-09-16	2015-10-09	No	3. not recovered/ not resolved	2	probable	NA	No
22	Oral herpes	Infections and infestations	2015-05-23	2015-06-26	No	1. recovered/resolved	1	unlikely	NA	No
22	White blood cell count decreased	Investigations	2015-05-27	2015-06-26	No	3. not recovered/ not resolved	1	probable	NA	No
22	Lymphocyte count decreased	Investigations	2014-12-22	2015-02-04	No	3. not recovered/ not resolved	2	probable	NA	No
22	Anaemia	Blood and lymphatic system disorders	2016-03-10	2016-04-08	No	1. recovered/resolved	1	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-08-14	2015-08-28	No	2. recovering/resolving	3	probable	NA	No
22	Neutrophil count decreased	Investigations	2015-07-22	2015-08-20	No	3. not recovered/ not resolved	1	probable	NA	No
22	Night sweats	Skin and subcutaneous tissue disorders	2015-04-23	2015-08-21	No	1. recovered/resolved	1	unlikely	NA	No
22	White blood cell count decreased	Investigations	2015-03-20	2015-04-10	No	3. not recovered/ not resolved	2	probable	NA	No
22	Lymphocyte count decreased	Investigations	2015-10-14	2015-12-17	No	3. not recovered/ not resolved	2	probable	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
22	White blood cell count decreased	Investigations	2015-09-11	2015-09-16	No	2. recovering/resolving	3	probable	NA	No
22	Neutrophil count decreased	Investigations	2016-08-23	NA	Yes	3. not recovered/ not resolved	2	probable	NA	No
22	White blood cell count decreased	Investigations	2015-10-09	2015-10-14	No	2. recovering/resolving	3	probable	NA	No
22	Lymphocyte count decreased	Investigations	2015-06-26	2015-07-22	No	2. recovering/resolving	3	probable	NA	No
22	Lymphocyte count decreased	Investigations	2015-02-26	2015-03-05	No	3. not recovered/ not resolved	2	probable	NA	No
22	Lymphocyte count decreased	Investigations	2016-02-11	2016-03-10	No	2. recovering/resolving	4	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-03-05	2015-03-23	No	2. recovering/resolving	3	probable	NA	No
22	Lymphocyte count decreased	Investigations	2015-10-09	2015-10-14	No	2. recovering/resolving	3	probable	NA	No
22	Neutrophil count decreased	Investigations	2014-12-30	2015-02-04	No	3. not recovered/ not resolved	2	probable	NA	No
22	Anaemia	Blood and lymphatic system disorders	2015-03-20	2015-04-10	No	3. not recovered/ not resolved	1	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-09-04	2015-09-16	No	2. recovering/resolving	3	probable	NA	No
22	Hypertension	Vascular disorders	2016-03-10	2016-05-06	No	2. recovering/resolving	2	possible	NA	No
22	Neutrophil count decreased	Investigations	2015-10-09	2015-10-14	No	1. recovered/resolved	4	probable	NA	No
22	Hypertension	Vascular disorders	2016-05-31	2016-06-28	No	2. recovering/resolving	3	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-07-22	2015-08-14	No	3. not recovered/ not resolved	2	probable	NA	No
22	Anaemia	Blood and lymphatic system disorders	2015-03-13	2015-03-20	No	2. recovering/resolving	2	possible	NA	No
22	White blood cell count decreased	Investigations	2015-05-22	2015-05-27	No	2. recovering/resolving	2	probable	NA	No
22	Oedema peripheral	General disorders and administration site conditions	2016-05-06	2016-08-23	No	1. recovered/resolved	1	possible	NA	No
22	Platelet count decreased	Investigations	2015-02-26	2015-03-05	No	1. recovered/resolved	1	probable	not related	No
22	Neutrophil count decreased	Investigations	2015-08-20	2015-08-21	No	1. recovered/resolved	2	probable	NA	No
22	Muscle spasms	Musculoskeletal and connective tissue disorders	2016-05-31	2016-06-28	No	1. recovered/resolved	1	possible	NA	No
22	White blood cell count decreased	Investigations	2015-10-14	2015-11-19	No	2. recovering/resolving	2	probable	NA	No
22	Platelet count decreased	Investigations	2014-12-12	2014-12-30	No	1. recovered/resolved	1	probable	NA	No
22	White blood cell count decreased	Investigations	2014-12-22	2015-02-04	No	3. not recovered/ not resolved	2	probable	NA	No
22	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2014-11-15	NA	Yes	NA	1	possible	NA	No
22	White blood cell count decreased	Investigations	2015-06-26	2015-08-21	No	2. recovering/resolving	2	NA	NA	No
22	Lymphocyte count decreased	Investigations	2015-05-22	2015-05-27	No	2. recovering/resolving	3	probable	NA	No
22	Lymphocyte count decreased	Investigations	2014-11-21	2014-12-04	No	3. not recovered/ not resolved	3	probable	NA	No
22	Platelet count decreased	Investigations	2015-09-04	2015-10-14	No	1. recovered/resolved	1	possible	NA	No
22	White blood cell count decreased	Investigations	2015-11-19	2016-05-06	No	1. recovered/resolved	1	probable	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
22	White blood cell count decreased	Investigations	2014-11-14	2014-11-28	No	3. not recovered/ not resolved	3	probable	NA	No
22	Hypertension	Vascular disorders	2016-06-28	2016-07-26	No	2. recovering/resolving	2	possible	NA	No
22	Lymphocyte count decreased	Investigations	2015-05-27	2015-06-26	No	3. not recovered/ not resolved	2	probable	NA	No
22	Platelet count decreased	Investigations	2014-10-31	2014-11-14	No	3. not recovered/ not resolved	1	probable	NA	No
22	Lymphocyte count decreased	Investigations	2016-04-08	2016-05-06	No	3. not recovered/ not resolved	2	possible	NA	No
22	White blood cell count decreased	Investigations	2014-12-12	2014-12-19	No	3. not recovered/ not resolved	1	probable	NA	No
22	Otitis media	Infections and infestations	2015-10-15	2015-11-19	No	2. recovering/resolving	2	possible	NA	No
22	Platelet count decreased	Investigations	2015-03-13	2015-04-23	No	1. recovered/resolved	1	possible	NA	No
22	White blood cell count decreased	Investigations	2015-03-13	2015-03-20	No	2. recovering/resolving	3	probable	NA	No
22	Lymphocyte count decreased	Investigations	2015-02-04	2015-02-26	No	2. recovering/resolving	3	probable	NA	No
22	Neutrophil count decreased	Investigations	2015-01-30	2015-02-04	No	1. recovered/resolved	3	probable	not related	No
22	White blood cell count decreased	Investigations	2016-05-31	2016-06-28	No	3. not recovered/ not resolved	1	probable	NA	No
22	Anaemia	Blood and lymphatic system disorders	2015-05-15	2016-01-14	No	1. recovered/resolved	1	possible	NA	No
22	Anaemia	Blood and lymphatic system disorders	2015-04-10	2015-05-15	No	2. recovering/resolving	2	possible	NA	No
22	Blood alkaline phosphatase decreased	Investigations	2016-05-31	2016-08-23	No	1. recovered/resolved	1	possible	NA	No
22	C-reactive protein increased	Investigations	2015-10-09	2015-12-17	No	1. recovered/resolved	1	possible	NA	No
22	White blood cell count decreased	Investigations	2014-11-28	2014-12-12	No	3. not recovered/ not resolved	2	probable	NA	No
22	Hypertension	Vascular disorders	2016-05-06	2016-05-31	No	1. recovered/resolved	1	possible	NA	No
22	Anaemia	Blood and lymphatic system disorders	2016-05-06	NA	Yes	3. not recovered/ not resolved	1	probable	NA	No
22	Neutrophil count decreased	Investigations	2016-05-31	2016-06-28	No	3. not recovered/ not resolved	1	probable	NA	No
23	Gamma-glutamyltransferase increased	Investigations	2014-12-30	2015-01-05	No	3. not recovered/ not resolved	4	unlikely	unlikely	No
23	Fatigue	General disorders and administration site conditions	2015-09-01	2016-02-07	No	3. not recovered/ not resolved	1	possible	possible	No
23	Nausea	Gastrointestinal disorders	2015-06-23	2016-02-07	No	3. not recovered/ not resolved	1	possible	possible	No
23	Gamma-glutamyltransferase increased	Investigations	2015-01-20	2015-02-02	No	4. recovered/ resolved with sequel	4	possible	possible	No
23	Alanine amino-transferase increased	Investigations	2015-01-20	2015-02-02	No	1. recovered/resolved	3	possible	possible	No
23	Alanine amino-transferase increased	Investigations	2014-12-30	2015-01-14	No	1. recovered/resolved	3	possible	possible	No
23	Gamma-glutamyltransferase increased	Investigations	2014-11-21	2014-12-29	No	3. not recovered/ not resolved	3	unlikely	unlikely	No
23	Alanine amino-transferase increased	Investigations	2014-11-27	2014-12-22	No	1. recovered/resolved	3	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE	
23	Weight creased	in-	Investigations	2015-08-04	2016-02-07	No	3. not recovered/ not resolved	1	possible	possible	No
23	Tremor		Nervous system disorders	2015-09-01	2016-02-07	No	3. not recovered/ not resolved	1	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
23	Gamma-glutamyltransferase increased	Investigations	2015-01-06	2015-01-19	No	1. recovered/resolved	3	unlikely	unlikely	No
24	Dizziness postural	Nervous system disorders	2015-05-07	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
24	Inflammation	General disorders and administration site conditions	2015-08-19	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
24	Dehydration	Metabolism and nutrition disorders	2015-06-25	2015-07-01	No	1. recovered/resolved	2	unlikely	unlikely	Yes
24	Cholecystitis	Hepatobiliary disorders	2015-02-09	2015-02-12	No	1. recovered/resolved	2	unlikely	unlikely	Yes
24	Leukopenia	Blood and lymphatic system disorders	2015-04-07	2015-05-25	No	2. recovering/resolving	4	related	related	No
24	Peripheral sensory neuropathy	Nervous system disorders	2014-12-15	2015-01-05	No	2. recovering/resolving	2	related	not related	No
24	Pruritus	Skin and subcutaneous tissue disorders	2014-11-09	2014-11-10	No	1. recovered/resolved	2	related	not assessable	No
24	Anaemia	Blood and lymphatic system disorders	2015-12-09	2016-01-06	No	1. recovered/resolved	3	not related	not related	No
24	C-reactive protein increased	Investigations	2014-12-19	2015-04-06	No	1. recovered/resolved	2	related	not related	No
24	Neutropenia	Blood and lymphatic system disorders	2015-02-09	2015-02-16	No	1. recovered/resolved	1	related	related	No
24	Atrial flutter	Cardiac disorders	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
24	Blood creatinine increased	Investigations	2015-02-09	2015-02-16	No	2. recovering/resolving	2	not related	not assessable	No
24	Diverticulitis	Infections and infestations	2015-12-29	2016-01-02	No	1. recovered/resolved	2	not related	not related	No
24	Upper respiratory tract infection	Respiratory, thoracic and mediastinal disorders	2016-04-09	2016-04-19	No	1. recovered/resolved	2	possible	possible	Yes
24	Myalgia	Musculoskeletal and connective tissue disorders	2014-11-13	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
24	Nausea	Gastrointestinal disorders	2014-11-30	2014-12-18	No	1. recovered/resolved	2	related	not assessable	No
24	Fatigue	General disorders and administration site conditions	2014-11-13	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
24	Abdominal pain lower	Gastrointestinal disorders	2014-11-30	2015-09-16	No	1. recovered/resolved	2	related	not assessable	No
24	Peripheral sensory neuropathy	Nervous system disorders	2015-02-02	2015-02-08	No	2. recovering/resolving	2	related	related	No
24	Oedema	General disorders and administration site conditions	2015-03-16	2015-03-22	No	1. recovered/resolved	1	not related	not related	No
24	Blood alkaline phosphatase increased	Investigations	2015-02-17	2015-03-15	No	1. recovered/resolved	2	not related	not related	No
24	Thrombocytopenia	Blood and lymphatic system disorders	2015-05-26	2015-10-13	No	1. recovered/resolved	1	related	related	No
24	Anaemia	Blood and lymphatic system disorders	2015-05-26	2015-08-05	No	2. recovering/resolving	3	related	related	No
24	Asthenia	General disorders and administration site conditions	2015-01-08	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
24	Neutropenia	Blood and lymphatic system disorders	2015-04-07	2015-04-18	No	1. recovered/resolved	2	possible	possible	Yes
24	Gamma-glutamyltransferase increased	Investigations	2015-02-17	2015-03-15	No	1. recovered/resolved	3	not related	not related	No
24	Weight decreased	Investigations	2015-04-23	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
24	Alanine aminotransferase increased	Investigations	2015-02-09	2015-02-16	No	1. recovered/resolved	3	not related	not assessable	No
24	Neuralgia	Nervous system disorders	2015-01-22	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
24	Malnutrition	Metabolism and nutrition disorders	2015-06-23	2015-07-08	No	2. recovering/resolving	3	not related	not related	No
24	Blood creatinine increased	Investigations	2015-02-09	2016-04-26	No	2. recovering/resolving	2	not related	not related	No
24	Oedema	General disorders and administration site conditions	2015-07-09	2015-08-05	No	1. recovered/resolved	1	not related	not related	No
24	Acute myocardial infarction	Cardiac disorders	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
24	Depression	Psychiatric disorders	2015-02-07	2015-02-16	No	1. recovered/resolved	2	not related	not related	No
24	Malnutrition	Metabolism and nutrition disorders	2015-07-09	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
24	Leukopenia	Blood and lymphatic system disorders	2015-02-09	2015-02-16	No	1. recovered/resolved	1	related	related	No
24	Leukopenia	Blood and lymphatic system disorders	2015-12-09	2016-01-06	No	1. recovered/resolved	1	related	related	No
24	Neutropenia	Blood and lymphatic system disorders	2015-04-07	2015-05-25	No	2. recovering/resolving	4	related	related	No
24	Dehydration	Metabolism and nutrition disorders	2014-12-07	2014-12-11	No	1. recovered/resolved	2	unlikely	not assessable	Yes
24	C-reactive protein increased	Investigations	2014-12-19	2015-03-15	No	1. recovered/resolved	2	related	not related	No
24	Nausea	Gastrointestinal disorders	2015-02-02	2015-02-16	No	1. recovered/resolved	2	not related	related	No
24	Dyspepsia	Gastrointestinal disorders	2016-08-17	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
24	Gastritis	Gastrointestinal disorders	2014-12-07	2014-12-11	No	1. recovered/resolved	2	unlikely	not assessable	Yes
24	Decreased appetite	Metabolism and nutrition disorders	2015-02-05	2015-02-16	No	1. recovered/resolved	2	not related	not related	No
24	Aspartate aminotransferase increased	Investigations	2015-02-09	2015-02-16	No	1. recovered/resolved	2	not related	not assessable	No
24	Pollakiuria	Renal and urinary disorders	2015-02-02	NA	Yes	3. not recovered/ not resolved	2	not related	related	No
24	Diarrhoea	Gastrointestinal disorders	2016-04-27	2016-05-24	No	1. recovered/resolved	2	not related	not assessable	No
24	Asthenia	General disorders and administration site conditions	2014-11-30	2015-01-07	No	2. recovering/resolving	3	related	not assessable	No
24	Infection	Infections and infestations	2015-04-07	2015-04-18	No	1. recovered/resolved	2	possible	possible	Yes
24	Neutropenia	Blood and lymphatic system disorders	2015-09-16	2015-10-13	No	1. recovered/resolved	2	related	related	No
24	Bone pain	Musculoskeletal and connective tissue disorders	2014-11-20	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
24	Leukopenia	Blood and lymphatic system disorders	2015-09-16	2015-10-13	No	1. recovered/resolved	3	related	related	No
24	Inflammation	General disorders and administration site conditions	2015-08-06	2015-08-18	No	2. recovering/resolving	2	not related	not related	No
24	Gamma-glutamyltransferase increased	Investigations	2015-02-09	2015-02-16	No	2. recovering/resolving	4	not related	not assessable	No
24	Glomerular filtration rate decreased	Investigations	2015-02-09	2016-03-29	No	2. recovering/resolving	3	not related	not related	No
24	Pneumonia	Infections and infestations	2015-07-11	2015-07-20	No	1. recovered/resolved	3	possible	unlikely	Yes
24	Hot flush	Vascular disorders	2014-11-10	2014-11-11	No	1. recovered/resolved	2	not related	not assessable	No
24	Glomerular filtration rate decreased	Investigations	2016-03-30	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
24	Leukopenia	Blood and lymphatic system disorders	2015-05-26	2015-08-05	No	1. recovered/resolved	3	related	related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
24	Neutropenia	Blood and lymphatic system disorders	2015-05-26	2015-08-05	No	1. recovered/resolved	3	related	related	No
24	Acute kidney injury	Renal and urinary disorders	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
24	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-01-08	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
24	Infection	Infections and infestations	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
24	Blood alkaline phosphatase increased	Investigations	2015-02-09	2015-02-16	No	2. recovering/resolving	3	not related	not assessable	No
24	Nausea	Gastrointestinal disorders	2015-06-23	2015-07-08	No	1. recovered/resolved	2	not related	not related	No
24	Thrombocytopenia	Blood and lymphatic system disorders	2015-04-07	2015-05-25	No	2. recovering/resolving	2	related	related	No
24	Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	2015-04-23	2015-09-16	No	1. recovered/resolved	2	not related	not related	No
25	Polyneuropathy	Nervous system disorders	2015-02-05	NA	Yes	NA	1	possible	NA	No
25	Neutrophil count decreased	Investigations	2015-01-30	2015-02-05	No	1. recovered/resolved	3	probable	NA	No
25	Neutrophil count decreased	Investigations	2015-01-16	2015-01-30	No	3. not recovered/ not resolved	2	probable	NA	No
25	Cough	Respiratory, thoracic and mediastinal disorders	2015-07-09	2015-08-24	No	1. recovered/resolved	1	possible	NA	No
25	Platelet count decreased	Investigations	2014-12-05	2014-12-12	No	1. recovered/resolved	1	possible	NA	No
25	Neutrophil count decreased	Investigations	2014-12-19	2014-12-30	No	1. recovered/resolved	1	probable	NA	No
25	Sepsis	Infections and infestations	2015-03-23	2015-06-03	No	1. recovered/resolved	4	possible	NA	Yes
25	Erectile dysfunction	Reproductive system and breast disorders	2015-02-05	NA	NA	NA	1	possible	NA	No
25	Anaemia	Blood and lymphatic system disorders	2015-01-09	2015-10-09	No	1. recovered/resolved	1	possible	NA	No
25	White blood cell count decreased	Investigations	2014-12-19	2014-12-30	No	1. recovered/resolved	1	probable	NA	No
25	Hypocalcaemia	Metabolism and nutrition disorders	2015-07-09	2015-08-24	No	1. recovered/resolved	2	possible	NA	No
25	Blood urea increased	Investigations	2015-01-09	2015-01-16	No	1. recovered/resolved	1	possible	NA	No
25	Bronchopulmonary aspergillosis	Infections and infestations	2015-04-02	2015-05-07	No	1. recovered/resolved	3	possible	NA	Yes
25	Nasopharyngitis	Infections and infestations	2015-01-09	2015-02-05	No	1. recovered/resolved	2	possible	NA	No
25	Neutrophil count decreased	Investigations	2014-12-05	2014-12-12	No	1. recovered/resolved	3	probable	NA	No
25	Alanine aminotransferase increased	Investigations	2015-01-16	2017-05-18	No	1. recovered/resolved	1	possible	NA	No
25	Hypokalaemia	Metabolism and nutrition disorders	2015-01-09	2015-02-05	No	1. recovered/resolved	1	possible	NA	No
25	White blood cell count decreased	Investigations	2015-01-30	2015-02-05	No	1. recovered/resolved	2	probable	NA	No
25	Blood urea increased	Investigations	2015-02-05	2015-07-14	No	1. recovered/resolved	1	possible	NA	No
25	White blood cell count decreased	Investigations	2015-03-13	2015-06-24	No	1. recovered/resolved	1	probable	NA	No
25	White blood cell count decreased	Investigations	2014-12-05	2014-12-12	No	1. recovered/resolved	1	probable	NA	No
26	Leukopenia	Blood and lymphatic system disorders	2014-12-02	2014-12-09	No	1. recovered/resolved	3	possible	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
26	Sepsis	Infections and infestations	2015-01-09	2015-01-09	No	3. not recovered/ not resolved	4	not related	not assessable	No
26	Pneumonia fungal	Infections and infestations	2014-12-22	2014-12-30	No	1. recovered/resolved	3	unlikely	not assessable	Yes
26	Disease progression	General disorders and administration site conditions	2015-01-09	2015-01-09	No	5. fatal	5	not related	not assessable	Yes
26	Pneumonia	Infections and infestations	2015-01-09	2015-01-09	No	3. not recovered/ not resolved	3	unlikely	not assessable	No
26	Leukopenia	Blood and lymphatic system disorders	2015-11-25	2015-12-02	No	1. recovered/resolved	1	related	not assessable	No
27	Pneumonia	Infections and infestations	2015-02-15	2015-02-23	No	1. recovered/resolved	3	probable	probable	Yes
27	Myocardial infarction	Cardiac disorders	2015-04-25	2015-06-05	No	4. recovered/ resolved with sequel	4	not related	not related	Yes
27	Disease progression	General disorders and administration site conditions	2015-06-19	2015-07-01	No	5. fatal	5	not related	not related	Yes
27	Clostridium difficile infection	Infections and infestations	2015-02-15	2015-02-23	No	1. recovered/resolved	3	probable	probable	Yes
27	Neutropenia	Blood and lymphatic system disorders	2015-02-17	2015-06-18	No	1. recovered/resolved	3	possible	possible	No
27	Pneumonia	Infections and infestations	2014-12-10	2014-12-28	No	1. recovered/resolved	2	not related	not related	Yes
27	Gastroenteritis norovirus	Infections and infestations	2015-02-15	2015-02-23	No	1. recovered/resolved	3	probable	probable	Yes
27	Atrial fibrillation	Cardiac disorders	2015-04-09	2015-04-16	No	1. recovered/resolved	3	not related	not related	Yes
28	Anaemia	Blood and lymphatic system disorders	2014-12-19	2015-01-19	No	1. recovered/resolved	1	related	not assessable	No
28	Pneumonia	Infections and infestations	2014-12-30	2015-01-05	No	1. recovered/resolved	3	possible	possible	Yes
28	Constipation	Gastrointestinal disorders	2015-03-17	2015-04-13	No	1. recovered/resolved	2	not related	not related	No
28	Insomnia	Psychiatric disorders	2015-11-26	NA	Yes	1. recovered/resolved	1	not related	not related	No
28	Bronchitis	Infections and infestations	2014-12-29	2015-01-19	No	1. recovered/resolved	2	related	not assessable	No
28	Mood altered	Psychiatric disorders	2014-12-19	2015-11-25	No	2. recovering/resolving	2	not related	not assessable	No
28	Leukopenia	Blood and lymphatic system disorders	2014-12-19	2015-01-19	No	1. recovered/resolved	1	related	not assessable	No
28	Insomnia	Psychiatric disorders	2014-12-19	2015-11-25	No	2. recovering/resolving	2	not related	not assessable	No
28	Upper respiratory tract infection	Infections and infestations	2016-03-11	2016-03-14	No	1. recovered/resolved	2	related	related	No
28	Rash	Skin and subcutaneous tissue disorders	2014-12-19	2015-01-19	No	1. recovered/resolved	1	related	not assessable	No
28	Upper respiratory tract infection	Infections and infestations	2015-10-01	2015-10-28	No	1. recovered/resolved	1	not related	not related	No
28	Polyneuropathy	Nervous system disorders	2015-01-20	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
28	Muscular weakness	Musculoskeletal and connective tissue disorders	2015-03-17	2015-09-02	No	1. recovered/resolved	2	not related	not related	No
28	Nasopharyngitis	Infections and infestations	2015-11-26	2015-12-27	No	1. recovered/resolved	1	not related	not related	No
28	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-01-20	2015-02-15	No	1. recovered/resolved	1	not related	not assessable	No
28	Mood altered	Psychiatric disorders	2015-11-26	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
28	Neutropenia	Blood and lymphatic system disorders	2014-12-19	2015-01-19	No	1. recovered/resolved	3	related	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
29	Neutropenia	Blood and lymphatic system disorders	2014-12-29	2015-01-23	No	2. recovering/resolving	2	related	not related	No
29	Gastritis	Gastrointestinal disorders	2015-01-22	2015-07-14	No	1. recovered/resolved	2	not related	not assessable	No
29	Neutropenia	Blood and lymphatic system disorders	2015-03-20	2015-04-16	No	3. not recovered/ not resolved	1	related	not assessable	No
29	Neutropenia	Blood and lymphatic system disorders	2015-04-17	2015-05-17	No	1. recovered/resolved	3	related	not assessable	No
29	Pneumonia	Infections and infestations	2015-02-01	2015-02-07	No	1. recovered/resolved	2	possible	not assessable	Yes
29	Insomnia	Psychiatric disorders	2015-01-22	2015-07-14	No	1. recovered/resolved	2	not related	not assessable	No
29	Leukopenia	Blood and lymphatic system disorders	2015-03-20	2015-04-16	No	3. not recovered/ not resolved	1	related	not assessable	No
29	Leukopenia	Blood and lymphatic system disorders	2015-04-17	2015-05-17	No	1. recovered/resolved	2	related	not assessable	No
29	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2015-02-19	2015-07-14	No	1. recovered/resolved	2	not related	not assessable	No
29	Oral discomfort	Gastrointestinal disorders	2015-01-22	2015-07-14	No	1. recovered/resolved	2	not related	not assessable	No
29	Leukopenia	Blood and lymphatic system disorders	2014-12-29	2015-02-18	No	1. recovered/resolved	1	related	not related	No
29	Pneumonia	Infections and infestations	2015-03-02	2015-03-10	No	1. recovered/resolved	3	possible	not assessable	Yes
29	Asthenia	General disorders and administration site conditions	2015-02-19	2015-07-14	No	1. recovered/resolved	2	not related	not assessable	No
29	Thrombocytopenia	Blood and lymphatic system disorders	2015-04-17	2015-05-17	No	1. recovered/resolved	1	related	not assessable	No
29	Infection	Infections and infestations	2015-04-13	2015-07-15	No	1. recovered/resolved	1	possible	not assessable	Yes
29	Neutropenia	Blood and lymphatic system disorders	2015-01-22	2015-02-18	No	1. recovered/resolved	1	related	not assessable	No
29	Pneumonia	Infections and infestations	2015-02-01	2015-02-07	No	1. recovered/resolved	2	possible	possible	Yes
29	Dizziness	Nervous system disorders	2014-12-10	2014-12-22	No	1. recovered/resolved	2	related	not related	No
29	Anaemia	Blood and lymphatic system disorders	2014-12-29	2015-06-15	No	1. recovered/resolved	1	related	not related	No
29	Polyneuropathy	Nervous system disorders	2014-12-29	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
29	Dizziness	Nervous system disorders	2014-12-15	2014-12-17	No	1. recovered/resolved	3	related	not related	Yes
29	Skin discolouration	Skin and subcutaneous tissue disorders	2014-12-15	2015-07-14	No	1. recovered/resolved	1	not related	not related	No
30	Leukopenia	Blood and lymphatic system disorders	2015-04-13	2015-05-05	No	1. recovered/resolved	3	possible	not related	No
30	Neutropenia	Blood and lymphatic system disorders	2015-07-05	2015-07-09	No	1. recovered/resolved	4	possible	possible	No
30	Organic brain syndrome	Psychiatric disorders	2015-04-14	2015-07-27	No	3. not recovered/ not resolved	NA	not related	not related	No
30	Thrombocytopenia	Blood and lymphatic system disorders	2016-03-02	2016-03-16	No	1. recovered/resolved	2	possible	possible	No
30	Atypical pneumonia	Infections and infestations	2015-07-04	2015-07-27	No	5. fatal	5	possible	possible	Yes
30	Leukopenia	Blood and lymphatic system disorders	2015-07-04	2015-07-05	No	1. recovered/resolved	3	possible	possible	No
30	Neutropenia	Blood and lymphatic system disorders	2015-04-13	2015-04-14	No	1. recovered/resolved	4	possible	possible	No
30	Leukopenia	Blood and lymphatic system disorders	2015-06-08	2015-06-15	No	1. recovered/resolved	3	possible	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
30	Rash	Skin and subcutaneous tissue disorders	2015-04-13	2015-06-15	No	1. recovered/resolved	2	not related	possible	No
30	Bronchitis	Infections and infestations	2015-04-14	2015-05-08	No	4. recovered/ resolved with sequel	3	possible	possible	Yes
30	Leukopenia	Blood and lymphatic system disorders	2015-07-05	2015-07-07	No	1. recovered/resolved	4	possible	possible	No
30	Neutropenia	Blood and lymphatic system disorders	2015-07-04	2016-07-05	No	1. recovered/resolved	3	possible	possible	No
30	Fall	Injury, poisoning and procedural complications	2015-04-13	2015-04-15	No	1. recovered/resolved	1	not related	not related	No
30	Cough	Respiratory, thoracic and mediastinal disorders	2015-01-19	2015-07-27	No	1. recovered/resolved	2	not related	not assessable	No
30	C-reactive protein increased	Investigations	2015-01-19	2015-07-27	No	1. recovered/resolved	2	not related	not assessable	No
30	Neutropenia	Blood and lymphatic system disorders	2015-01-26	2015-02-02	No	1. recovered/resolved	3	possible	not assessable	No
30	Neutropenia	Blood and lymphatic system disorders	2015-03-16	2015-03-30	No	1. recovered/resolved	4	possible	possible	No
30	Neutropenia	Blood and lymphatic system disorders	2015-03-30	2015-04-13	No	1. recovered/resolved	2	not assessable	not assessable	No
30	Leukopenia	Blood and lymphatic system disorders	2015-03-16	2015-03-30	No	1. recovered/resolved	3	possible	possible	No
31	Bone marrow failure	Blood and lymphatic system disorders	2015-01-02	2015-01-03	No	5. fatal	5	not related	not related	Yes
32	Leukopenia	Blood and lymphatic system disorders	2015-04-13	2015-04-14	No	1. recovered/resolved	1	probable	not related	No
32	White blood cell count decreased	Investigations	2015-07-27	2015-08-03	No	1. recovered/resolved	2	related	not related	No
32	Neutrophil count decreased	Investigations	2015-02-09	2015-02-23	No	1. recovered/resolved	3	probable	not related	No
32	Neutropenia	Blood and lymphatic system disorders	2015-12-14	2016-01-19	No	1. recovered/resolved	3	possible	related	No
32	Platelet count decreased	Investigations	2015-04-10	2015-04-12	No	1. recovered/resolved	3	probable	not related	No
32	Neutrophil count decreased	Investigations	2015-06-22	2015-06-29	No	1. recovered/resolved	4	possible	related	No
32	Neutrophil count decreased	Investigations	2015-02-02	2015-02-09	No	1. recovered/resolved	4	possible	not related	No
32	Herpes zoster	Infections and infestations	2015-11-17	2015-11-22	No	1. recovered/resolved	3	not related	not related	No
32	Neutrophil count decreased	Investigations	2015-05-18	2015-06-08	No	1. recovered/resolved	4	possible	related	No
32	Pneumonia	Infections and infestations	2015-11-03	2015-11-23	No	1. recovered/resolved	3	unlikely	unlikely	Yes
32	Platelet count decreased	Investigations	2015-01-12	2015-02-02	No	1. recovered/resolved	3	possible	not related	No
32	Febrile neutropenia	Blood and lymphatic system disorders	2015-05-20	2015-06-02	No	1. recovered/resolved	3	possible	possible	Yes
32	Platelet count decreased	Investigations	2015-04-13	2015-04-17	No	1. recovered/resolved	3	probable	not related	No
32	Pyrexia	General disorders and administration site conditions	2015-12-01	2015-12-10	No	1. recovered/resolved	2	unlikely	unlikely	Yes
32	Neutrophil count decreased	Investigations	2015-03-09	2015-03-16	No	1. recovered/resolved	4	probable	not related	No
32	Neutrophil count decreased	Investigations	2015-07-13	2015-08-03	No	1. recovered/resolved	3	possible	related	No
32	Neutropenia	Blood and lymphatic system disorders	2015-10-12	2015-12-01	No	1. recovered/resolved	3	possible	related	No
32	Mucosal inflammation	General disorders and administration site conditions	2015-10-05	2015-10-12	No	1. recovered/resolved	2	unlikely	probable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
32	White blood cell count decreased	Investigations	2015-06-22	2015-06-29	No	1. recovered/resolved	2	related	not related	No
32	Infection	Infections and infestations	2015-04-10	2015-04-24	No	1. recovered/resolved	3	probable	not related	Yes
32	Febrile neutropenia	Blood and lymphatic system disorders	2015-05-17	2015-05-20	No	3. not recovered/ not resolved	3	possible	probable	No
32	Platelet count decreased	Investigations	2015-05-12	2015-05-18	No	1. recovered/resolved	3	possible	related	No
32	Neutropenia	Blood and lymphatic system disorders	2015-06-15	2015-06-21	No	1. recovered/resolved	3	possible	related	No
32	Febrile neutropenia	Blood and lymphatic system disorders	2015-03-16	2015-03-26	No	1. recovered/resolved	3	probable	not related	No
32	Anaemia	Blood and lymphatic system disorders	2015-03-16	2015-03-23	No	1. recovered/resolved	3	probable	not related	No
32	Leukopenia	Blood and lymphatic system disorders	2015-04-22	2015-04-29	No	1. recovered/resolved	1	related	not related	No
32	Anaemia	Blood and lymphatic system disorders	2015-04-10	2015-04-23	No	1. recovered/resolved	3	probable	not related	No
32	Leukopenia	Blood and lymphatic system disorders	2015-05-18	2015-06-08	No	1. recovered/resolved	2	related	not related	No
32	Anaemia	Blood and lymphatic system disorders	2015-01-26	2015-02-02	No	1. recovered/resolved	3	possible	not related	No
32	Anaemia	Blood and lymphatic system disorders	2015-05-12	2015-06-08	No	1. recovered/resolved	3	probable	not related	No
32	Platelet count decreased	Investigations	2015-12-14	2016-01-21	No	1. recovered/resolved	3	probable	not related	No
32	Infection	Infections and infestations	2015-04-08	2015-04-10	No	3. not recovered/ not resolved	2	probable	not related	No
32	Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2015-02-26	2015-02-26	No	1. recovered/resolved	2	not related	not related	Yes
33	White blood cell count decreased	Investigations	2015-02-19	2015-03-12	No	3. not recovered/ not resolved	1	probable	NA	No
33	Neutrophil count decreased	Investigations	2015-03-12	2015-03-16	No	2. recovering/resolving	3	possible	NA	No
33	Neutrophil count decreased	Investigations	2015-03-19	2015-03-27	No	1. recovered/resolved	1	possible	NA	No
33	White blood cell count decreased	Investigations	2015-03-12	2015-03-19	No	2. recovering/resolving	2	probable	NA	No
33	Platelet count decreased	Investigations	2015-03-12	2015-03-19	No	2. recovering/resolving	2	possible	NA	No
33	Hot flush	Vascular disorders	2015-03-16	NA	Yes	NA	1	unlikely	NA	No
33	Lymphocyte count decreased	Investigations	2015-05-15	2015-05-26	No	1. recovered/resolved	2	possible	possible	No
33	Platelet count decreased	Investigations	2015-05-15	2015-06-09	No	2. recovering/resolving	1	possible	possible	No
33	Anaemia	Blood and lymphatic system disorders	2015-03-12	2015-03-16	No	2. recovering/resolving	2	possible	NA	No
33	White blood cell count decreased	Investigations	2015-01-29	2015-02-12	No	3. not recovered/ not resolved	1	probable	NA	No
33	Agitation	Psychiatric disorders	2015-03-16	NA	Yes	NA	1	unlikely	NA	No
33	Anaemia	Blood and lymphatic system disorders	2015-02-19	2015-02-26	No	2. recovering/resolving	2	possible	NA	No
33	White blood cell count decreased	Investigations	2015-03-19	2015-04-24	No	1. recovered/resolved	1	probable	NA	No
33	Neutrophil count decreased	Investigations	2015-06-09	2015-06-12	No	2. recovering/resolving	3	possible	possible	No
33	Platelet count decreased	Investigations	2015-05-12	2015-05-15	No	2. recovering/resolving	2	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
33	Anaemia	Blood and lymphatic system disorders	2015-06-16	2015-06-23	No	2. recovering/resolving	2	possible	possible	No
33	Neutrophil count decreased	Investigations	2015-06-12	NA	Yes	3. not recovered/ not resolved	2	possible	possible	No
33	Neutrophil count decreased	Investigations	2015-02-19	2015-02-26	No	2. recovering/resolving	2	possible	NA	No
33	Neutrophil count decreased	Investigations	2015-02-12	2015-02-19	No	2. recovering/resolving	3	possible	NA	No
33	Platelet count decreased	Investigations	2015-06-09	NA	Yes	3. not recovered/ not resolved	2	possible	possible	No
33	Lymphocyte count decreased	Investigations	2015-06-12	2015-06-23	No	2. recovering/resolving	2	possible	possible	No
33	Neutrophil count decreased	Investigations	2015-03-16	2015-03-19	No	2. recovering/resolving	2	possible	NA	No
33	Nausea	Gastrointestinal disorders	2015-05-15	NA	Yes	NA	1	possible	possible	No
33	Fatigue	General disorders and administration site conditions	2015-04-16	2015-05-15	No	2. recovering/resolving	2	unlikely	NA	No
33	White blood cell count decreased	Investigations	2015-02-12	2015-02-19	No	2. recovering/resolving	2	probable	NA	No
33	Erythema	Skin and subcutaneous tissue disorders	2015-04-16	NA	NA	NA	1	unlikely	NA	No
33	Muscle spasms	Musculoskeletal and connective tissue disorders	2015-05-15	NA	Yes	NA	1	unlikely	unlikely	No
33	White blood cell count decreased	Investigations	2015-05-12	2015-06-23	No	2. recovering/resolving	2	probable	probable	No
33	Neutrophil count decreased	Investigations	2015-02-26	2015-03-12	No	3. not recovered/ not resolved	1	possible	NA	No
33	Platelet count decreased	Investigations	2015-06-12	NA	Yes	3. not recovered/ not resolved	1	possible	possible	No
33	White blood cell count decreased	Investigations	2015-04-28	2015-05-12	No	3. not recovered/ not resolved	1	probable	NA	No
33	Fatigue	General disorders and administration site conditions	2015-05-15	NA	Yes	3. not recovered/ not resolved	1	unlikely	unlikely	No
33	Anaemia	Blood and lymphatic system disorders	2015-06-12	2015-06-16	No	3. not recovered/ not resolved	1	possible	possible	No
33	Neutrophil count decreased	Investigations	2015-05-12	2015-05-15	No	2. recovering/resolving	3	possible	possible	No
33	White blood cell count decreased	Investigations	2015-06-23	NA	Yes	3. not recovered/ not resolved	1	probable	probable	No
33	Neutrophil count decreased	Investigations	2015-04-02	2015-04-16	No	1. recovered/resolved	2	possible	NA	No
33	Anaemia	Blood and lymphatic system disorders	2015-05-26	2015-06-12	No	2. recovering/resolving	2	possible	possible	No
33	Lymphocyte count decreased	Investigations	2015-03-16	2015-04-24	No	2. recovering/resolving	2	possible	NA	No
33	Anaemia	Blood and lymphatic system disorders	2015-03-27	2015-05-15	No	2. recovering/resolving	2	possible	NA	No
33	Nasopharyngitis	Infections and infestations	2015-03-08	2015-04-16	No	1. recovered/resolved	1	possible	NA	No
33	Platelet count decreased	Investigations	2015-02-05	2015-02-26	No	2. recovering/resolving	2	probable	NA	No
33	Platelet count decreased	Investigations	2015-04-09	2015-04-16	No	2. recovering/resolving	2	possible	NA	No
33	Muscle spasms	Musculoskeletal and connective tissue disorders	2015-05-15	NA	Yes	NA	1	unlikely	unlikely	No
33	Anaemia	Blood and lymphatic system disorders	2015-02-05	2015-02-12	No	2. recovering/resolving	2	possible	NA	No
34	Erythema	Skin and subcutaneous tissue disorders	2016-04-04	2016-04-08	No	4. recovered/ resolved with sequel	1	not related	not related	Yes

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
34	Aortic aneurysm	Vascular disorders	2015-03-03	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
34	Ear discomfort	Ear and labyrinth disorders	2016-09-05	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
34	Neuropathy peripheral	Nervous system disorders	2016-01-11	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Polyneuropathy	Nervous system disorders	2015-06-29	2015-10-18	No	2. recovering/resolving	2	not related	not related	No
34	Leukopenia	Blood and lymphatic system disorders	2015-06-29	2015-07-26	No	1. recovered/resolved	2	related	related	No
34	Anaemia	Blood and lymphatic system disorders	2015-03-09	2015-04-06	No	1. recovered/resolved	2	related	not related	No
34	Urinary tract infection	Infections and infestations	2015-03-09	2015-04-06	No	1. recovered/resolved	2	related	not assessable	No
34	Renal pain	Renal and urinary disorders	2015-03-06	2015-03-15	No	1. recovered/resolved	2	not related	not assessable	No
34	Neuropathy peripheral	Nervous system disorders	2016-01-11	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
34	Dyspepsia	Gastrointestinal disorders	2015-01-26	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Nausea	Gastrointestinal disorders	2015-02-04	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
34	Spinal pain	Musculoskeletal and connective tissue disorders	2015-03-03	2016-02-21	No	2. recovering/resolving	3	not related	not assessable	No
34	Neutropenia	Blood and lymphatic system disorders	2015-06-29	2015-07-26	No	1. recovered/resolved	3	related	related	No
34	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2015-05-04	2015-06-14	No	1. recovered/resolved	1	not related	not related	No
34	Polyneuropathy	Nervous system disorders	2016-07-11	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-04-13	2015-05-03	No	1. recovered/resolved	2	related	not related	No
34	Back pain	Musculoskeletal and connective tissue disorders	2016-09-05	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Fall	Injury, poisoning and procedural complications	2016-10-26	2016-10-26	No	2. recovering/resolving	2	not related	not assessable	No
34	Polyneuropathy	Nervous system disorders	2015-02-09	2015-03-05	No	2. recovering/resolving	2	not related	not assessable	No
34	Dizziness	Nervous system disorders	2015-02-04	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Tinnitus	Ear and labyrinth disorders	2015-01-26	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Diarrhoea	Gastrointestinal disorders	2016-04-26	2016-05-09	No	2. recovering/resolving	3	not related	not related	No
34	C-reactive protein increased	Investigations	2015-03-09	2015-04-06	No	1. recovered/resolved	2	not related	not related	No
34	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2015-03-23	2015-05-03	No	2. recovering/resolving	2	not related	not related	No
34	Anaemia	Blood and lymphatic system disorders	2015-05-04	2015-07-26	No	1. recovered/resolved	2	related	related	No
34	Gait disturbance	General disorders and administration site conditions	2015-06-29	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
34	Bone pain	Musculoskeletal and connective tissue disorders	2016-02-22	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Polyneuropathy	Nervous system disorders	2016-01-11	2016-02-21	No	2. recovering/resolving	2	not related	not related	No
34	Wound	Injury, poisoning and procedural complications	2016-10-26	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
34	Paraesthesia	Nervous system disorders	2015-03-16	2016-01-10	No	3. not recovered/ not resolved	1	not related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
34	Paraesthesia	Nervous system disorders	2015-01-26	2015-03-15	No	2. recovering/resolving	2	not related	not assessable	No
34	Weight decreased	Investigations	2015-04-07	2016-09-21	No	1. recovered/resolved	1	not related	not related	No
34	Upper respiratory tract infection	Infections and infestations	2015-02-23	2015-03-02	No	1. recovered/resolved	2	related	not assessable	No
34	Rash	Skin and subcutaneous tissue disorders	2016-10-04	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
35	Monoplegia	Nervous system disorders	2016-01-06	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
35	Gait disturbance	General disorders and administration site conditions	2015-02-25	2015-04-12	No	1. recovered/resolved	2	related	not assessable	No
35	Nasopharyngitis	Infections and infestations	2015-07-06	2015-08-02	No	1. recovered/resolved	1	related	not assessable	No
35	Blood creatinine increased	Investigations	2015-10-19	2015-12-20	No	1. recovered/resolved	2	not related	not related	No
35	Femur fracture	Injury, poisoning and procedural complications	2016-01-18	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
35	Oedema	General disorders and administration site conditions	2015-05-11	2015-08-30	No	2. recovering/resolving	2	not related	not assessable	No
35	Squamous cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2015-11-18	2015-11-18	No	1. recovered/resolved	3	not related	not assessable	Yes
35	Anaemia	Blood and lymphatic system disorders	2015-03-16	2015-04-12	No	2. recovering/resolving	2	related	not assessable	No
35	Listless	Psychiatric disorders	2015-11-23	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
35	Blood creatinine increased	Investigations	2015-03-16	2015-04-12	No	1. recovered/resolved	2	related	not assessable	No
35	Memory impairment	Nervous system disorders	2015-02-25	2015-05-10	No	1. recovered/resolved	2	related	not assessable	No
35	Oedema	General disorders and administration site conditions	2015-02-04	2015-02-17	No	2. recovering/resolving	2	not related	not assessable	No
35	Angina pectoris	Cardiac disorders	2015-10-17	2015-10-18	No	1. recovered/resolved	2	not related	not assessable	No
35	Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2015-11-18	2015-11-18	No	1. recovered/resolved	3	unlikely	not assessable	Yes
35	Chest pain	General disorders and administration site conditions	2015-07-17	2015-07-21	No	1. recovered/resolved	3	not related	not assessable	Yes
35	Fatigue	General disorders and administration site conditions	2015-06-08	2015-09-27	No	1. recovered/resolved	2	related	not assessable	No
35	Neuropathy peripheral	Nervous system disorders	2016-01-18	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
35	Neutropenia	Blood and lymphatic system disorders	2015-03-16	2015-04-12	No	1. recovered/resolved	2	related	not assessable	No
35	Influenza	Infections and infestations	2015-03-07	2015-03-15	No	1. recovered/resolved	2	not related	not assessable	No
35	Hyperglycaemia	Metabolism and nutrition disorders	2015-02-18	2015-03-15	No	1. recovered/resolved	3	not related	not assessable	No
35	Restless legs syndrome	Nervous system disorders	2015-08-31	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
35	Dry mouth	Gastrointestinal disorders	2015-02-04	2015-02-17	No	1. recovered/resolved	2	related	not assessable	No
35	Groin pain	Musculoskeletal and connective tissue disorders	2016-01-06	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
35	Polyneuropathy	Nervous system disorders	2015-04-13	2015-05-10	No	2. recovering/resolving	2	not related	not assessable	No
35	Asthenia	General disorders and administration site conditions	2015-11-23	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
36	Colitis	Gastrointestinal disorders	2015-06-29	2015-07-08	No	1. recovered/resolved	2	not related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
36	Eye pain	Eye disorders	2015-11-12	2015-12-09	No	1. recovered/resolved	1	not related	not related	No
36	Colitis	Gastrointestinal disorders	2015-12-06	2015-12-06	No	1. recovered/resolved	2	related	related	No
36	Leukopenia	Blood and lymphatic system disorders	2015-10-15	2015-11-11	No	1. recovered/resolved	2	related	related	No
36	Neutropenia	Blood and lymphatic system disorders	2015-10-15	2015-11-11	No	1. recovered/resolved	3	related	related	No
36	Neutropenia	Blood and lymphatic system disorders	2015-05-28	2015-06-24	No	1. recovered/resolved	2	related	not related	No
36	Upper respiratory tract infection	Infections and infestations	2016-02-29	2016-03-03	No	1. recovered/resolved	2	related	related	No
36	Fatigue	General disorders and administration site conditions	2015-05-28	NA	Yes	3. not recovered/ not resolved	2	related	related	No
36	Leukopenia	Blood and lymphatic system disorders	2015-05-28	2015-06-24	No	1. recovered/resolved	2	related	not related	No
36	Sinusitis	Infections and infestations	2016-06-13	2016-06-17	No	1. recovered/resolved	2	related	related	No
36	Polyneuropathy	Nervous system disorders	2016-09-15	2016-10-12	No	2. recovering/resolving	2	related	not assessable	No
36	Insomnia	Psychiatric disorders	2015-03-05	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
36	Dysphonia	Respiratory, thoracic and mediastinal disorders	2015-02-14	2015-03-04	No	1. recovered/resolved	1	related	not assessable	No
36	Neutropenia	Blood and lymphatic system disorders	2015-07-23	2015-09-15	No	1. recovered/resolved	1	related	not related	No
36	Anaemia	Blood and lymphatic system disorders	2015-05-28	2015-08-17	No	1. recovered/resolved	2	related	not related	No
36	Thrombocytopenia	Blood and lymphatic system disorders	2015-04-29	2015-06-24	No	1. recovered/resolved	1	related	not related	No
36	Palpitations	Cardiac disorders	2015-06-25	2015-07-06	No	1. recovered/resolved	2	related	related	No
36	Bronchitis	Infections and infestations	2016-03-21	2016-03-30	No	1. recovered/resolved	2	not related	not assessable	No
36	Dysphonia	Respiratory, thoracic and mediastinal disorders	2015-02-23	2015-03-04	No	1. recovered/resolved	1	related	not assessable	No
36	Asthenia	General disorders and administration site conditions	2015-05-28	NA	Yes	3. not recovered/ not resolved	2	related	related	No
36	Abdominal pain upper	Gastrointestinal disorders	2015-08-19	2015-09-15	No	1. recovered/resolved	2	related	not related	No
36	Thrombocytopenia	Blood and lymphatic system disorders	2015-08-18	2016-02-03	No	1. recovered/resolved	1	related	not related	No
36	Polyneuropathy	Nervous system disorders	2016-07-21	2016-08-17	No	2. recovering/resolving	2	related	not assessable	No
36	Leukopenia	Blood and lymphatic system disorders	2015-07-23	2015-09-15	No	1. recovered/resolved	1	related	not related	No
36	Neutropenia	Blood and lymphatic system disorders	2015-03-05	2015-03-31	No	1. recovered/resolved	3	related	not related	No
36	Neck pain	Musculoskeletal and connective tissue disorders	2016-08-18	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
36	Anaemia	Blood and lymphatic system disorders	2016-03-03	2016-06-22	No	2. recovering/resolving	2	related	related	No
36	Neck pain	Musculoskeletal and connective tissue disorders	2015-05-28	2015-07-22	No	1. recovered/resolved	2	not related	not related	No
36	Colitis	Gastrointestinal disorders	2015-07-12	2015-08-17	No	1. recovered/resolved	2	not related	related	No
37	Constipation	Gastrointestinal disorders	2015-03-09	2015-04-07	No	1. recovered/resolved	2	not related	not assessable	No
37	Tremor	Nervous system disorders	2015-07-28	2015-08-26	No	1. recovered/resolved	2	not related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
37	Diarrhoea	Gastrointestinal disorders	2015-04-18	2015-04-24	No	1. recovered/resolved	2	unlikely	not assessable	Yes
37	Tremor	Nervous system disorders	2015-02-15	2017-01-30	No	3. not recovered/ not resolved	2	not related	not related	No
37	Febrile infection	Infections and infestations	2015-02-18	2015-02-25	No	1. recovered/resolved	3	unlikely	not assessable	Yes
37	Asthenia	General disorders and administration site conditions	2015-02-06	2017-01-30	No	3. not recovered/ not resolved	1	not related	not assessable	No
37	Epistaxis	Respiratory, thoracic and mediastinal disorders	2015-01-30	2015-01-30	No	1. recovered/resolved	1	not related	not assessable	No
37	Polyneuropathy	Nervous system disorders	2015-04-07	2017-01-30	No	3. not recovered/ not resolved	1	not related	not assessable	No
37	Tooth fracture	Injury, poisoning and procedural complications	2015-10-04	2015-10-27	No	1. recovered/resolved	2	not related	not related	No
37	Decreased appetite	Metabolism and nutrition disorders	2015-03-09	2016-04-07	No	1. recovered/resolved	1	not related	not assessable	No
38	Thrombocytopenia	Blood and lymphatic system disorders	2015-01-31	2015-02-23	No	1. recovered/resolved	3	possible	not related	No
38	Oedema peripheral	General disorders and administration site conditions	2015-01-30	2015-02-03	No	1. recovered/resolved	2	not related	not related	Yes
38	Anaemia	Blood and lymphatic system disorders	2015-02-16	2015-02-16	No	1. recovered/resolved	3	possible	not related	No
38	Pleural effusion	Respiratory, thoracic and mediastinal disorders	2015-02-23	2015-02-25	No	5. fatal	5	not related	not related	Yes
39	General physical health deterioration	General disorders and administration site conditions	2015-08-18	2015-08-19	No	1. recovered/resolved	2	not related	not assessable	No
39	Leukopenia	Blood and lymphatic system disorders	2015-03-30	2015-04-13	No	1. recovered/resolved	3	possible	not assessable	No
39	Leukopenia	Blood and lymphatic system disorders	2015-02-09	2015-03-16	No	1. recovered/resolved	3	possible	not assessable	No
39	Musculoskeletal pain	Musculoskeletal and connective tissue disorders	2015-03-09	2015-03-30	No	1. recovered/resolved	1	not related	not assessable	No
39	Femoral neck fracture	Injury, poisoning and procedural complications	2015-04-14	2015-04-28	No	1. recovered/resolved	3	not related	not assessable	Yes
39	Leukopenia	Blood and lymphatic system disorders	2015-08-25	2015-10-19	No	1. recovered/resolved	3	possible	not assessable	No
39	Leukopenia	Blood and lymphatic system disorders	2015-07-06	2015-07-22	No	1. recovered/resolved	3	possible	not assessable	No
39	Neutropenia	Blood and lymphatic system disorders	2015-03-02	2015-03-30	No	1. recovered/resolved	1	not assessable	not assessable	No
39	Polyneuropathy	Nervous system disorders	2015-03-09	NA	Yes	1. recovered/resolved	2	possible	not assessable	No
39	Vomiting	Gastrointestinal disorders	2015-08-18	2015-08-19	No	1. recovered/resolved	2	not related	not assessable	No
40	Pain	General disorders and administration site conditions	2015-03-12	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
40	Blood creatinine increased	Investigations	2015-03-13	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
40	Asthenia	General disorders and administration site conditions	2015-03-12	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
40	Hypercalcaemia	Metabolism and nutrition disorders	2015-03-12	NA	Yes	3. not recovered/ not resolved	3	not related	not related	Yes
41	Neutropenia	Blood and lymphatic system disorders	2015-05-28	2015-06-03	No	1. recovered/resolved	2	related	not related	No
41	Fatigue	General disorders and administration site conditions	2015-06-11	2015-07-30	No	1. recovered/resolved	2	not related	related	No
41	Neutropenia	Blood and lymphatic system disorders	2015-07-16	2015-07-23	No	1. recovered/resolved	4	related	related	No
41	C-reactive protein increased	Investigations	2015-03-12	2015-11-19	No	1. recovered/resolved	2	not related	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
41	Leukopenia	Blood and lymphatic system disorders	2015-05-28	2015-06-11	No	1. recovered/resolved	1	related	not related	No
41	Leukopenia	Blood and lymphatic system disorders	2015-09-04	2015-09-29	No	1. recovered/resolved	2	related	related	No
41	Application site inflammation	General disorders and administration site conditions	2015-08-06	2015-08-20	No	1. recovered/resolved	1	not related	not related	No
41	Muscular weakness	Musculoskeletal and connective tissue disorders	2015-09-04	2015-09-17	No	1. recovered/resolved	2	not related	not related	No
41	Leukopenia	Blood and lymphatic system disorders	2015-08-27	2015-09-04	No	1. recovered/resolved	3	related	related	No
41	Toothache	Gastrointestinal disorders	2015-05-22	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
41	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-09-04	2015-10-07	No	1. recovered/resolved	2	not related	not related	No
41	Constipation	Gastrointestinal disorders	2015-05-08	2015-06-25	No	1. recovered/resolved	1	not related	not related	No
41	Cough	Respiratory, thoracic and mediastinal disorders	2015-03-25	2015-05-22	No	1. recovered/resolved	2	not related	not related	No
41	Arthralgia	Musculoskeletal and connective tissue disorders	2015-03-15	2015-06-11	No	1. recovered/resolved	2	not related	not related	No
41	Leukopenia	Blood and lymphatic system disorders	2015-07-23	2015-08-20	No	1. recovered/resolved	2	related	related	No
41	Productive cough	Respiratory, thoracic and mediastinal disorders	2015-06-20	2015-07-09	No	1. recovered/resolved	1	not related	not related	No
41	Leukopenia	Blood and lymphatic system disorders	2015-06-18	2015-07-02	No	1. recovered/resolved	2	related	related	No
41	Micturition urgency	Renal and urinary disorders	2015-06-11	NA	Yes	NA	2	not related	not related	No
41	Neutropenia	Blood and lymphatic system disorders	2015-06-18	2015-06-25	No	1. recovered/resolved	4	related	related	No
41	Chest pain	General disorders and administration site conditions	2015-03-08	2015-03-10	No	1. recovered/resolved	3	not related	NA	Yes
41	Sleep disorder	Psychiatric disorders	2015-05-22	2015-06-18	No	1. recovered/resolved	1	not related	not related	No
41	Neutropenia	Blood and lymphatic system disorders	2015-06-11	2015-06-18	No	1. recovered/resolved	2	related	related	No
41	Leukopenia	Blood and lymphatic system disorders	2015-07-02	2015-07-09	No	1. recovered/resolved	1	related	related	No
41	Neutropenia	Blood and lymphatic system disorders	2015-06-25	2015-07-07	No	1. recovered/resolved	3	related	related	No
41	Fatigue	General disorders and administration site conditions	2015-03-15	2015-06-11	No	1. recovered/resolved	1	not related	not related	No
41	Leukopenia	Blood and lymphatic system disorders	2015-07-16	2015-07-23	No	1. recovered/resolved	3	related	related	No
41	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-06-20	2015-09-03	No	1. recovered/resolved	1	not related	not related	No
42	Muscle spasms	Musculoskeletal and connective tissue disorders	2015-04-01	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
42	Thrombocytopenia	Blood and lymphatic system disorders	2015-03-12	2015-04-02	No	1. recovered/resolved	2	related	not assessable	No
42	Nausea	Gastrointestinal disorders	2015-06-17	NA	Yes	3. not recovered/ not resolved	1	not related	related	No
42	Fatigue	General disorders and administration site conditions	2015-07-15	NA	Yes	3. not recovered/ not resolved	2	related	related	No
42	Constipation	Gastrointestinal disorders	2015-07-15	2015-07-29	No	1. recovered/resolved	1	not related	not related	No
42	Cough	Respiratory, thoracic and mediastinal disorders	2015-03-15	2015-04-15	No	1. recovered/resolved	1	not related	not related	No
42	Renal failure	Renal and urinary disorders	2015-07-15	NA	Yes	3. not recovered/ not resolved	2	not related	related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
42	Antimicrobial susceptibility test resistant	Investigations	2015-07-15	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
42	Alanine amino-transferase increased	Investigations	2015-05-28	2015-06-01	No	1. recovered/resolved	3	not related	not related	No
42	Oral candidiasis	Infections and infestations	2015-03-15	2015-04-15	No	1. recovered/resolved	1	related	not related	No
42	Febrile infection	Infections and infestations	2015-05-28	2015-06-04	No	1. recovered/resolved	3	related	not related	Yes
42	Diabetes mellitus	Metabolism and nutrition disorders	2015-07-29	NA	Yes	3. not recovered/ not resolved	3	not related	not related	No
42	Muscular weakness	Musculoskeletal and connective tissue disorders	2015-04-20	2015-04-26	No	1. recovered/resolved	1	not related	not related	No
42	Burning mouth syndrome	Gastrointestinal disorders	2015-03-15	NA	Yes	3. not recovered/ not resolved	1	related	not related	No
42	Arthralgia	Musculoskeletal and connective tissue disorders	2015-03-15	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
42	Anogenital warts	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2015-09-15	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
42	Alanine amino-transferase increased	Investigations	2015-06-01	2015-06-11	No	1. recovered/resolved	1	not related	not related	No
42	Dry eye	Eye disorders	2015-03-15	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
43	Neutropenia	Blood and lymphatic system disorders	2015-05-08	2015-05-17	No	1. recovered/resolved	4	related	related	No
43	Acute kidney injury	Renal and urinary disorders	2016-02-09	2016-03-17	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
43	Platelet count decreased	Investigations	2015-03-27	2015-04-07	No	2. recovering/resolving	2	probable	not related	No
43	Pneumonia	Infections and infestations	2016-01-22	2016-01-29	No	1. recovered/resolved	2	probable	probable	Yes
43	Febrile neutropenia	Blood and lymphatic system disorders	2016-01-22	2016-01-29	No	1. recovered/resolved	2	probable	probable	Yes
44	Back pain	Musculoskeletal and connective tissue disorders	2015-07-02	2017-03-01	No	3. not recovered/ not resolved	1	unlikely	NA	No
44	Hypokalaemia	Metabolism and nutrition disorders	2015-04-02	2015-04-13	No	1. recovered/resolved	3	possible	NA	No
44	Neutrophil count decreased	Investigations	2015-04-01	2015-07-02	No	1. recovered/resolved	3	probable	NA	No
44	White blood cell count decreased	Investigations	2015-04-13	2015-07-02	No	1. recovered/resolved	1	possible	NA	No
44	Hyponatraemia	Metabolism and nutrition disorders	2015-04-01	2015-04-02	No	2. recovering/resolving	3	possible	NA	No
44	Platelet count decreased	Investigations	2015-03-26	2015-04-01	No	3. not recovered/ not resolved	1	possible	NA	No
44	Hyponatraemia	Metabolism and nutrition disorders	2015-04-02	2015-04-13	No	1. recovered/resolved	1	possible	NA	No
44	Anaemia	Blood and lymphatic system disorders	2015-04-02	2015-04-13	No	2. recovering/resolving	2	possible	NA	No
44	Gamma-glutamyltransferase increased	Investigations	2015-07-02	2015-07-21	No	1. recovered/resolved	1	possible	NA	No
44	Platelet count decreased	Investigations	2015-04-01	2015-04-13	No	1. recovered/resolved	2	possible	NA	No
44	General physical health deterioration	General disorders and administration site conditions	2015-04-02	2015-04-13	No	2. recovering/resolving	3	possible	NA	Yes
44	Headache	Nervous system disorders	2015-07-21	2015-07-15	No	1. recovered/resolved	1	possible	NA	No
44	Limb discomfort	Musculoskeletal and connective tissue disorders	2015-07-21	2017-03-01	No	3. not recovered/ not resolved	1	unlikely	NA	No
44	Hyponatraemia	Metabolism and nutrition disorders	2015-03-26	2015-04-01	No	3. not recovered/ not resolved	1	possible	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
44	White blood cell count decreased	Investigations	2015-04-01	2015-04-13	No	2. recovering/resolving	3	possible	NA	No
44	Anaemia	Blood and lymphatic system disorders	2015-07-02	2015-07-21	No	2. recovering/resolving	2	possible	NA	No
44	Hyperkalaemia	Metabolism and nutrition disorders	2015-04-01	2015-04-02	No	3. not recovered/ not resolved	1	possible	NA	No
44	Hypocalcaemia	Metabolism and nutrition disorders	2015-04-02	2015-07-02	No	1. recovered/resolved	1	possible	NA	No
45	Oral herpes	Infections and infestations	2015-03-15	2015-04-15	No	1. recovered/resolved	2	possible	not related	No
45	Post procedural haemorrhage	Injury, poisoning and procedural complications	2015-03-31	2015-04-19	No	1. recovered/resolved	3	not related	not related	Yes
45	Bronchitis	Infections and infestations	2015-10-27	2015-11-02	No	1. recovered/resolved	3	possible	unlikely	Yes
45	Tracheostomy	Surgical and medical procedures	2015-06-17	2015-06-22	No	3. not recovered/ not resolved	3	not related	not related	Yes
45	Laryngeal infiltration	Laryngeal infiltration	2015-03-20	2015-03-24	No	1. recovered/resolved	3	not related	not related	Yes
45	Anaemia	Blood and lymphatic system disorders	2015-06-25	2015-06-25	No	1. recovered/resolved	3	possible	possible	No
45	Dysphonia	Respiratory, thoracic and mediastinal disorders	2015-03-27	2017-03-13	No	1. recovered/resolved	3	not related	not related	No
45	Anaemia	Blood and lymphatic system disorders	2015-03-31	2015-03-31	No	1. recovered/resolved	3	possible	not related	No
46	Neutropenia	Blood and lymphatic system disorders	2015-05-12	2015-06-09	No	1. recovered/resolved	3	related	not assessable	No
46	Pyrexia	General disorders and administration site conditions	2015-04-06	2015-04-06	No	1. recovered/resolved	2	related	not assessable	No
46	Flatulence	Gastrointestinal disorders	2015-08-13	NA	Yes	2. recovering/resolving	2	not related	not assessable	No
46	Post herpetic neuralgia	Nervous system disorders	2015-12-04	2015-12-15	No	1. recovered/resolved	1	not related	not related	No
46	Neutropenia	Blood and lymphatic system disorders	2015-11-03	2015-12-15	No	1. recovered/resolved	3	related	not related	No
46	Leukopenia	Blood and lymphatic system disorders	2016-01-20	2016-03-15	No	2. recovering/resolving	3	related	not assessable	No
46	Neutropenia	Blood and lymphatic system disorders	2015-09-11	2015-11-02	No	3. not recovered/ not resolved	2	related	not assessable	No
46	Infection	Infections and infestations	2016-01-13	2016-01-19	No	1. recovered/resolved	2	not related	not related	No
46	Tremor	Nervous system disorders	2015-11-03	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
46	Limb discomfort	Musculoskeletal and connective tissue disorders	2016-02-17	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
46	Infection	Infections and infestations	2016-04-13	2016-04-15	No	1. recovered/resolved	2	not related	not assessable	No
46	Upper respiratory tract infection	Infections and infestations	2016-03-06	2016-03-12	No	1. recovered/resolved	2	related	not related	No
46	Cystitis	Infections and infestations	2015-10-09	2015-11-02	No	1. recovered/resolved	2	not related	not related	No
46	Urinary bladder haemorrhage	Renal and urinary disorders	2015-03-27	2015-03-30	No	1. recovered/resolved	2	unlikely	unlikely	Yes
46	Neutropenia	Blood and lymphatic system disorders	2015-04-14	2015-05-11	No	2. recovering/resolving	4	related	not assessable	No
46	Leukopenia	Blood and lymphatic system disorders	2015-11-03	2015-12-15	No	1. recovered/resolved	3	related	not related	No
46	Neutropenia	Blood and lymphatic system disorders	2016-01-20	2016-03-15	No	2. recovering/resolving	3	related	not assessable	No
46	Neutropenia	Blood and lymphatic system disorders	2016-03-16	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
46	Neutropenia	Blood and lymphatic system disorders	2015-07-07	2015-08-12	No	1. recovered/resolved	4	related	not assessable	No
46	Nasopharyngitis	Infections and infestations	2015-10-08	2015-11-02	No	1. recovered/resolved	1	not related	not assessable	No
46	Bronchitis	Infections and infestations	2015-12-04	2015-12-15	No	1. recovered/resolved	2	not related	not related	No
46	Leukopenia	Blood and lymphatic system disorders	2016-03-16	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
46	Thrombocytopenia	Blood and lymphatic system disorders	2015-04-14	2015-05-11	No	2. recovering/resolving	3	related	not assessable	No
46	Leukopenia	Blood and lymphatic system disorders	2015-05-12	2015-06-09	No	1. recovered/resolved	2	related	not assessable	No
46	Leukopenia	Blood and lymphatic system disorders	2015-07-07	2015-08-12	No	1. recovered/resolved	3	related	not assessable	No
46	Fatigue	General disorders and administration site conditions	2015-11-03	2015-12-15	No	1. recovered/resolved	1	not related	not related	No
46	Leukopenia	Blood and lymphatic system disorders	2015-04-14	2015-05-11	No	2. recovering/resolving	3	related	not assessable	No
46	Fatigue	General disorders and administration site conditions	2015-12-16	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
46	Limb discomfort	Musculoskeletal and connective tissue disorders	2016-02-17	NA	Yes	3. not recovered/ not resolved	1	not related	not assessable	No
47	Anaemia	Blood and lymphatic system disorders	2015-12-07	2016-01-04	No	1. recovered/resolved	2	possible	possible	No
47	Neutropenia	Blood and lymphatic system disorders	2015-07-14	2015-07-21	No	1. recovered/resolved	1	possible	not related	No
47	Neutropenia	Blood and lymphatic system disorders	2016-02-17	2016-03-09	No	1. recovered/resolved	4	possible	possible	No
47	Neutropenia	Blood and lymphatic system disorders	2015-08-31	2015-09-07	No	1. recovered/resolved	1	possible	possible	No
47	Leukopenia	Blood and lymphatic system disorders	2015-12-21	2016-01-04	No	1. recovered/resolved	3	possible	possible	No
47	Leukopenia	Blood and lymphatic system disorders	2015-09-07	2015-09-14	No	1. recovered/resolved	3	possible	possible	No
47	Fatigue	General disorders and administration site conditions	2015-05-20	2015-05-26	No	1. recovered/resolved	1	not related	not related	No
47	Anaemia	Blood and lymphatic system disorders	2015-11-16	2015-11-23	No	1. recovered/resolved	2	possible	possible	No
47	Neutropenia	Blood and lymphatic system disorders	2015-10-26	2015-12-07	No	1. recovered/resolved	3	possible	possible	No
47	Vertigo	Ear and labyrinth disorders	2015-05-20	2015-05-26	No	1. recovered/resolved	1	not related	not related	No
47	Neutropenia	Blood and lymphatic system disorders	2015-06-23	2015-07-14	No	1. recovered/resolved	2	possible	not related	No
47	Leukopenia	Blood and lymphatic system disorders	2015-12-07	2015-12-21	No	1. recovered/resolved	2	possible	possible	No
47	Neutropenia	Blood and lymphatic system disorders	2015-08-11	2015-08-31	No	1. recovered/resolved	3	possible	possible	No
47	Leukopenia	Blood and lymphatic system disorders	2015-08-31	2015-09-07	No	1. recovered/resolved	1	possible	possible	No
47	Leukopenia	Blood and lymphatic system disorders	2015-11-09	2015-11-16	No	1. recovered/resolved	2	possible	possible	No
47	Neutropenia	Blood and lymphatic system disorders	2016-01-18	2016-01-27	No	1. recovered/resolved	4	possible	possible	No
47	Anaemia	Blood and lymphatic system disorders	2016-01-18	2016-03-09	No	1. recovered/resolved	2	possible	possible	No
47	Haemorrhoids	Gastrointestinal disorders	2015-12-07	2015-12-21	No	1. recovered/resolved	1	possible	possible	No
47	Flank pain	Musculoskeletal and connective tissue disorders	2015-05-26	2015-08-31	No	1. recovered/resolved	2	unlikely	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
47	Neutropenia	Blood and lymphatic system disorders	2015-06-10	2015-06-23	No	1. recovered/resolved	1	possible	not related	No
47	Constipation	Gastrointestinal disorders	2015-07-28	2015-11-23	No	1. recovered/resolved	2	possible	possible	No
47	Abdominal pain upper	Gastrointestinal disorders	2015-05-20	2015-05-26	No	1. recovered/resolved	1	not related	not related	No
47	Headache	Nervous system disorders	2015-05-20	2015-05-26	No	1. recovered/resolved	1	not related	not related	No
47	Leukopenia	Blood and lymphatic system disorders	2015-08-11	2015-08-31	No	1. recovered/resolved	3	possible	possible	No
47	Thrombocytopenia	Blood and lymphatic system disorders	2015-05-06	2015-05-13	No	1. recovered/resolved	1	possible	not related	No
47	Anaemia	Blood and lymphatic system disorders	2016-01-04	2016-01-18	No	3. not recovered/ not resolved	1	possible	possible	No
47	Anaemia	Blood and lymphatic system disorders	2015-04-29	2015-11-16	No	1. recovered/resolved	1	possible	not related	No
47	Leukopenia	Blood and lymphatic system disorders	2015-11-16	2015-12-07	No	1. recovered/resolved	3	possible	possible	No
47	Neutropenia	Blood and lymphatic system disorders	2015-12-21	2016-01-04	No	1. recovered/resolved	4	possible	possible	No
47	Acanthosis nigricans	Skin and subcutaneous tissue disorders	2015-06-23	2015-12-07	No	1. recovered/resolved	1	possible	not related	No
47	Neutropenia	Blood and lymphatic system disorders	2015-09-14	2015-10-12	No	1. recovered/resolved	3	possible	possible	No
47	Leukopenia	Blood and lymphatic system disorders	2016-01-18	2016-01-27	No	1. recovered/resolved	3	possible	possible	No
47	Anaemia	Blood and lymphatic system disorders	2015-11-23	2015-12-07	No	1. recovered/resolved	1	possible	possible	No
47	Leukopenia	Blood and lymphatic system disorders	2015-07-14	2016-07-21	No	1. recovered/resolved	1	possible	not related	No
47	Leukopenia	Blood and lymphatic system disorders	2016-01-27	2016-02-03	No	1. recovered/resolved	2	possible	possible	No
47	Gingivitis	Infections and infestations	2016-01-04	2016-01-18	No	3. not recovered/ not resolved	2	possible	possible	No
47	Nasopharyngitis	Infections and infestations	2015-05-15	2015-05-15	No	1. recovered/resolved	1	possible	not related	No
47	Leukopenia	Blood and lymphatic system disorders	2016-02-17	2016-03-09	No	1. recovered/resolved	2	possible	possible	No
47	Blood glucose abnormal	Investigations	2015-05-06	2015-08-31	No	2. recovering/resolving	2	unlikely	not related	No
47	Folliculitis	Infections and infestations	2015-09-14	2015-12-07	No	1. recovered/resolved	2	possible	possible	No
47	Neutropenia	Blood and lymphatic system disorders	2015-09-07	2015-09-14	No	3. not recovered/ not resolved	4	possible	possible	No
47	Mucosal inflammation	General disorders and administration site conditions	2015-05-06	2015-05-20	No	1. recovered/resolved	2	not related	not related	No
48	Syncope	Nervous system disorders	2015-05-18	2015-05-18	No	1. recovered/resolved	4	unlikely	NA	No
48	Anaemia	Blood and lymphatic system disorders	2015-05-18	2015-05-26	No	2. recovering/resolving	2	probable	NA	No
48	Hyponatraemia	Metabolism and nutrition disorders	2015-05-21	NA	Yes	NA	1	possible	NA	No
48	Fall	Injury, poisoning and procedural complications	2015-05-18	2015-05-18	No	1. recovered/resolved	2	unlikely	NA	No
48	White blood cell count decreased	Investigations	2015-05-20	2015-05-26	No	2. recovering/resolving	2	probable	NA	No
48	Neutrophil count decreased	Investigations	2015-05-19	NA	Yes	3. not recovered/ not resolved	4	probable	NA	Yes
48	Blood creatinine increased	Investigations	2015-05-18	2015-05-26	No	2. recovering/resolving	2	possible	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
48	Platelet count decreased	Investigations	2015-05-20	2015-05-21	No	3. not recovered/ not resolved	2	probable	NA	No
48	Hypocalcaemia	Metabolism and nutrition disorders	2015-05-21	2015-05-26	No	1. recovered/resolved	1	possible	NA	No
48	Fatigue	General disorders and administration site conditions	2015-05-18	2015-05-26	No	2. recovering/resolving	2	probable	NA	No
48	Platelet count decreased	Investigations	2015-05-18	2015-05-20	No	2. recovering/resolving	3	probable	NA	No
48	White blood cell count decreased	Investigations	2015-05-26	NA	Yes	3. not recovered/ not resolved	1	probable	NA	No
48	Night sweats	Skin and subcutaneous tissue disorders	2015-05-26	NA	Yes	3. not recovered/ not resolved	1	possible	NA	No
48	White blood cell count decreased	Investigations	2015-05-18	2015-05-20	No	2. recovering/resolving	3	probable	NA	No
48	Glomerular filtration rate decreased	Investigations	2015-05-07	2015-05-18	No	3. not recovered/ not resolved	2	possible	NA	No
48	Back pain	Musculoskeletal and connective tissue disorders	2015-05-26	NA	Yes	3. not recovered/ not resolved	1	unlikely	NA	No
48	Glomerular filtration rate decreased	Investigations	2015-05-18	2015-05-26	No	2. recovering/resolving	3	possible	NA	No
48	Stomatitis	Gastrointestinal disorders	2015-05-26	NA	Yes	NA	1	probable	NA	No
48	Fatigue	General disorders and administration site conditions	2015-05-26	NA	Yes	3. not recovered/ not resolved	1	probable	NA	No
48	Platelet count decreased	Investigations	2015-05-21	2015-05-26	No	2. recovering/resolving	3	probable	NA	No
48	Hypocalcaemia	Metabolism and nutrition disorders	2015-05-20	2015-05-21	No	2. recovering/resolving	2	possible	NA	No
48	Hyperuricaemia	Metabolism and nutrition disorders	2015-05-20	2015-05-26	No	1. recovered/resolved	1	possible	NA	No
48	White blood cell count decreased	Investigations	2015-05-07	2015-05-18	No	3. not recovered/ not resolved	2	probable	NA	No
48	Glomerular filtration rate decreased	Investigations	2015-05-26	NA	Yes	3. not recovered/ not resolved	2	possible	NA	No
48	Hyponatraemia	Metabolism and nutrition disorders	2015-05-18	2015-05-21	No	2. recovering/resolving	3	possible	NA	No
48	Contusion	Injury, poisoning and procedural complications	2015-05-18	2015-05-18	No	1. recovered/resolved	1	not related	NA	No
49	Paraesthesia	Nervous system disorders	2015-08-03	NA	Yes	NA	1	possible	NA	No
49	White blood cell count decreased	Investigations	2016-04-25	NA	Yes	3. not recovered/ not resolved	2	probable	possible	No
49	Disease progression	General disorders and administration site conditions	2015-08-31	NA	Yes	3. not recovered/ not resolved	2	unlikely	unlikely	No
49	Gastrointestinal infection	Infections and infestations	2016-03-15	2016-04-25	No	1. recovered/resolved	1	possible	possible	No
49	White blood cell count decreased	Investigations	2016-03-16	2016-04-14	No	1. recovered/resolved	1	possible	possible	No
49	Lymphocyte count decreased	Investigations	2016-01-20	2016-02-18	No	2. recovering/resolving	3	possible	possible	No
49	White blood cell count decreased	Investigations	2015-09-28	2015-10-28	No	3. not recovered/ not resolved	1	possible	possible	No
49	Paraesthesia	Nervous system disorders	2015-08-03	NA	Yes	NA	1	possible	NA	No
49	Anaemia	Blood and lymphatic system disorders	2015-10-28	2015-11-24	No	1. recovered/resolved	1	probable	probable	No
49	Lymphocyte count decreased	Investigations	2015-11-25	2015-12-18	No	2. recovering/resolving	2	possible	possible	No
49	White blood cell count decreased	Investigations	2015-12-23	2016-01-06	No	1. recovered/resolved	1	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
49	Lymphocyte count decreased	Investigations	2016-01-19	2016-01-20	No	3. not recovered/ not resolved	1	possible	possible	No
49	Lymphocyte count decreased	Investigations	2015-09-02	2015-09-28	No	1. recovered/resolved	2	possible	possible	No
49	Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	2015-07-06	2015-08-31	No	1. recovered/resolved	1	unlikely	NA	No
49	Constipation	Gastrointestinal disorders	2015-09-28	2015-10-26	No	1. recovered/resolved	1	possible	possible	No
49	Lymphocyte count decreased	Investigations	2015-09-30	2015-10-28	No	3. not recovered/ not resolved	2	probable	probable	No
49	Lymphocyte count decreased	Investigations	2015-10-28	2015-11-11	No	2. recovering/resolving	3	probable	probable	No
49	Hypophosphataemia	Metabolism and nutrition disorders	2015-10-28	2015-11-11	No	1. recovered/resolved	2	possible	possible	No
49	Lymphocyte count decreased	Investigations	2016-05-11	NA	NA	NA	2	possible	possible	No
49	Bone pain	Musculoskeletal and connective tissue disorders	2016-05-11	NA	NA	NA	2	unlikely	unlikely	No
49	Hypophosphataemia	Metabolism and nutrition disorders	2015-09-02	2015-09-16	No	2. recovering/resolving	2	possible	possible	No
49	White blood cell count decreased	Investigations	2016-01-19	2016-02-18	No	1. recovered/resolved	2	possible	possible	No
49	Lymphocyte count decreased	Investigations	2016-01-06	2016-01-19	No	2. recovering/resolving	2	possible	possible	No
49	Lymphocyte count decreased	Investigations	2016-03-30	2016-04-14	No	1. recovered/resolved	3	probable	possible	No
49	Rib fracture	Injury, poisoning and procedural complications	2016-05-11	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
49	Neutrophil count decreased	Investigations	2015-06-08	2015-06-15	No	1. recovered/resolved	1	possible	NA	No
49	Anaemia	Blood and lymphatic system disorders	2015-09-02	2015-10-26	No	1. recovered/resolved	1	possible	possible	No
49	Lymphocyte count decreased	Investigations	2016-04-25	2016-05-11	No	2. recovering/resolving	3	probable	possible	No
49	Polyneuropathy	Nervous system disorders	2016-05-11	NA	Yes	3. not recovered/ not resolved	2	possible	possible	No
49	Fatigue	General disorders and administration site conditions	2015-08-03	2015-09-28	No	3. not recovered/ not resolved	1	possible	NA	No
49	Neutrophil count decreased	Investigations	2016-04-25	2016-05-11	No	3. not recovered/ not resolved	1	probable	possible	No
49	Hypophosphataemia	Metabolism and nutrition disorders	2016-01-06	2016-03-30	No	1. recovered/resolved	1	possible	possible	No
49	White blood cell count decreased	Investigations	2015-10-28	2015-11-11	No	1. recovered/resolved	2	probable	probable	No
49	Nausea	Gastrointestinal disorders	2015-08-05	NA	NA	NA	1	possible	possible	No
49	Pain in extremity	Musculoskeletal and connective tissue disorders	2015-06-04	2015-11-15	No	3. not recovered/ not resolved	1	possible	NA	No
49	Lymphocyte count decreased	Investigations	2015-11-11	2015-11-24	No	1. recovered/resolved	2	probable	possible	No
49	Hypophosphataemia	Metabolism and nutrition disorders	2015-09-16	2015-09-30	No	1. recovered/resolved	1	possible	possible	No
49	Lymphocyte count decreased	Investigations	2015-12-23	2016-01-06	No	2. recovering/resolving	3	possible	possible	No
49	Muscular weakness	Musculoskeletal and connective tissue disorders	2015-08-03	NA	NA	NA	1	unlikely	NA	No
49	White blood cell count decreased	Investigations	2015-06-08	2015-06-15	No	1. recovered/resolved	1	possible	NA	No
49	Pain	General disorders and administration site conditions	2015-11-15	NA	Yes	3. not recovered/ not resolved	3	unlikely	unlikely	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
49	Rib fracture	Injury, poisoning and procedural complications	2015-09-28	NA	Yes	2. recovering/resolving	1	not related	not related	No
49	Platelet count decreased	Investigations	2015-12-18	2015-12-23	No	1. recovered/resolved	1	possible	possible	No
49	Nasopharyngitis	Infections and infestations	2015-09-14	2015-09-28	No	1. recovered/resolved	1	possible	possible	No
49	Neutrophil count decreased	Investigations	2015-06-30	2015-07-06	No	1. recovered/resolved	2	probable	NA	No
49	Spinal pain	Musculoskeletal and connective tissue disorders	2016-01-19	NA	Yes	NA	3	not related	not related	No
49	White blood cell count decreased	Investigations	2015-09-16	2015-09-28	No	2. recovering/resolving	2	possible	possible	No
49	Neutrophil count decreased	Investigations	2015-09-28	2015-09-30	No	1. recovered/resolved	2	probable	probable	No
49	Platelet count decreased	Investigations	2016-05-11	NA	Yes	3. not recovered/ not resolved	1	possible	possible	No
49	Neutrophil count decreased	Investigations	2015-06-01	2015-06-08	No	2. recovering/resolving	2	probable	NA	No
49	Neutrophil count decreased	Investigations	2016-05-11	NA	NA	NA	2	probable	possible	No
49	Platelet count decreased	Investigations	2015-11-11	2015-11-24	No	1. recovered/resolved	1	possible	possible	No
49	Lymphocyte count decreased	Investigations	2015-12-18	2015-12-23	No	2. recovering/resolving	1	possible	possible	No
49	Pruritus	Skin and subcutaneous tissue disorders	2015-05-13	2015-05-22	No	1. recovered/resolved	2	possible	NA	No
49	White blood cell count decreased	Investigations	2015-06-30	2015-07-06	No	1. recovered/resolved	1	probable	NA	No
49	Pain in extremity	Musculoskeletal and connective tissue disorders	2015-10-26	NA	NA	NA	1	not related	not related	No
49	Lymphocyte count decreased	Investigations	2016-02-18	2016-03-30	No	3. not recovered/ not resolved	2	possible	possible	No
49	Fatigue	General disorders and administration site conditions	2015-09-28	2015-10-26	No	1. recovered/resolved	2	possible	possible	No
49	Thoracic vertebral fracture	Injury, poisoning and procedural complications	2015-09-28	NA	Yes	2. recovering/resolving	1	not related	not related	No
49	Anaemia	Blood and lymphatic system disorders	2015-11-25	NA	Yes	NA	1	possible	possible	No
49	Neutrophil count decreased	Investigations	2016-01-19	2016-01-20	No	1. recovered/resolved	2	possible	possible	No
49	White blood cell count decreased	Investigations	2015-12-18	2015-12-23	No	2. recovering/resolving	2	possible	possible	No
49	Neutrophil count decreased	Investigations	2015-12-18	2015-12-23	No	1. recovered/resolved	2	possible	possible	No
50	Diarrhoea	Gastrointestinal disorders	2015-07-11	2015-08-11	No	1. recovered/resolved	3	possible	not assessable	Yes
50	Leukopenia	Blood and lymphatic system disorders	2015-06-29	2015-07-27	No	1. recovered/resolved	2	related	not related	No
50	Infection	Infections and infestations	2015-06-15	2015-06-18	No	1. recovered/resolved	2	possible	not assessable	Yes
50	Pancytopenia	Blood and lymphatic system disorders	2015-06-15	2015-06-18	No	1. recovered/resolved	2	possible	not assessable	Yes
50	Thrombocytopenia	Blood and lymphatic system disorders	2015-06-29	NA	Yes	3. not recovered/ not resolved	3	related	not related	No
51	Anaemia	Blood and lymphatic system disorders	2015-11-25	2015-12-04	No	1. recovered/resolved	3	not related	not related	No
51	Sleep disorder	Psychiatric disorders	2015-07-07	2015-08-31	No	2. recovering/resolving	2	not related	not assessable	No
51	Diarrhoea	Gastrointestinal disorders	2015-08-01	2015-08-31	No	1. recovered/resolved	2	not related	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
51	Peritonitis	Infections and infestations	2015-10-12	2015-11-02	No	1. recovered/resolved	3	not related	not related	Yes
51	Asthenia	General disorders and administration site conditions	2015-07-07	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
51	Sleep disorder	Psychiatric disorders	2015-09-01	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
51	Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2015-07-07	2015-08-31	No	1. recovered/resolved	2	related	not assessable	No
51	Thrombocytopenia	Blood and lymphatic system disorders	2015-09-01	2015-09-14	No	1. recovered/resolved	2	related	not related	No
51	Large intestine perforation	Gastrointestinal disorders	2015-10-12	2015-11-02	No	1. recovered/resolved	3	not related	not related	Yes
51	Thrombocytopenia	Blood and lymphatic system disorders	2015-07-07	2015-08-03	No	1. recovered/resolved	2	related	not assessable	No
51	Polyneuropathy	Nervous system disorders	2015-09-29	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
51	Neutropenia	Blood and lymphatic system disorders	2015-07-07	2015-07-21	No	2. recovering/resolving	4	related	not assessable	No
51	Muscle spasms	Musculoskeletal and connective tissue disorders	2015-08-04	NA	Yes	3. not recovered/ not resolved	2	related	not related	No
51	Anaemia	Blood and lymphatic system disorders	2015-09-01	2015-09-14	No	1. recovered/resolved	3	related	not related	No
51	General physical health deterioration	General disorders and administration site conditions	2015-11-13	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
51	Fatigue	General disorders and administration site conditions	2015-07-07	NA	Yes	3. not recovered/ not resolved	2	related	not assessable	No
52	Hyperhidrosis	Skin and subcutaneous tissue disorders	2015-10-29	2015-11-26	No	1. recovered/resolved	1	probable	not assessable	No
52	Vitreous haemorrhage	Eye disorders	2016-01-01	2016-02-17	No	1. recovered/resolved	1	not related	not assessable	No
52	Diarrhoea	Gastrointestinal disorders	2016-02-17	2016-03-02	No	1. recovered/resolved	2	not related	not related	No
52	Hyperhidrosis	Skin and subcutaneous tissue disorders	2015-09-02	2015-10-01	No	1. recovered/resolved	1	probable	not assessable	No
53	Pneumonia	Infections and infestations	2016-02-01	2016-02-05	No	1. recovered/resolved	3	related	related	Yes
53	Myoclonus	Nervous system disorders	2015-09-21	2015-09-23	No	1. recovered/resolved	3	probable	not related	Yes
53	Nasopharyngitis	Infections and infestations	2015-12-28	2016-01-11	No	1. recovered/resolved	2	possible	possible	No
54	Platelet count decreased	Investigations	2015-08-03	2015-08-07	No	1. recovered/resolved	1	possible	NA	No
54	Back pain	Musculoskeletal and connective tissue disorders	2015-08-20	NA	Yes	2. recovering/resolving	2	not related	NA	No
54	Nausea	Gastrointestinal disorders	2015-08-20	NA	NA	NA	2	possible	NA	No
54	Abdominal pain upper	Gastrointestinal disorders	2015-08-20	NA	Yes	NA	2	unlikely	NA	No
54	Abscess	Infections and infestations	2015-08-03	2015-08-24	No	1. recovered/resolved	1	not related	NA	No
54	Hypocalcaemia	Metabolism and nutrition disorders	2015-07-22	2015-08-03	No	3. not recovered/ not resolved	1	possible	NA	No
54	Mental disorder	Psychiatric disorders	2015-08-11	NA	NA	NA	1	NA	NA	No
54	Anaemia	Blood and lymphatic system disorders	2015-08-10	2015-08-11	No	2. recovering/resolving	3	possible	NA	No
54	Back pain	Musculoskeletal and connective tissue disorders	2015-07-22	2015-08-03	No	2. recovering/resolving	2	unlikely	NA	No
54	Fatigue	General disorders and administration site conditions	2015-08-24	NA	NA	NA	2	possible	NA	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
54	Constipation	Gastrointestinal disorders	2015-08-03	NA	NA	NA	1	possible	NA	No
54	Hypocalcaemia	Metabolism and nutrition disorders	2015-07-02	2015-07-07	No	3. not recovered/ not resolved	1	possible	NA	No
54	Pain	General disorders and administration site conditions	2015-08-24	NA	Yes	NA	2	unlikely	NA	No
54	Hypocalcaemia	Metabolism and nutrition disorders	2015-07-07	2015-07-22	No	2. recovering/resolving	3	possible	NA	No
54	White blood cell count decreased	Investigations	2015-07-07	2015-07-22	No	1. recovered/resolved	1	probable	NA	No
54	Malaise	General disorders and administration site conditions	2015-08-20	NA	NA	NA	2	possible	NA	No
54	Decreased appetite	Metabolism and nutrition disorders	2015-08-24	NA	Yes	NA	1	unlikely	NA	No
54	Disease progression	General disorders and administration site conditions	2015-08-27	NA	Yes	3. not recovered/ not resolved	3	not related	NA	Yes
54	Platelet count decreased	Investigations	2015-07-07	2015-07-17	No	1. recovered/resolved	2	possible	NA	No
54	Restlessness	Psychiatric disorders	2015-07-22	NA	NA	NA	1	unlikely	NA	No
54	Platelet count decreased	Investigations	2015-08-24	NA	NA	NA	2	possible	NA	No
54	Platelet count decreased	Investigations	2015-06-30	2015-07-07	No	3. not recovered/ not resolved	1	possible	NA	No
54	Hypocalcaemia	Metabolism and nutrition disorders	2015-08-03	2015-08-24	No	1. recovered/resolved	2	possible	NA	No
54	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2015-07-22	NA	NA	NA	2	possible	NA	No
54	Platelet count decreased	Investigations	2015-08-10	2015-08-11	No	1. recovered/resolved	1	possible	NA	No
54	Hyponatraemia	Metabolism and nutrition disorders	2015-07-02	2015-07-22	No	1. recovered/resolved	1	possible	NA	No
55	Anaemia	Blood and lymphatic system disorders	2015-07-21	2015-09-15	No	1. recovered/resolved	3	not related	not assessable	No
55	Neuropathy peripheral	Nervous system disorders	2015-09-04	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
55	Leukopenia	Blood and lymphatic system disorders	2015-09-16	2015-09-20	No	1. recovered/resolved	3	related	not related	No
55	Anaemia	Blood and lymphatic system disorders	2015-09-16	2015-09-20	No	1. recovered/resolved	2	not related	not related	No
55	Thrombocytopenia	Blood and lymphatic system disorders	2015-08-13	2015-09-03	No	1. recovered/resolved	1	related	related	No
55	Leukopenia	Blood and lymphatic system disorders	2015-09-04	2015-09-15	No	1. recovered/resolved	2	related	not related	No
55	Neutropenia	Blood and lymphatic system disorders	2015-09-04	2015-09-15	No	1. recovered/resolved	2	related	not related	No
55	Neutropenia	Blood and lymphatic system disorders	2015-09-16	2015-09-20	No	1. recovered/resolved	3	related	not related	No
55	Anaemia	Blood and lymphatic system disorders	2015-09-21	NA	Yes	3. not recovered/ not resolved	3	not related	not related	No
55	Septic shock	Infections and infestations	2015-10-11	2015-10-12	No	5. fatal	5	possible	not assessable	Yes
56	Fatigue	General disorders and administration site conditions	2016-02-05	2016-05-22	No	1. recovered/resolved	1	related	not assessable	No
56	Cough	Respiratory, thoracic and mediastinal disorders	2016-03-07	2016-03-11	No	1. recovered/resolved	2	not related	not assessable	No
56	Diarrhoea	Gastrointestinal disorders	2016-08-22	2016-08-25	No	1. recovered/resolved	2	not related	not assessable	No
56	Leukopenia	Blood and lymphatic system disorders	2015-12-10	2016-01-07	No	1. recovered/resolved	2	related	not assessable	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
56	Infection	Infections and infestations	2015-08-04	2015-08-10	No	1. recovered/resolved	2	related	not assessable	No
56	Insomnia	Psychiatric disorders	2016-12-12	NA	Yes	3. not recovered/ not resolved	2	not related	not assessable	No
56	Upper respi- ratory tract infection	Respiratory, thoracic and mediastinal disorders	2015-09-28	2015-10-12	No	1. recovered/resolved	2	related	not assessable	No
56	Peripheral sen- sory neuropathy	Nervous system disorders	2015-08-18	2016-04-24	No	1. recovered/resolved	1	not related	not assessable	No
56	Respiratory tract infection	Infections and infestations	2016-04-15	2016-04-15	No	1. recovered/resolved	2	not related	not related	No
56	Muscle spasms	Musculoskeletal and connective tissue disorders	2016-04-25	2016-05-22	No	1. recovered/resolved	1	related	not assessable	No
56	Polyneuropathy	Nervous system disorders	2016-05-23	NA	Yes	3. not recovered/ not resolved	1	not related	not related	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-10-22	2015-11-18	No	1. recovered/resolved	4	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-08-24	2015-08-31	No	1. recovered/resolved	4	possible	not related	No
57	Neutropenia	Blood and lymphatic system disorders	2015-09-21	2015-10-06	No	1. recovered/resolved	4	possible	possible	No
57	Anaemia	Blood and lymphatic system disorders	2015-08-31	2015-09-03	No	1. recovered/resolved	3	possible	not related	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-09-03	2015-09-07	No	1. recovered/resolved	4	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-08-31	2015-09-07	No	1. recovered/resolved	3	possible	not related	No
57	Bone pain	Musculoskeletal and connective tissue disorders	2015-08-20	NA	Yes	3. not recovered/ not resolved	2	not related	not related	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-12-23	2015-12-28	No	1. recovered/resolved	3	possible	possible	No
57	Anaemia	Blood and lymphatic system disorders	2015-12-18	2015-12-28	No	1. recovered/resolved	3	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-11-03	2015-11-06	No	1. recovered/resolved	4	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2016-01-06	2016-01-13	No	1. recovered/resolved	3	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2016-01-28	2016-02-05	No	1. recovered/resolved	3	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2016-01-06	2016-01-13	No	1. recovered/resolved	3	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-12-03	2015-12-09	No	1. recovered/resolved	3	possible	possible	No
57	Somnolence	Nervous system disorders	2015-08-20	NA	Yes	3. not recovered/ not resolved	2	unlikely	not related	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-09-17	2015-09-29	No	1. recovered/resolved	3	possible	possible	No
57	Anaemia	Blood and lymphatic system disorders	2016-01-20	2016-01-28	No	1. recovered/resolved	3	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-10-13	2015-10-22	No	1. recovered/resolved	3	possible	possible	No
57	Bacterial infec- tion	Infections and infestations	2015-09-15	2016-03-31	No	1. recovered/resolved	2	unlikely	unlikely	No
57	Neutropenia	Blood and lymphatic system disorders	2015-12-09	2015-12-23	No	2. recovering/resolving	2	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-09-07	2015-09-14	No	1. recovered/resolved	4	possible	possible	No
57	Hypercalcaemia	Metabolism and nutrition disorders	2015-08-20	2015-08-26	No	3. not recovered/ not resolved	1	unlikely	not related	Yes
57	Fatigue	General disorders and administration site conditions	2015-10-06	2016-03-31	No	1. recovered/resolved	1	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
57	Neutropenia	Blood and lymphatic system disorders	2015-10-22	2015-10-27	No	1. recovered/resolved	4	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-09-10	2015-09-17	No	1. recovered/resolved	4	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-08-21	2015-08-31	No	1. recovered/resolved	4	possible	not related	No
57	Anaemia	Blood and lymphatic system disorders	2015-09-22	2015-09-29	No	1. recovered/resolved	3	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-08-31	2015-09-03	No	1. recovered/resolved	3	possible	not related	No
57	Neutropenia	Blood and lymphatic system disorders	2015-12-23	2016-01-06	No	1. recovered/resolved	4	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-09-29	2015-10-13	No	1. recovered/resolved	4	possible	possible	No
57	Anaemia	Blood and lymphatic system disorders	2015-10-13	2015-11-06	No	1. recovered/resolved	3	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-09-24	2015-09-29	No	1. recovered/resolved	3	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-09-07	2015-09-10	No	1. recovered/resolved	3	possible	possible	No
57	Gingivitis	Infections and infestations	2015-09-07	2015-09-14	No	3. not recovered/ not resolved	2	possible	possible	No
57	Anaemia	Blood and lymphatic system disorders	2015-11-26	2015-12-03	No	1. recovered/resolved	3	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2016-01-28	2016-02-05	No	1. recovered/resolved	3	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-12-28	2016-01-06	No	1. recovered/resolved	4	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-10-27	2015-11-03	No	1. recovered/resolved	3	possible	possible	No
57	Neutropenia	Blood and lymphatic system disorders	2015-11-26	2015-12-03	No	1. recovered/resolved	4	possible	possible	No
57	Thrombocytopenia	Blood and lymphatic system disorders	2015-11-26	2015-12-09	No	3. not recovered/ not resolved	3	possible	possible	No
57	Condition ag- gravated	General disorders and administration site conditions	2015-09-10	2015-09-17	No	1. recovered/resolved	3	possible	possible	Yes
58	White blood cell count decreased	Investigations	2016-01-05	2016-01-13	No	3. not recovered/ not resolved	1	probable	probable	No
58	White blood cell count decreased	Investigations	2016-03-07	2016-03-15	No	2. recovering/resolving	2	possible	possible	No
58	Hyperkalaemia	Metabolism and nutrition disorders	2015-12-28	2016-01-05	No	1. recovered/resolved	2	possible	possible	No
58	Anaemia	Blood and lymphatic system disorders	2016-01-05	2016-02-02	No	3. not recovered/ not resolved	1	probable	probable	No
58	Hyperkalaemia	Metabolism and nutrition disorders	2016-01-27	2016-01-29	No	1. recovered/resolved	2	possible	possible	No
58	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2016-01-05	2016-03-30	No	3. not recovered/ not resolved	2	possible	possible	No
58	Neutrophil count decreased	Investigations	2015-10-01	2015-10-06	No	1. recovered/resolved	3	probable	NA	No
58	Hyponatraemia	Metabolism and nutrition disorders	2016-03-30	2016-04-09	No	3. not recovered/ not resolved	3	possible	possible	No
58	White blood cell count decreased	Investigations	2015-12-28	2015-12-30	No	3. not recovered/ not resolved	2	probable	probable	No
58	Hyponatraemia	Metabolism and nutrition disorders	2016-03-01	2016-03-07	No	2. recovering/resolving	3	possible	possible	No
58	White blood cell count decreased	Investigations	2016-03-01	2016-03-07	No	3. not recovered/ not resolved	1	probable	possible	No
58	Hypercalcaemia	Metabolism and nutrition disorders	2016-04-05	2016-04-09	No	3. not recovered/ not resolved	2	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
58	White blood cell count decreased	Investigations	2016-03-15	2016-03-22	No	3. not recovered/ not resolved	1	possible	possible	No
58	Anaemia	Blood and lymphatic system disorders	2016-04-04	2016-04-09	No	3. not recovered/ not resolved	2	possible	possible	No
58	White blood cell count decreased	Investigations	2015-08-14	2015-08-21	No	3. not recovered/ not resolved	1	possible	NA	No
58	Oedema peripheral	General disorders and administration site conditions	2016-01-05	2016-04-09	No	3. not recovered/ not resolved	1	possible	possible	No
58	Skin infection	Infections and infestations	2016-03-01	2016-04-09	No	3. not recovered/ not resolved	2	possible	possible	No
58	White blood cell count decreased	Investigations	2016-04-04	2016-04-09	No	3. not recovered/ not resolved	3	possible	possible	No
58	Anaemia	Blood and lymphatic system disorders	2015-08-07	2015-08-14	No	1. recovered/resolved	1	possible	NA	No
58	White blood cell count decreased	Investigations	2016-02-24	2016-03-01	No	2. recovering/resolving	2	possible	possible	No
58	White blood cell count decreased	Investigations	2016-01-13	2016-01-20	No	2. recovering/resolving	2	probable	probable	No
58	White blood cell count decreased	Investigations	2015-11-16	2015-12-07	No	2. recovering/resolving	2	probable	NA	No
58	Anaemia	Blood and lymphatic system disorders	2015-08-21	2015-08-27	No	1. recovered/resolved	1	possible	NA	No
58	Productive cough	Respiratory, thoracic and mediastinal disorders	2015-08-27	2016-04-09	No	3. not recovered/ not resolved	1	possible	NA	No
58	Neutrophil count decreased	Investigations	2016-03-22	2016-03-30	No	1. recovered/resolved	3	possible	possible	No
58	Influenza	Infections and infestations	2016-04-05	2016-04-09	No	5. fatal	5	possible	possible	Yes
58	Neutrophil count decreased	Investigations	2015-12-28	2016-04-09	No	3. not recovered/ not resolved	2	probable	probable	No
58	Dyspnoea	Respiratory, thoracic and mediastinal disorders	2016-03-30	2016-04-09	No	3. not recovered/ not resolved	3	possible	possible	No
58	White blood cell count decreased	Investigations	2015-08-21	2015-09-03	No	1. recovered/resolved	3	possible	NA	No
58	Cough	Respiratory, thoracic and mediastinal disorders	2016-03-01	2016-04-09	No	3. not recovered/ not resolved	1	possible	possible	No
58	White blood cell count decreased	Investigations	2015-12-30	2016-01-05	No	2. recovering/resolving	3	probable	probable	No
58	Neutrophil count decreased	Investigations	2015-12-01	2016-04-09	No	3. not recovered/ not resolved	3	probable	possible	No
58	White blood cell count decreased	Investigations	2016-01-20	2016-01-27	No	3. not recovered/ not resolved	1	probable	probable	No
58	White blood cell count decreased	Investigations	2015-12-07	2015-12-08	No	1. recovered/resolved	1	probable	possible	No
58	Neutrophil count decreased	Investigations	2015-09-15	2015-09-22	No	3. not recovered/ not resolved	3	probable	NA	No
58	Neutrophil count decreased	Investigations	2016-01-13	2016-01-21	No	1. recovered/resolved	2	probable	probable	No
58	Anaemia	Blood and lymphatic system disorders	2016-02-02	2016-03-07	No	3. not recovered/ not resolved	2	possible	possible	No
58	Hyperkalaemia	Metabolism and nutrition disorders	2016-02-11	2016-02-17	No	2. recovering/resolving	2	possible	possible	No
58	Anaemia	Blood and lymphatic system disorders	2015-11-05	2015-12-01	No	1. recovered/resolved	1	possible	NA	No
58	Anaemia	Blood and lymphatic system disorders	2016-03-15	2016-04-04	No	3. not recovered/ not resolved	1	possible	possible	No
58	Neutrophil count decreased	Investigations	2015-10-26	2015-11-05	No	1. recovered/resolved	1	probable	NA	No
58	Neutrophil count decreased	Investigations	2016-02-24	2016-03-01	No	1. recovered/resolved	3	possible	possible	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
58	White blood cell count decreased	Investigations	2016-03-22	2016-03-30	No	2. recovering/resolving	3	possible	possible	No
58	Neutrophil count decreased	Investigations	2015-08-07	2015-08-14	No	1. recovered/resolved	1	probable	NA	No
58	Diarrhoea	Gastrointestinal disorders	2015-12-08	2016-04-09	No	3. not recovered/ not resolved	2	possible	unlikely	No
58	Neutrophil count decreased	Investigations	2016-04-04	2016-04-09	No	3. not recovered/ not resolved	2	possible	possible	No
58	Neutrophil count decreased	Investigations	2016-03-07	2016-03-15	No	1. recovered/resolved	1	possible	possible	No
58	White blood cell count decreased	Investigations	2016-02-11	2016-02-24	No	3. not recovered/ not resolved	1	possible	possible	No
58	Neutrophil count decreased	Investigations	2015-09-22	2015-10-01	No	2. recovering/resolving	4	probable	NA	No
58	Hyperkalaemia	Metabolism and nutrition disorders	2015-12-21	2015-12-28	No	3. not recovered/ not resolved	1	possible	possible	No
58	White blood cell count decreased	Investigations	2015-11-05	2015-11-16	No	3. not recovered/ not resolved	1	possible	NA	No
58	White blood cell count decreased	Investigations	2015-12-14	2015-12-28	No	3. not recovered/ not resolved	1	probable	possible	No
58	Contusion	Injury, poisoning and procedural complications	2015-11-05	2016-04-09	No	3. not recovered/ not resolved	1	not related	NA	No
58	White blood cell count decreased	Investigations	2015-08-07	2015-08-14	No	2. recovering/resolving	3	possible	NA	No
58	Hyperkalaemia	Metabolism and nutrition disorders	2016-01-13	2016-01-20	No	2. recovering/resolving	3	possible	possible	No
58	White blood cell count decreased	Investigations	2015-09-15	2015-10-06	No	1. recovered/resolved	3	possible	NA	No
58	Anaemia	Blood and lymphatic system disorders	2016-03-07	2016-03-15	No	2. recovering/resolving	3	possible	possible	No
58	Neutrophil count decreased	Investigations	2015-08-27	2015-09-03	No	1. recovered/resolved	4	probable	NA	No
58	Anaemia	Blood and lymphatic system disorders	2015-12-07	2015-12-21	No	1. recovered/resolved	1	probable	possible	No
58	Lymphocyte count decreased	Investigations	2015-12-08	2016-04-09	No	3. not recovered/ not resolved	3	probable	possible	No
58	Anaemia	Blood and lymphatic system disorders	2015-10-01	2015-10-06	No	1. recovered/resolved	1	possible	NA	No
58	White blood cell count decreased	Investigations	2016-01-27	2016-02-12	No	2. recovering/resolving	2	possible	possible	No
59	Diarrhoea	Gastrointestinal disorders	2015-12-08	2015-12-14	No	1. recovered/resolved	2	possible	possible	No
59	Insomnia	Psychiatric disorders	2016-01-29	NA	Yes	3. not recovered/ not resolved	1	possible	possible	No
59	Nasopharyngitis	Infections and infestations	2016-02-15	2016-03-15	No	1. recovered/resolved	2	possible	possible	No
59	Constipation	Gastrointestinal disorders	2015-09-15	2015-10-09	No	1. recovered/resolved	1	possible	possible	No
59	Sternal fracture	Injury, poisoning and procedural complications	2015-11-01	2015-11-13	No	1. recovered/resolved	2	possible	possible	No
60	Hypocalcaemia	Metabolism and nutrition disorders	2017-03-16	2017-04-20	No	1. recovered/resolved	3	unlikely	unlikely	No
60	Sepsis	Infections and infestations	2016-02-24	2016-03-25	No	1. recovered/resolved	3	possible	unlikely	Yes
60	Pneumonia	Infections and infestations	2016-02-24	2016-03-25	No	1. recovered/resolved	3	possible	unlikely	Yes
60	Leukopenia	Blood and lymphatic system disorders	2015-09-18	2015-09-29	No	1. recovered/resolved	3	possible	not related	No
60	Neutropenia	Blood and lymphatic system disorders	2015-09-18	2015-09-24	No	1. recovered/resolved	3	possible	not related	No

Table 1025: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
60	Lumbar vertebral fracture	Injury, poisoning and procedural complications	2015-10-01	2015-10-03	No	1. recovered/resolved	3	not related	not related	Yes
60	Hypertension	Vascular disorders	2017-04-15	2017-08-17	No	1. recovered/resolved	3	possible	possible	No
60	Neutropenia	Blood and lymphatic system disorders	2015-12-15	2015-12-28	No	1. recovered/resolved	3	possible	possible	No
60	Vitamin D deficiency	Metabolism and nutrition disorders	2017-04-21	2017-08-11	No	1. recovered/resolved	2	not related	not related	No

Table 1026: Listing of all serious adverse events during treatment - Safety

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
1	Hyperglycaemia	Metabolism and nutrition disorders	2014-07-14	2014-07-18	No	1. recovered/resolved	3	not related	not assessable	Yes
2	Sinusitis	Infections and infestations	2014-10-28	2014-11-04	No	1. recovered/resolved	2	not related	not related	Yes
2	Bronchitis	Infections and infestations	2014-10-28	2014-11-04	No	1. recovered/resolved	2	not related	not related	Yes
2	Chronic sinusitis	Infections and infestations	2014-12-09	2014-12-18	No	1. recovered/resolved	2	unlikely	unlikely	Yes
2	Respiratory tract infection	Infections and infestations	2014-08-30	2014-09-06	No	1. recovered/resolved	2	possible	possible	Yes
2	Acute sinusitis	Infections and infestations	2014-12-09	2014-12-18	No	1. recovered/resolved	2	unlikely	unlikely	Yes
2	Bronchitis	Infections and infestations	2014-12-09	2014-12-18	No	1. recovered/resolved	2	unlikely	unlikely	Yes
8	Pneumocystis jirovecii pneumonia	Infections and infestations	2015-02-01	2015-02-25	No	1. recovered/resolved	3	possible	possible	Yes
8	Acute myocardial infarction	Cardiac disorders	2014-12-21	2014-12-23	No	1. recovered/resolved	4	unlikely	unlikely	Yes
9	Pneumonia	Infections and infestations	2015-01-01	2015-01-20	No	1. recovered/resolved	3	possible	possible	Yes
9	Disease progression	General disorders and administration site conditions	2015-01-27	NA	Yes	3. not recovered/ not resolved	3	not related	not related	Yes
11	Back pain	Musculoskeletal and connective tissue disorders	2014-10-24	2014-10-31	No	1. recovered/resolved	3	not related	not related	Yes
11	Back pain	Musculoskeletal and connective tissue disorders	2015-01-07	2015-01-24	No	3. not recovered/ not resolved	3	unlikely	not related	Yes
11	Hangover	General disorders and administration site conditions	2015-01-07	2015-01-24	No	3. not recovered/ not resolved	3	unlikely	not related	Yes
11	Back pain	Musculoskeletal and connective tissue disorders	2014-11-17	2014-11-24	No	1. recovered/resolved	3	not related	not related	Yes
11	Hangover	General disorders and administration site conditions	2014-12-03	2014-12-22	No	1. recovered/resolved	3	not related	not related	Yes
12	Bronchitis	Infections and infestations	2015-01-26	2015-02-03	No	1. recovered/resolved	3	unlikely	unlikely	Yes
12	Febrile neutropenia	Blood and lymphatic system disorders	2015-01-26	2015-02-03	No	1. recovered/resolved	3	unlikely	unlikely	Yes
14	Bronchitis	Infections and infestations	2016-04-14	2016-04-19	No	1. recovered/resolved	3	probable	not related	Yes
15	Dehydration	Metabolism and nutrition disorders	2014-10-05	2014-10-15	No	1. recovered/resolved	3	not related	probable	Yes
15	Blood creatinine increased	Investigations	2014-11-20	2014-11-24	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Pneumonia	Infections and infestations	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Acute kidney injury	Renal and urinary disorders	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Renal failure	Renal and urinary disorders	2014-11-28	2014-12-12	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Pleural effusion	Respiratory, thoracic and mediastinal disorders	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Renal hypertension	Renal and urinary disorders	2014-12-18	2014-12-31	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Pneumonia	Infections and infestations	2014-10-27	2014-11-10	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Renal failure	Renal and urinary disorders	2014-12-18	2014-12-31	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Dehydration	Metabolism and nutrition disorders	2014-10-27	2014-11-10	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
15	Pneumonia	Infections and infestations	2014-10-05	2014-10-15	No	1. recovered/resolved	3	not related	probable	Yes

Table 1026: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
19	Pneumonia	Infections and infestations	2014-11-25	2014-12-04	No	1. recovered/resolved	2	related	related	Yes
19	Disease progression	General disorders and administration site conditions	2014-12-07	2014-12-16	No	5. fatal	5	not related	not related	Yes
20	Pneumonia	Infections and infestations	2015-10-05	2015-10-23	No	1. recovered/resolved	3	possible	possible	Yes
20	Diarrhoea	Gastrointestinal disorders	2015-10-27	2015-11-04	No	1. recovered/resolved	2	unlikely	not related	Yes
24	Dehydration	Metabolism and nutrition disorders	2015-06-25	2015-07-01	No	1. recovered/resolved	2	unlikely	unlikely	Yes
24	Cholecystitis	Hepatobiliary disorders	2015-02-09	2015-02-12	No	1. recovered/resolved	2	unlikely	unlikely	Yes
24	Atrial flutter	Cardiac disorders	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
24	Upper respiratory tract infection	Respiratory, thoracic and mediastinal disorders	2016-04-09	2016-04-19	No	1. recovered/resolved	2	possible	possible	Yes
24	Neutropenia	Blood and lymphatic system disorders	2015-04-07	2015-04-18	No	1. recovered/resolved	2	possible	possible	Yes
24	Acute myocardial infarction	Cardiac disorders	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
24	Dehydration	Metabolism and nutrition disorders	2014-12-07	2014-12-11	No	1. recovered/resolved	2	unlikely	not assessable	Yes
24	Gastritis	Gastrointestinal disorders	2014-12-07	2014-12-11	No	1. recovered/resolved	2	unlikely	not assessable	Yes
24	Infection	Infections and infestations	2015-04-07	2015-04-18	No	1. recovered/resolved	2	possible	possible	Yes
24	Pneumonia	Infections and infestations	2015-07-11	2015-07-20	No	1. recovered/resolved	3	possible	unlikely	Yes
24	Acute kidney injury	Renal and urinary disorders	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
24	Infection	Infections and infestations	2015-02-27	2015-03-15	No	1. recovered/resolved	4	possible	possible	Yes
25	Sepsis	Infections and infestations	2015-03-23	2015-06-03	No	1. recovered/resolved	4	possible	NA	Yes
25	Bronchopulmonary aspergillosis	Infections and infestations	2015-04-02	2015-05-07	No	1. recovered/resolved	3	possible	NA	Yes
26	Pneumonia fungal	Infections and infestations	2014-12-22	2014-12-30	No	1. recovered/resolved	3	unlikely	not assessable	Yes
26	Disease progression	General disorders and administration site conditions	2015-01-09	2015-01-09	No	5. fatal	5	not related	not assessable	Yes
27	Pneumonia	Infections and infestations	2015-02-15	2015-02-23	No	1. recovered/resolved	3	probable	probable	Yes
27	Myocardial infarction	Cardiac disorders	2015-04-25	2015-06-05	No	4. recovered/ resolved with sequel	4	not related	not related	Yes
27	Disease progression	General disorders and administration site conditions	2015-06-19	2015-07-01	No	5. fatal	5	not related	not related	Yes
27	Clostridium difficile infection	Infections and infestations	2015-02-15	2015-02-23	No	1. recovered/resolved	3	probable	probable	Yes
27	Pneumonia	Infections and infestations	2014-12-10	2014-12-28	No	1. recovered/resolved	2	not related	not related	Yes
27	Gastroenteritis norovirus	Infections and infestations	2015-02-15	2015-02-23	No	1. recovered/resolved	3	probable	probable	Yes
27	Atrial fibrillation	Cardiac disorders	2015-04-09	2015-04-16	No	1. recovered/resolved	3	not related	not related	Yes
28	Pneumonia	Infections and infestations	2014-12-30	2015-01-05	No	1. recovered/resolved	3	possible	possible	Yes
29	Pneumonia	Infections and infestations	2015-02-01	2015-02-07	No	1. recovered/resolved	2	possible	not assessable	Yes
29	Pneumonia	Infections and infestations	2015-03-02	2015-03-10	No	1. recovered/resolved	3	possible	not assessable	Yes

Table 1026: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
29	Infection	Infections and infestations	2015-04-13	2015-07-15	No	1. recovered/resolved	1	possible	not assessable	Yes
29	Pneumonia	Infections and infestations	2015-02-01	2015-02-07	No	1. recovered/resolved	2	possible	possible	Yes
29	Dizziness	Nervous system disorders	2014-12-15	2014-12-17	No	1. recovered/resolved	3	related	not related	Yes
30	Atypical pneumonia	Infections and infestations	2015-07-04	2015-07-27	No	5. fatal	5	possible	possible	Yes
30	Bronchitis	Infections and infestations	2015-04-14	2015-05-08	No	4. recovered/ resolved with sequel	3	possible	possible	Yes
31	Bone marrow failure	Blood and lymphatic system disorders	2015-01-02	2015-01-03	No	5. fatal	5	not related	not related	Yes
32	Pneumonia	Infections and infestations	2015-11-03	2015-11-23	No	1. recovered/resolved	3	unlikely	unlikely	Yes
32	Febrile neutropenia	Blood and lymphatic system disorders	2015-05-20	2015-06-02	No	1. recovered/resolved	3	possible	possible	Yes
32	Pyrexia	General disorders and administration site conditions	2015-12-01	2015-12-10	No	1. recovered/resolved	2	unlikely	unlikely	Yes
32	Infection	Infections and infestations	2015-04-10	2015-04-24	No	1. recovered/resolved	3	probable	not related	Yes
32	Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2015-02-26	2015-02-26	No	1. recovered/resolved	2	not related	not related	Yes
34	Erythema	Skin and subcutaneous tissue disorders	2016-04-04	2016-04-08	No	4. recovered/ resolved with sequel	1	not related	not related	Yes
35	Squamous cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2015-11-18	2015-11-18	No	1. recovered/resolved	3	not related	not assessable	Yes
35	Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2015-11-18	2015-11-18	No	1. recovered/resolved	3	unlikely	not assessable	Yes
35	Chest pain	General disorders and administration site conditions	2015-07-17	2015-07-21	No	1. recovered/resolved	3	not related	not assessable	Yes
37	Diarrhoea	Gastrointestinal disorders	2015-04-18	2015-04-24	No	1. recovered/resolved	2	unlikely	not assessable	Yes
37	Febrile infection	Infections and infestations	2015-02-18	2015-02-25	No	1. recovered/resolved	3	unlikely	not assessable	Yes
38	Oedema peripheral	General disorders and administration site conditions	2015-01-30	2015-02-03	No	1. recovered/resolved	2	not related	not related	Yes
38	Pleural effusion	Respiratory, thoracic and mediastinal disorders	2015-02-23	2015-02-25	No	5. fatal	5	not related	not related	Yes
39	Femoral neck fracture	Injury, poisoning and procedural complications	2015-04-14	2015-04-28	No	1. recovered/resolved	3	not related	not assessable	Yes
40	Hypercalcaemia	Metabolism and nutrition disorders	2015-03-12	NA	Yes	3. not recovered/ not resolved	3	not related	not related	Yes
41	Chest pain	General disorders and administration site conditions	2015-03-08	2015-03-10	No	1. recovered/resolved	3	not related	NA	Yes
42	Febrile infection	Infections and infestations	2015-05-28	2015-06-04	No	1. recovered/resolved	3	related	not related	Yes
43	Acute kidney injury	Renal and urinary disorders	2016-02-09	2016-03-17	No	4. recovered/ resolved with sequel	3	not related	not related	Yes
43	Pneumonia	Infections and infestations	2016-01-22	2016-01-29	No	1. recovered/resolved	2	probable	probable	Yes
43	Febrile neutropenia	Blood and lymphatic system disorders	2016-01-22	2016-01-29	No	1. recovered/resolved	2	probable	probable	Yes
44	General physical health deterioration	General disorders and administration site conditions	2015-04-02	2015-04-13	No	2. recovering/resolving	3	possible	NA	Yes
45	Post procedural haemorrhage	Injury, poisoning and procedural complications	2015-03-31	2015-04-19	No	1. recovered/resolved	3	not related	not related	Yes
45	Bronchitis	Infections and infestations	2015-10-27	2015-11-02	No	1. recovered/resolved	3	possible	unlikely	Yes
45	Tracheostomy	Surgical and medical procedures	2015-06-17	2015-06-22	No	3. not recovered/ not resolved	3	not related	not related	Yes

Table 1026: (continued)

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
45	Laryngeal infiltration	Laryngeal infiltration	2015-03-20	2015-03-24	No	1. recovered/resolved	3	not related	not related	Yes
46	Urinary bladder haemorrhage	Renal and urinary disorders	2015-03-27	2015-03-30	No	1. recovered/resolved	2	unlikely	unlikely	Yes
48	Neutrophil count decreased	Investigations	2015-05-19	NA	Yes	3. not recovered/ not resolved	4	probable	NA	Yes
50	Diarrhoea	Gastrointestinal disorders	2015-07-11	2015-08-11	No	1. recovered/resolved	3	possible	not assessable	Yes
50	Infection	Infections and infestations	2015-06-15	2015-06-18	No	1. recovered/resolved	2	possible	not assessable	Yes
50	Pancytopenia	Blood and lymphatic system disorders	2015-06-15	2015-06-18	No	1. recovered/resolved	2	possible	not assessable	Yes
51	Peritonitis	Infections and infestations	2015-10-12	2015-11-02	No	1. recovered/resolved	3	not related	not related	Yes
51	Large intestine perforation	Gastrointestinal disorders	2015-10-12	2015-11-02	No	1. recovered/resolved	3	not related	not related	Yes
53	Pneumonia	Infections and infestations	2016-02-01	2016-02-05	No	1. recovered/resolved	3	related	related	Yes
53	Myoclonus	Nervous system disorders	2015-09-21	2015-09-23	No	1. recovered/resolved	3	probable	not related	Yes
54	Disease progression	General disorders and administration site conditions	2015-08-27	NA	Yes	3. not recovered/ not resolved	3	not related	NA	Yes
55	Septic shock	Infections and infestations	2015-10-11	2015-10-12	No	5. fatal	5	possible	not assessable	Yes
57	Hypercalcaemia	Metabolism and nutrition disorders	2015-08-20	2015-08-26	No	3. not recovered/ not resolved	1	unlikely	not related	Yes
57	Condition aggravated	General disorders and administration site conditions	2015-09-10	2015-09-17	No	1. recovered/resolved	3	possible	possible	Yes
58	Influenza	Infections and infestations	2016-04-05	2016-04-09	No	5. fatal	5	possible	possible	Yes
60	Sepsis	Infections and infestations	2016-02-24	2016-03-25	No	1. recovered/resolved	3	possible	unlikely	Yes
60	Pneumonia	Infections and infestations	2016-02-24	2016-03-25	No	1. recovered/resolved	3	possible	unlikely	Yes
60	Lumbar vertebral fracture	Injury, poisoning and procedural complications	2015-10-01	2015-10-03	No	1. recovered/resolved	3	not related	not related	Yes

Table 1027: Listing of all adverse events during treatment with fatal outcome -
Safety

ID	PT	SOC	Start	End	Ongoing	Outcome	CTC	Relationship Pom	Relationship Cyclo	SAE
15	Pneumonia	Infections and infestations	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Pleural effusion	Respiratory, thoracic and mediastinal disorders	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
15	Acute kidney injury	Renal and urinary disorders	2015-01-08	2015-01-25	No	5. fatal	5	not related	not related	Yes
19	Disease progression	General disorders and administration site conditions	2014-12-07	2014-12-16	No	5. fatal	5	not related	not related	Yes
30	Atypical pneumonia	Infections and infestations	2015-07-04	2015-07-27	No	5. fatal	5	possible	possible	Yes
58	Influenza	Infections and infestations	2016-04-05	2016-04-09	No	5. fatal	5	possible	possible	Yes
31	Bone marrow failure	Blood and lymphatic system disorders	2015-01-02	2015-01-03	No	5. fatal	5	not related	not related	Yes
38	Pleural effusion	Respiratory, thoracic and mediastinal disorders	2015-02-23	2015-02-25	No	5. fatal	5	not related	not related	Yes
26	Disease progression	General disorders and administration site conditions	2015-01-09	2015-01-09	No	5. fatal	5	not related	not assessable	Yes
27	Disease progression	General disorders and administration site conditions	2015-06-19	2015-07-01	No	5. fatal	5	not related	not related	Yes
55	Septic shock	Infections and infestations	2015-10-11	2015-10-12	No	5. fatal	5	possible	not assessable	Yes