

Extract from Tables Listings and Graphs for HYPАЗ Study Final Analysis Report

Title: Adverse Events  
Number: 5.1.1  
Population: Safety (N=27)

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
1	Pain-Throat (Category:Pain)	1	2011-07-13	2011-07-14	No	None	Probably unrelated	No
1	Pain-Abdomen (Category:Pain)	1	2011-07-04	2011-07-06	No	None	Probably unrelated	No
1	Diarrhea (Category:Gastrointestinal)	2	2011-07-20	2011-07-20	No	Treatment given	Unrelated	No
1	Taste alteration (dysgeusia) (Category:Gastrointestinal)	1	2011-07-27		Yes	None	Probably related	No
1	Hypopigmentation (Category:Dermatology/Skin)	1	2011-07-27		Yes	None	Probably related	No
1	Hair loss/alopecia (scalp or body) (Category:Dermatology/Skin)	1	2011-07-27		Yes	None	Probably related	No
1	Diarrhea (Category:Gastrointestinal)	1	2011-08-12	2011-08-12	No	None	Probably unrelated	No
1	Constipation (Category:Gastrointestinal)	1	2011-10-19		Yes	None	Probably unrelated	No
1	Infection-Urinary tract NOS (Category:Infection-Renal/Genitourinary)	2	2011-10-20		Yes	Treatment given	Probably unrelated	No
1	Fatigue (Category:Constitutional Symptoms)	NA	2011-10		Yes	None	Unrelated	No
1	Dyspnea (shortness of breath) (Category:Pulmonary/Upper Respiratory)	NA	2011-10		Yes	None	Unrelated	No
1	Hemoglobin (Category:Blood/Bone Marrow)	3	2011-10-13	2011-10-20	No	Treatment given	Probably unrelated	No
1	Anorexia (Category:Gastrointestinal)	1	2011-10		Yes	None	Unrelated	No
2	Bilirubin/Hyperbilirubinemia (Category:Metabolic/Laboratory)	3	2012-03-15		Yes	Subject withdrawn from study	Possibly related	Yes
2	Diarrhea (Category:Gastrointestinal)	1	2011-09-14		Yes	Treatment given	Definitely related	No
2	Fatigue (Category:Constitutional Symptoms)	1	2011-		Yes	None	Possibly	No

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2	Mucositis/stomatitis-Oral cavity (Category:Gastrointestinal)	1	08-15 2011-10-01	2011-10-19	No	Treatment given	related Possibly related	No
2	Pain-Extremity limb (Category:Pain)	2	2011-10-01	2011-10-02	No	Treatment given	Unrelated	No
2	Hypertension (Category:Cardiac General)	2	2011-10-05	2012-03-16	No	Treatment given	Probably related	No
2	Pain-Head/headache (Category:Pain-Neurology)	1	2011-10-19	2011-10-24	No	None	Unrelated	No
2	Hypopigmentation (Category:Dermatology/Skin)	1	2011-11-02		Yes	None	Definitely related	No
2	Distension/bloating, abdominal (Category:Gastrointestinal)	1	2011-12-17		Yes	None	Possibly related	No
2	Glucose, serum-high (hyperglycemia) (Category:Metabolic/Laboratory)	1	2012-01-25	2012-01-26	No	None	Possibly related	No
2	Nausea (Category:Gastrointestinal)	1	2011-12-17		Yes	None	Probably related	No
2	Neuropathy:sensory (Category:Neurology)	1	2011-12		No	None	Unrelated	No
2	GGT (Gamma-Glutamyl transpeptidase) (Category:Metabolic/Laboratory)	4	2011-08-04		Yes	None	Possibly related	No
3	Vomiting (Category:Gastrointestinal)	1	2011-09-26	2011-10-03	No	Subject withdrawn from study	Unrelated	No
3	Constipation (Category:Gastrointestinal)	1	2011-09-16		Yes	Subject withdrawn from study	Unrelated	No
3	Pain-Back (Category:Pain)	2	2011-09-11		Yes	Treatment given	Unrelated	No
3	Nausea (Category:Gastrointestinal)	1	2011-09-26		Yes	Treatment given	Probably unrelated	No
3	Pain-Abdomen (Category:Pain)	3	2011-09-20	2011-10-03	No	Subject withdrawn from study	Unrelated	No
4	Voice changes/dysarthria (Category:Pulmonary/Upper Respiratory)	1	2012-02		Yes	None	Definitely related	No

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4	Pain-Bone (Category:Pain)	1	2012-02		Yes	Treatment given	Unrelated	No
4	Pain-Abdomen (Category:Pain)	1	2012-02	2013-01	No	Treatment given	Unrelated	No
4	Weight Loss (Category:Constitutional Symptoms)	1	2011-09	2012-09	No	None	Unrelated	No
4	Pain-Abdomen (Category:Pain)	1	2012-02		Yes	Treatment given	Unrelated	No
4	Fatigue (Category:Constitutional Symptoms)	1	2012-03		Yes	Treatment given	Unrelated	No
4	Anorexia (Category:Gastrointestinal)	1	2012-03	2013-01	No	Treatment given	Unrelated	No
4	Dry mouth/salivary gland-Xerostomia (Category:Gastrointestinal)	1	2012-03		Yes	None	Unrelated	No
4	Constipation (Category:Gastrointestinal)	1	2012-03	2012-05-09	No	Treatment given	Unrelated	No
4	Nausea (Category:Gastrointestinal)	1	2012-06		Yes	Treatment given	Possibly related	No
4	Voice changes/dysarthria (Category:Pulmonary/Upper Respiratory)	1	2012-02-15		Yes	None	Possibly related	No
4	Pain-Abdomen (Category:Pain)	1	2012-01-18		Yes	Treatment given	Unrelated	No
5	Distension/bloating, abdominal (Category:Gastrointestinal)	1			Yes	None	Unrelated	No
5	Constipation (Category:Gastrointestinal)	1			Yes	Treatment given	Unrelated	No
5	Pain-Back (Category:Pain)	1			Yes	None	Unrelated	No
5	Allergic rhinitis (Category:Allergy/Immunology)	1			Yes	Treatment given	Unrelated	No
5	Anorexia (Category:Gastrointestinal)	1			Yes	None	Unrelated	No
5	Cough (Category:Pulmonary/Upper Respiratory)	2	2012-05-05		Yes	Subject withdrawn from study	Possibly related	No
5	Hemoglobin (Category:Blood/Bone Marrow)	3	2012-05-09		Yes	Subject withdrawn from study	Possibly related	No
5	Dyspnea (shortness of breath) (Category:Pulmonary/Upper Respiratory)	2	2012-05		Yes	Subject withdrawn from	Possibly related	No

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5	Nausea (Category:Gastrointestinal)	2	2012-05-06		Yes	study Subject withdrawn from study	Possibly related	No
5	Diarrhea (Category:Gastrointestinal)	1			Yes	Treatment given	Unrelated	No
5	Vomiting (Category:Gastrointestinal)	1	2012-04		Yes	Treatment given	Unrelated	No
5	Fatigue (Category:Constitutional Symptoms)	2	2012-05-06		Yes	Subject withdrawn from study	Possibly related	No
5	Infection-Urinary tract NOS (Category:Infection-Renal/Genitourinary)	1	2012-04-25	2012-04-30	No	Treatment given	Unrelated	No
6	Diarrhea (Category:Gastrointestinal)	1	2012-06-16	2012-06-17	No	None	Probably related	No
6	Rash: hand-foot skin reaction (Category:Dermatology/Skin)	1	2012-06-01	2012-06-27	No	Treatment given	Probably related	No
6	Renal/Genitourinary-Other (hydronephrosis) (Category:Renal/Genitourinary)	1	2012-08-08	2012-08-10	No	Treatment given	Unrelated	No
6	Otitis, external ear (non-infectious) (Category:Auditory/Ear)	1	2012-08-11	2012-10-03	No	Treatment given	Unrelated	No
6	Ocular surface disease (Category:Ocular/Visual)	1	2012-08-15	2012-10-03	No	Treatment given	Unrelated	No
6	Nausea (Category:Gastrointestinal)	1	2012-08-10	2012-08-10	No	Treatment given	Probably related	No
6	Pain-Muscle (Category:Pain)	1	2012-10-21		Yes	NA	Probably unrelated	NA
6	Renal/Genitourinary-Other (hydronephrosis) (Category:Renal/Genitourinary)	1	2012-08-10		Yes	Treatment given	NA	No
6	Pain-Abdomen (Category:Pain)	1	2012-05-30	2012-06-11	No	Treatment given	Unrelated	No
6	Nausea (Category:Gastrointestinal)	2	2012-08-10	2012-10-03	No	None	Probably related	No
6	Obstruction GU-Ureter (Category:Renal/Genitourinary)	3	2012-08-08	2012-08-10	No	Dose delayed	Probably unrelated	Yes
6	Obstruction GU-Ureter (Category:Renal/Genitourinary)	3	2012-12-07	2012-12-07	No	Dose delayed	Unrelated	Yes

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Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
6	Hypertension (Category:Cardiac General)	2	2012-06-06	2012-08-08	No	Treatment given	Definitely related	No
6	Infection-Bladder (urinary) (Category:Infection-Renal/Genitourinary)	1	2012-05-30	2012-06-11	No	Treatment given	Unrelated	No
6	Constipation (Category:Gastrointestinal)	1	2012-08-10		Yes	Treatment given	Unrelated	No
7	Infection with normal ANC (Category:Infection-General)	4	2012-06-27	2012-06-28	No	None	Unrelated	Yes
7	Fever (Category:Constitutional Symptoms)	1	2012-06-20	2012-06-20	No	Treatment given	Unrelated	No
7	Diarrhea (Category:Gastrointestinal)	1	2012-06-28	2012-07-10	No	Treatment given	Probably unrelated	No
7	Fatigue (Category:Constitutional Symptoms)	1	2012-06-27		Yes	None	Unrelated	No
7	Rigors/chills (Category:Constitutional Symptoms)	1	2012-06-20	2012-06-20	No	Treatment given	Unrelated	No
7	Rigors/chills (Category:Constitutional Symptoms)	1	2012-07-07	2012-07-07	No	Treatment given	Unrelated	No
7	Pain-Abdomen (Category:Pain)	1	2012-07-18		Yes	Treatment given	Unrelated	No
8	Fatigue (Category:Constitutional Symptoms)	2		2012-08-01	No	None	Unrelated	No
8	Diarrhea (Category:Gastrointestinal)	1	2012-08-15	2012-08-31	No	Treatment given	Probably related	No
8	Sodium, serum-low/Hyponatremia (Category:Metabolic/Laboratory)	3	2012-09-26		Yes	None	Unrelated	No
8	Diarrhea (Category:Gastrointestinal)	2	2012-10-10	2012-10-14	No	Treatment given	Possibly related	No
8	Anorexia (Category:Gastrointestinal)	1	2012-09-12	2012-09-14	No	Treatment given	Unrelated	No
8	Nausea (Category:Gastrointestinal)	1	2012-11-21		Yes	Treatment given	Unrelated	No
8	Skin-Other (Category:Dermatology/Skin)	1	2012-09-26		No	None	Probably unrelated	No
8	Vomiting (Category:Gastrointestinal)	1	2012-09-12	2012-09-19	No	None	Probably related	No

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Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
8	Anorexia (Category:Gastrointestinal)	1	2012-11-21	2012-12-19	No	None	Unrelated	No
8	Nausea (Category:Gastrointestinal)	2	2012-10-10	2012-10-14	No	None	Probably unrelated	No
8	Diarrhea (Category:Gastrointestinal)	2	2012-11-21	2012-12-19	No	None	Probably related	No
8	Fatigue (Category:Constitutional Symptoms)	1	2012-08-31		Yes	None	Unrelated	No
8	Nausea (Category:Gastrointestinal)	1	2012-09-16	2012-09-19	No	None	Probably unrelated	No
8	Diarrhea (Category:Gastrointestinal)	1	2012-09-12	2012-09-19	No	Treatment given	Probably related	No
11	Left ventricular diastolic dysfunction (Category:Cardiac General)	1	2013-03-03		Yes	Treatment given	Unrelated	No
11	Rash/desquamation (Category:Dermatology/Skin)	2	2013-01-30	2013-02-15	No	Treatment given	Possibly related	No
11	Diarrhea (Category:Gastrointestinal)	3	2013-03-01	2013-03-07	No	Dose delayed	Possibly related	Yes
11	Anorexia (Category:Gastrointestinal)	1	2013-03-13		Yes	None	Possibly related	No
11	Fatigue (Category:Constitutional Symptoms)	1	2013-03-13		Yes	None	Possibly related	No
11	Pain-Abdomen (Category:Pain)	1	2013-06-24		Yes	Treatment given	Unrelated	No
11	Pain-Abdomen (Category:Pain)	1	2013-03-01	2013-03-13	No	None	Probably related	No
11	Rash-Acne-Acneiform (Category:Dermatology/Skin)	1	2013-02-15	2013-05-09	No	Treatment given	Possibly related	No
11	Rash/desquamation (Category:Dermatology/Skin)	2	2013-05-09	2013-06-05	No	Subject withdrawn from study	Possibly related	No
11	Constipation (Category:Gastrointestinal)	1			Yes	None	NA	No
11	Rhinitis (Category:Allergy/Immunology)	1	2012-11-11		Yes	Treatment given	NA	No
11	Pain-Muscle (Category:Pain)	2	2013-03-06	2013-03-07	No	Treatment given	Unrelated	No

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Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
11	Pain-Muscle (Category:Pain)	1	2013-02-15		Yes	Treatment given	Unrelated	No
11	Rash/desquamation (Category:Dermatology/Skin)	1	2013-06-06		Yes	Treatment given	Possibly related	No
11	Palpitations (Category:Cardiac Arrhythmia)	1	2013-03		Yes	Treatment given	Unrelated	No
12	Fever (Category:Constitutional Symptoms)	1	2013-02-25	2013-02-25	No	None	Unrelated	No
12	Hemoglobin (Category:Blood/Bone Marrow)	2	2013-02-27	2013-03-01	No	None	Unrelated	No
12	Constipation (Category:Gastrointestinal)	1	2013-03-11		Yes	Treatment given	Unrelated	No
12	Hiccoughs-hiccups, singultus (Category:Pulmonary/Upper Respiratory)	3	2013-03-10	2013-03-17	No	Treatment given	Unrelated	No
12	Hemoglobin (Category:Blood/Bone Marrow)	2	2013-03-15	2013-03-27	No	Treatment given	Unrelated	No
12	ALT, SGPT (Category:Metabolic/Laboratory)	1	2013-03-15		Yes	None	Unrelated	No
12	Fatigue (Category:Constitutional Symptoms)	3	2013-05-09		Yes	None	Unrelated	No
12	Anorexia (Category:Gastrointestinal)	3	2013-04		Yes	Treatment given	Unrelated	No
12	Nausea (Category:Gastrointestinal)	1	2013-05-03	2013-05-23	No	None	Unrelated	No
12	Taste alteration (dysgeusia) (Category:Gastrointestinal)	2	2013-04-25		Yes	None	Possibly related	No
12	Pain-Abdomen (Category:Pain)	2	2013-05-08		Yes	Treatment given	Unrelated	No
12	Distension/bloating, abdominal (Category:Gastrointestinal)	2	2013-05-09		Yes	Treatment given	Unrelated	No
12	Weight Loss (Category:Constitutional Symptoms)	3	2013-04		Yes	Treatment given	Unrelated	No
12	Vomiting (Category:Gastrointestinal)	1	2013-05-09	2013-05-23	No	None	Unrelated	No
12	Pancreas, exocrine enzyme deficiency (Category:Hepatobiliary/Pancreas)	2	2013-02-28		Yes	Treatment given	Unrelated	No

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Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
13	Infection with unknown ANC-Pharynx (Category:Infection-Pulmonary/Upper Respiratory)	3	2013-04-18	2013-04-22	No	Dose delayed	Probably unrelated	Yes
13	Nausea (Category:Gastrointestinal)	1	2013-03-09	2013-03-09	No	None	Probably related	No
13	Diarrhea (Category:Gastrointestinal)	1	2013-03-15	2013-05-22	No	Treatment given	Probably related	No
13	Pain-Oral cavity (Category:Pain)	2	2013-03-31		Yes	Treatment given	Unrelated	No
13	Weight Loss (Category:Constitutional Symptoms)	2	2013-03-22		Yes	Subject withdrawn from study	Possibly related	No
13	Dyspnea (shortness of breath) (Category:Pulmonary/Upper Respiratory)	3	2013-04-18	2013-04-22	No	Dose delayed	Probably unrelated	Yes
13	Pain-Oral cavity (Category:Pain)	3	2013-04-18		Yes	Treatment given	Unrelated	Yes
14	Fatigue (Category:Constitutional Symptoms)	1	2013-04-04	2013-04-10	No	None	Possibly related	No
14	Hypopigmentation (Category:Dermatology/Skin)	1	2013-05-02	2013-06-13	No	None	Possibly related	No
14	Alopecia (Category:Dermatology/Skin)	1	2013-05-02	2013-06-13	No	None	Possibly related	No
14	Rash/desquamation (Category:Dermatology/Skin)	1	2013-04-25		NA	None	Possibly related	No
14	Mucositis/stomatitis (Category:Gastrointestinal)	1	2013-05-02	2013-05-09	No	None	Possibly related	No
14	Dry skin (Category:Dermatology/Skin)	1	2013-05-02		NA	None	Possibly related	No
14	Anorexia (Category:Gastrointestinal)	1	2013-05-16		NA	None	Possibly related	No
14	Mucositis/stomatitis (Category:Gastrointestinal)	2	2013-05-21	2013-06-13	No	None	Possibly related	No
14	Mucositis/stomatitis (Category:Gastrointestinal)	1	2013-06-13	2013-06-06	No	None	Possibly related	No
14	Hemorrhage, GU-Uterus (Category:Hemorrhage/Bleeding)	1	2013-05-28	2013-06-11	No	None	Possibly related	No
14	Rash: hand-foot skin reaction	1	2013-		NA	None	Probably	No

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14	(Category:Dermatology/Skin) Hemorrhage,Pulmonary/Upper Respiratory,Nose	1	06-12 2013-08-22	2013-08-22	No	None	related Probably related	No
14	(Category:Hemorrhage/Bleeding) Diarrhea (Category:Gastrointestinal)	1	2013-07-16	2013-08	No	None	Probably unrelated	No
14	Fatigue (Category:Constitutional Symptoms)	1	2013-08-17		Yes	None	Possibly related	No
14	Infection-Oral cavity-gums (gingivitis) (Category:Infection-Gastrointestinal)	1	2013-07-11		Yes	None	NA	No
14	Hair loss/alopecia (scalp or body) (Category:Dermatology/Skin)	1	2013-08-22		Yes	None	Possibly related	No
14	Irregular menses (change from baseline) (Category:Sexual/Reproductive Function)	1	2013-09	2013-12	No	None	Possibly related	No
14	Hypopigmentation (Category:Dermatology/Skin)	1	2013-08-22		Yes	None	Possibly related	No
15	Nausea (Category:Gastrointestinal)	1	2013-05-01	2013-06-06	No	None	Possibly related	No
15	Anorexia (Category:Gastrointestinal)	3	2013-06-06	2013-06-26	No	Subject withdrawn from study	Probably unrelated	No
15	Fatigue (Category:Constitutional Symptoms)	1	2013-05-14	2013-05-23	No	None	Unrelated	No
15	Fatigue (Category:Constitutional Symptoms)	2	2013-05-23	2013-06-06	No	None	Unrelated	No
15	Fatigue (Category:Constitutional Symptoms)	3	2013-06-06		Yes	Subject withdrawn from study	Unrelated	No
15	Insomnia (Category:Constitutional Symptoms)	1	2013-05-10	2013-05-23	No	None	Possibly related	No
15	Hiccoughs-hiccups, singultus (Category:Pulmonary/Upper Respiratory)	1	2013-06-06		NA	None	Possibly related	No
15	Vomiting (Category:Gastrointestinal)	1	2013-06-06		NA	Subject withdrawn from study	Possibly related	No
15	Nausea (Category:Gastrointestinal)	1	2013-05-23		NA	None	Possibly related	No

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15	Voice changes/dysarthria (Category:Pulmonary/Upper Respiratory)	1	2013-04		No	None	Possibly related	No
15	Pain-Urethra (Category:Pain)	1	2013-05-16	2013-05-23	No	Treatment given	Unrelated	No
15	Infection-Oral cavity (Category:Infection-Gastrointestinal)	2	2013-05-23		Yes	Treatment given	Unrelated	No
15	Distension/bloating, abdominal (Category:Gastrointestinal)	1	2013-06-06		Yes	Subject withdrawn from study	Unrelated	No
15	Pain-Abdomen (Category:Pain)	1	2013-04		Yes	Treatment given	Probably unrelated	No
15	Dysphagia (Category:Gastrointestinal)	1	2013-05-23		Yes	None	Probably unrelated	No
15	Infection-Urinary tract NOS (Category:Infection-Renal/Genitourinary)	2	2013-05-23	2013-05-28	No	Treatment given	Unrelated	No
16	Dyspnea (shortness of breath) (Category:Pulmonary/Upper Respiratory)	3	2013-08-21	2013-08-28	No	Treatment given	Unrelated	Yes
16	Pain-Rectum (Category:Pain)	1	2013-07-03		Yes	Treatment given	Unrelated	No
16	Hemoglobin (Category:Blood/Bone Marrow)	3	2013-06-28	2013-06-28	No	Treatment given	Probably related	No
16	Hemoglobin (Category:Blood/Bone Marrow)	1	2013-07-04	2013-07-08	No	Treatment given	Probably related	No
16	Hemoglobin (Category:Blood/Bone Marrow)	1	2013-07-10	2013-07-24	No	Treatment given	Probably related	No
16	Pain-Abdomen (Category:Pain)	2	2013-07-24		Yes	Treatment given	Unrelated	No
16	Mood alteration-Anxiety (Category:Neurology)	2	2013-06-28		Yes	Treatment given	Unrelated	No
16	Fatigue (Category:Constitutional Symptoms)	3	2013-06-28	2013-06-28	No	Treatment given	Probably related	No
16	Distension/bloating, abdominal (Category:Gastrointestinal)	1	2013-06-28		Yes	None	Unrelated	No
16	Pain-Abdomen (Category:Pain)	1	2013-06-28		Yes	None	Unrelated	No
16	Vomiting (Category:Gastrointestinal)	1	2013-	2013-	No	None	Unrelated	No

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16	Fatigue (Category:Constitutional Symptoms)	1	07-24 2013-07-24	07-24 2013-07-24	No	Treatment given	Probably related	No
16	Dyspnea (shortness of breath) (Category:Pulmonary/Upper Respiratory)	3	07-29 2013-07-29	07-29 2013-07-29	No	Treatment given	Probably related	No
16	Muscle weakness-Extremity-lower (Category:Musculoskeletal/Soft Tissue)	1	07-31 2013-07-31	07-31 2013-07-31	No	Treatment given	Probably related	No
16	Fatigue (Category:Constitutional Symptoms)	3	07-30 2013-07-30	07-31 2013-07-31	No	Treatment given	Probably related	No
16	Dyspnea (shortness of breath) (Category:Pulmonary/Upper Respiratory)	2	07-27 2013-07-27	07-31 2013-07-31	No	Treatment given	Probably related	No
16	Hemoglobin (Category:Blood/Bone Marrow)	4	07-31 2013-07-31	07-31 2013-07-31	No	Treatment given	Probably related	No
16	Fatigue (Category:Constitutional Symptoms)	4	07-31 2013-07-31	07-31 2013-07-31	No	Treatment given	Probably related	No
16	Pain-Abdomen (Category:Pain)	3	07-31 2013-07-31		Yes	Subject withdrawn from study	Unrelated	No
16	Diarrhea (Category:Gastrointestinal)	1	06-25 2013-06-25	06-25 2013-06-25	No	None	Unrelated	No
16	ALT, SGPT (Category:Metabolic/Laboratory)	1	06-28 2013-06-28	07-17 2013-07-17	No	None	Probably related	No
16	Alkaline phosphatase (Category:Metabolic/Laboratory)	2	06-10 2013-06-10		Yes	None	Probably related	No
16	Pain-Abdomen (Category:Pain)	1	07-08 2013-07-08	07-24 2013-07-24	No	Treatment given	Unrelated	No
16	Pain-Back (Category:Pain)	1	07-10 2013-07-10		Yes	None	Unrelated	No
16	Anorexia (Category:Gastrointestinal)	1	07-17 2013-07-17		Yes	None	Possibly related	No
16	Fatigue (Category:Constitutional Symptoms)	1	07-17 2013-07-17	07-24 2013-07-24	No	Treatment given	Probably related	No
16	Heartburn (Category:Gastrointestinal)	1	08-26 2013-08-26	08-28 2013-08-28	No	Treatment given	Unrelated	No
17	Pain-Abdomen (Category:Pain)	2	08-29 2013-08-29		Yes	Subject withdrawn from	Probably unrelated	No

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17	Vision-blurred vision (Category:Ocular/Visual)	1	2013-08-29		Yes	study Subject withdrawn from	Possibly related	No
17	Urinary frequency (Category:Renal/Genitourinary)	2	2013-08-29		Yes	study Subject withdrawn from	Unrelated	No
17	Infection-Urinary tract NOS (Category:Infection-Renal/Genitourinary)	2	2013-08-29		Yes	study Subject withdrawn from	Unrelated	No
17	Weight Loss (Category:Constitutional Symptoms)	1	2013-07		Yes	None	Unrelated	No
17	Pain-Abdomen (Category:Pain)	1	2013-08-15	2013-08-29	No	Treatment given	Unrelated	No
17	Pain-Abdomen (Category:Pain)	3	2013-08-29		Yes	Subject withdrawn from study	Unrelated	No
17	Nausea (Category:Gastrointestinal)	1	2013-07	2013-08-15	No	Treatment given	Possibly related	No
17	Vomiting (Category:Gastrointestinal)	1	2013-07	2013-08-15	No	Treatment given	Possibly related	No
17	Sweating (Category:Constitutional Symptoms)	1	2013-08-01		Yes	None	NA	No
17	Rash: hand-foot skin reaction (Category:Dermatology/Skin)	1	2013-07-22		Yes	None	Unrelated	No
17	Pain-Abdomen (Category:Pain)	1	2013-07	2013-08-15	No	Treatment given	Probably unrelated	No
17	Constipation (Category:Gastrointestinal)	2	2013-08-01		Yes	Treatment given	Unrelated	No
18	Vomiting (Category:Gastrointestinal)	1	2013-07-22	2013-07-22	No	None	Unrelated	No
18	Diarrhea (Category:Gastrointestinal)	1	2013-07-20	2013-07-20	No	None	Unrelated	No
18	Pain-Back (Category:Pain)	1	2013-08-10		Yes	None	Unrelated	No
18	Hair loss/alopecia (scalp or body)	1	2013-		Yes	None	Probably	No

Extract from Tables Listings and Graphs for HYPAPZ Study Final Analysis Report

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
18	(Category:Dermatology/Skin) Diarrhea (Category:Gastrointestinal)	1	08-13 2013-08-29	2013-10-24	No	Treatment given	related Possibly related	No
18	Vision-flashing lights/floaters (Category:Ocular/Visual)	1	2013-09-23		Yes	None	Unrelated	No
18	Taste alteration (dysgeusia) (Category:Gastrointestinal)	2	2013-08-01		No	None	Probably related	No
18	Weight Loss (Category:Constitutional Symptoms)	1	2013-07-01	2013-07-31	No	None	Unrelated	No
18	Pain-Head/headache (Category:Pain-Neurology)	1	2013-08-01		Yes	None	Unrelated	No
18	Hair loss/alopecia (scalp or body) (Category:Dermatology/Skin)	1	2013-08-29		Yes	None	Probably related	No
18	Rash: hand-foot skin reaction (Category:Dermatology/Skin)	1	2013-07	2014-02-03	No	None	Probably related	No
18	Pain-Abdomen (Category:Pain)	1	2013-10-24	2014-01-08	No	Treatment given	Possibly related	No
18	Diarrhea (Category:Gastrointestinal)	1	2014-01-01	2014-01-14	No	Treatment given	Possibly related	No
18	Pain-Joint (Category:Pain)	1	2013-12-27	2013-12-28	No	None	Unrelated	No
18	Fatigue (Category:Constitutional Symptoms)	1	2014-01-01		Yes	Subject withdrawn from study	Possibly related	No
18	Pain-Buttock (Category:Pain)	1	2014-01-15		Yes	None	Unrelated	No
18	Thyroid function, low (hypothyroidism) (Category:Endocrine)	1	2013-09-27		Yes	None	Definitely related	No
19	Supraventricular arrhythmia-Sinus bradycardia (Category:Cardiac Arrhythmia)	1	2013-07-16	2013-08-08	No	Dose reduced	Possibly related	No
19	Fatigue (Category:Constitutional Symptoms)	3	2013-08-01	2013-09-04	No	None	Unrelated	No
19	Mood alteration-Depression (Category:Neurology)	1	2013-08-01		Yes	None	Probably unrelated	No
19	Dizziness (Category:Neurology)	1	2013-08-01		Yes	Dose reduced	Possibly related	No

Extract from Tables Listings and Graphs for HYPАЗ Study Final Analysis Report

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
19	Nausea (Category:Gastrointestinal)	1	2013-08-01		Yes	Dose reduced	Possibly related	No
19	Mood Alteration-Agitation (Category:Neurology)	1	2013-07-16	2013-07-16	No	None	Unrelated	No
19	Pain-Head/headache (Category:Pain-Neurology)	1	2013-09-05		Yes	Treatment given	Possibly related	No
19	Hypopigmentation (Category:Dermatology/Skin)	1	2013-08		Yes	None	Possibly related	No
19	Fatigue (Category:Constitutional Symptoms)	2	2013-09-05		Yes	None	Unrelated	No
20	Fatigue (Category:Constitutional Symptoms)	1	2013-10-09		Yes	None	Probably related	No
20	Mucositis/stomatitis-Oral cavity (Category:Gastrointestinal)	1	2013-10	2013-10-09	No	None	Probably related	No
20	Pain-NOS (Category:Pain)	1	2013-09	2013-09-25	No	None	Unrelated	No
20	Vomiting (Category:Gastrointestinal)	1	2013-08-07	2013-08-07	No	None	Possibly related	No
20	Nausea (Category:Gastrointestinal)	1	2013-09-03	2013-09-04	No	Treatment given	Possibly related	No
20	Pain-Muscle (Category:Pain)	1	2013-08	2013-09-15	No	None	Unrelated	No
20	Rash-Acne-Acneiform (Category:Dermatology/Skin)	1	2013-10-01		Yes	Treatment given	Probably related	No
20	Pain-Joint (Category:Pain)	1	2013-10-25		Yes	Treatment given	Unrelated	No
20	Pain-Back (Category:Pain)	2	2013-11-15	2013-11-16	No	Treatment given	Unrelated	No
20	Pain-Back (Category:Pain)	1	2013-11-16	2013-12-18	No	Treatment given	Unrelated	No
22	Fatigue (Category:Constitutional Symptoms)	1	2013-10-30		Yes	None	Probably related	No
22	Supraventricular arrhythmia-Sinus bradycardia (Category:Cardiac Arrhythmia)	2	2013-11-13	2013-11-20	No	Dose reduced	Possibly related	No
22	Thyroid function, low (hypothyroidism) (Category:Endocrine)	1	2013-11-13	2013-11-27	No	None	Probably related	No

Extract from Tables Listings and Graphs for HYPАЗ Study Final Analysis Report

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
22	Pain-Abdomen (Category:Pain)	1	2013-11-18		Yes	Treatment given	Probably unrelated	No
22	Cough (Category:Pulmonary/Upper Respiratory)	1	2013-11-01		Yes	None	Probably unrelated	No
22	Taste alteration (dysgeusia) (Category:Gastrointestinal)	1	2013-11-01		Yes	None	Possibly related	No
22	Anorexia (Category:Gastrointestinal)	1	2013-11-02		Yes	None	Possibly related	No
22	Nausea (Category:Gastrointestinal)	1	2013-11-22		Yes	None	Probably unrelated	No
22	Constipation (Category:Gastrointestinal)	1	2013-11-20	2013-11-27	No	Treatment given	Probably unrelated	No
23	Thrombosis/thrombus/embolism (Category:Vascular)	4	2013-12-30		Yes	Treatment given	Possibly related	Yes
23	Mucositis/stomatitis (Category:Gastrointestinal)	2	2013-11-17		Yes	Treatment given	Definitely related	No
23	Vomiting (Category:Gastrointestinal)	2	2013-11-17		Yes	Treatment given	Definitely related	No
23	Fatigue (Category:Constitutional Symptoms)	1	2013-11-15		Yes	None	Probably related	No
23	Nausea (Category:Gastrointestinal)	2	2013-11-20		Yes	Treatment given	Definitely related	No
23	Pain-Muscle (Category:Pain)	1	2013-10-21		Yes	None	Unrelated	No
23	Fever (Category:Constitutional Symptoms)	1	2013-10		Yes	None	Unrelated	No
23	Pain-Vagina (Category:Pain)	2	2013-10-30		Yes	None	Unrelated	No
23	Pain-Urethra (Category:Pain)	2	2013-10-13		Yes	Treatment given	Unrelated	No
23	Anorexia (Category:Gastrointestinal)	1	2013-12-01		Yes	None	Possibly related	No
23	Constipation (Category:Gastrointestinal)	1	2013-12-15		Yes	None	Unrelated	No
23	Vaginal discharge (non-infectious) (Category:Sexual/Reproductive Function)	1	2013-11-10		Yes	None	Unrelated	No

Extract from Tables Listings and Graphs for HYPАЗ Study Final Analysis Report

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
23	Dyspnea (shortness of breath) (Category:Pulmonary/Upper Respiratory)	3	2013-12-30	2014-01-29	No	Treatment given	Possibly related	Yes
24	Dizziness (Category:Neurology)	1	2013-12-04	2014-01-24	No	None	Probably unrelated	No
24	Voice changes/dysarthria (Category:Pulmonary/Upper Respiratory)	1	2013-12-04		Yes	None	Probably related	No
24	Hypertension (Category:Cardiac General)	1	2013-11-20		Yes	Treatment given	Definitely related	No
24	Pain-Joint (Category:Pain)	2	2013-11-29	2013-12-13	No	None	Unrelated	No
24	Fatigue (Category:Constitutional Symptoms)	1	2013-12-23		Yes	None	Probably related	No
24	Weight Loss (Category:Constitutional Symptoms)	1	2013-11		Yes	Treatment given	Probably related	No
24	AST, SGOT (Category:Metabolic/Laboratory)	1	2013-12-27	2014-01-24	No	None	Definitely related	No
24	Pain-Chest/thorax NOS (Category:Pain)	1	2013-11-15	2013-11-29	No	None	Unrelated	No
24	Pain-Back, Extremity-limb, Joint (Category:Pain)	2	2013-11-20	2013-12-13	No	None	Possibly related	No
24	Diarrhea (Category:Gastrointestinal)	1	2014-01-10	2014-01-11	No	Treatment given	Possibly related	No
24	Diarrhea (Category:Gastrointestinal)	1	2014-02-06	2014-02-06	No	Treatment given	Possibly related	No
24	Nausea (Category:Gastrointestinal)	1	2014-01-09	2014-01-11	No	None	Possibly related	No
24	Vomiting (Category:Gastrointestinal)	1	2014-01-09	2014-01-09	No	None	Possibly related	No
24	Joint function (Category:Musculoskeletal/Soft Tissue)	2	2013-11-29	2013-12-13	No	None	Unrelated	No
25	Infection with normal ANC (Category:Infection-General)	2	2013-11-29	2013-12-06	No	Treatment given	Unrelated	No
25	Diarrhea (Category:Gastrointestinal)	2	2013-11-25	2013-11-26	No	None	Unrelated	No
25	Pain-Joint (Category:Pain)	2	2013-12-01	2013-12-18	No	Treatment given	Unrelated	No

Extract from Tables Listings and Graphs for HYPАЗ Study Final Analysis Report

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
25	Nausea (Category:Gastrointestinal)	1	2013-12-23		Yes	None	Possibly related	No
25	Mucositis/stomatitis (Category:Gastrointestinal)	1	2013-12-20	2014-03-19	No	None	Probably related	No
25	Taste alteration (dysgeusia) (Category:Gastrointestinal)	1	2013-12-20		Yes	None	Probably related	No
25	Hypertension (Category:Cardiac General)	2	2013-12-18		Yes	Treatment given	Definitely related	No
25	Hypothyroidism (Category:Endocrine)	1	2013-12-30		Yes	None	Probably related	No
25	Pain-Joint (Category:Pain)	1	2013-12-18	2014-06-04	No	None	Unrelated	No
25	Hypopigmentation (Category:Dermatology/Skin)	1	2014-04-09		Yes	None	Unrelated	No
25	Hemorrhoids (Category:Gastrointestinal)	1			Yes	NA	Unrelated	No
25	Vomiting (Category:Gastrointestinal)	2	2013-11-25	2013-11-26	No	None	Unrelated	No
26	Diarrhea (Category:Gastrointestinal)	2	2014-01-17	2014-01-18	No	Treatment given	Possibly related	No
26	Nausea (Category:Gastrointestinal)	1	2014-01-14	2014-01-18	No	Treatment given	Possibly related	No
26	Anorexia (Category:Gastrointestinal)	2	2014-01-14		Yes	None	Probably related	No
26	Taste alteration (dysgeusia) (Category:Gastrointestinal)	1	2014-01-13		Yes	None	Probably related	No
26	Diarrhea (Category:Gastrointestinal)	3	2014-01-30	2014-02-01	No	Treatment given	Possibly related	No
26	Nausea (Category:Gastrointestinal)	2	2014-01-30	2014-02-01	No	Treatment given	Possibly related	No
26	Heartburn (Category:Gastrointestinal)	1	2014-01-08		Yes	Treatment given	Probably related	No
26	Fatigue (Category:Constitutional Symptoms)	1	2014-02-19	2014-07-03	No	None	Possibly related	No
26	Nausea (Category:Gastrointestinal)	1	2014-02-01		Yes	Treatment given	Possibly related	No
26	Diarrhea (Category:Gastrointestinal)	3	2014-	2014-	No	Treatment given	Probably	No

Extract from Tables Listings and Graphs for HYPAPZ Study Final Analysis Report

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
26	Vomiting (Category:Gastrointestinal)	1	03-26 2014-03-26	03-28 2014-03-28	No	Treatment given	related Probably related	No
26	Diarrhea (Category:Gastrointestinal)	1	2014-03-29		Yes	Treatment given	Probably related	No
26	Nausea (Category:Gastrointestinal)	NA	2014-03-29		Yes	Treatment given	Probably related	No
26	Mucositis/stomatitis (Category:Gastrointestinal)	1	2014-01-20		Yes	Treatment given	Probably related	No
26	Diarrhea (Category:Gastrointestinal)	1	2014-02-02	2014-03-25	No	Treatment given	Probably related	No
26	Rash: hand-foot skin reaction (Category:Dermatology/Skin)	1	2014-01-27	2014-04-04	No	None	Probably related	No
26	Infection-Urinary tract NOS (Category:Infection-Renal/Genitourinary)	1	2014-02-05	2014-03-18	No	Treatment given	Probably unrelated	No
26	Hypopigmentation (Category:Dermatology/Skin)	1	2014-03-01		Yes	None	Probably related	No
26	Pain-Muscle (Category:Pain)	1	2014-02-27		No	None	Probably unrelated	No
26	Infection-Upper airway NOS (Category:Infection-Pulmonary/Upper Respiratory)	1	2014-03-12	2014-03-19	No	None	Possibly related	No
26	Allergic reaction/hypersensitivity (Category:Allergy/Immunology)	1	2014-01-27		Yes	None	Possibly related	No
26	Mucositis/stomatitis-Oral cavity (Category:Gastrointestinal)	1	2014-05-28		Yes	None	Probably related	No
26	Hemorrhage, GU-Bladder (Category:Hemorrhage/Bleeding)	1	2014-06-20		Yes	None	Unrelated	No
26	Pain-Abdomen (Category:Pain)	1	2014-06-20		Yes	None	Unrelated	No
26	Obstruction GU-Ureter (Category:Renal/Genitourinary)	3	2014-06-20		Yes	None	Unrelated	No
26	Dry skin (Category:Dermatology/Skin)	1			Yes	None	Possibly related	No
26	Fatigue (Category:Constitutional Symptoms)	2	2014-07		Yes	None	Probably related	No
26	Taste alteration (dysgeusia) (Category:Gastrointestinal)	1	2014-		Yes	None	Probably	No

Extract from Tables Listings and Graphs for HYPaz Study Final Analysis Report

Person Id	Description	NCI CTCAE Grade	Start Date	Stop Date	Ongoing?	Action Taken	Related to study drug?	Serious?
28	Diarrhea (Category:Gastrointestinal)	1	2014-07-07		Yes	Treatment given	related	No
28	Hypopigmentation (Category:Dermatology/Skin)	1	2014-07-30		Yes	None	Probably related	No
28	Pain-Abdomen (Category:Pain)	3	2014-08-26	2014-08-29	No	Subject withdrawn from study	Probably unrelated	No
30	Fatigue (Category:Constitutional Symptoms)	3	2014-06-20		Yes	Subject withdrawn from study	Possibly related	No
30	Anorexia (Category:Gastrointestinal)	3	2014-07-02		Yes	Subject withdrawn from study	Possibly related	No
30	Nausea (Category:Gastrointestinal)	1	2014-07-02		Yes	Subject withdrawn from study	Possibly related	No
30	Vomiting (Category:Gastrointestinal)	1	2014-07-02		Yes	Subject withdrawn from study	Possibly related	No
30	Hemorrhage, GU-Bladder (Category:Hemorrhage/Bleeding)	3	2014-07-07	2014-07-12	No	Subject withdrawn from study	Probably unrelated	Yes
30	Bilirubin/Hyperbilirubinemia (Category:Metabolic/Laboratory)	3	2014-07-11		Yes	Subject withdrawn from study	Probably unrelated	Yes
30	Potassium, serum-low (hypokalemia (Category:Metabolic/Laboratory)	1	2014-07-19	2014-07-30	No	Treatment given	Unrelated	No
31	Nausea (Category:Gastrointestinal)	2	2014-07-11		Yes	None	Unrelated	No

Extract from Tables Listings and Graphs for HYPАЗ Study Final Analysis Report

Title: Adverse Events by Grade, Relatedness, Seriousness

Number: 5.1.2

Population: Safety (N=27)

AE Category	Overall	Grade 1	Grade 2	Grade 3	Grade 4	Related	Unrelated	Serious
Gastrointestinal	26/26 (100%)	25/26 (96.2%)	13/26 (50%)	5/26 (19.2%)	0/26 (0%)	23/26 (88.5%)	17/26 (65.4%)	1/26 (3.8%)
Pain	22/26 (84.6%)	18/26 (69.2%)	11/26 (42.3%)	5/26 (19.2%)	0/26 (0%)	4/26 (15.4%)	21/26 (80.8%)	1/26 (3.8%)
Constitutional Symptoms	21/26 (80.8%)	16/26 (61.5%)	6/26 (23.1%)	5/26 (19.2%)	1/26 (3.8%)	14/26 (53.8%)	10/26 (38.5%)	0/26 (0%)
Dermatology/Skin	13/26 (50%)	13/26 (50%)	1/26 (3.8%)	0/26 (0%)	0/26 (0%)	10/26 (38.5%)	3/26 (11.5%)	0/26 (0%)
Pulmonary/Upper Respiratory	12/26 (46.2%)	6/26 (23.1%)	2/26 (7.7%)	4/26 (15.4%)	0/26 (0%)	8/26 (30.8%)	5/26 (19.2%)	3/26 (11.5%)
Infection	10/26 (38.5%)	4/26 (15.4%)	4/26 (15.4%)	1/26 (3.8%)	1/26 (3.8%)	1/26 (3.8%)	9/26 (34.6%)	2/26 (7.7%)
Metabolic/Laboratory	6/26 (23.1%)	5/26 (19.2%)	1/26 (3.8%)	3/26 (11.5%)	1/26 (3.8%)	3/26 (11.5%)	3/26 (11.5%)	2/26 (7.7%)
Renal/Genitourinary	6/26 (23.1%)	3/26 (11.5%)	3/26 (11.5%)	2/26 (7.7%)	0/26 (0%)	0/26 (0%)	6/26 (23.1%)	1/26 (3.8%)
Cardiac General	5/26 (19.2%)	2/26 (7.7%)	3/26 (11.5%)	0/26 (0%)	0/26 (0%)	4/26 (15.4%)	1/26 (3.8%)	0/26 (0%)
Neurology	5/26 (19.2%)	4/26 (15.4%)	1/26 (3.8%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	5/26 (19.2%)	0/26 (0%)
Blood/Bone Marrow	4/26 (15.4%)	1/26 (3.8%)	1/26 (3.8%)	3/26 (11.5%)	1/26 (3.8%)	2/26 (7.7%)	2/26 (7.7%)	0/26 (0%)
Allergy/Immunology	3/26 (11.5%)	3/26 (11.5%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	1/26 (3.8%)	0/26 (0%)
Ocular/Visual	3/26 (11.5%)	3/26 (11.5%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	2/26 (7.7%)	0/26 (0%)
Cardiac Arrhythmia	3/26 (11.5%)	2/26 (7.7%)	1/26 (3.8%)	0/26 (0%)	0/26 (0%)	2/26 (7.7%)	1/26 (3.8%)	0/26 (0%)
Hemorrhage/Bleeding	3/26 (11.5%)	2/26 (7.7%)	0/26 (0%)	1/26 (3.8%)	0/26 (0%)	1/26 (3.8%)	2/26 (7.7%)	1/26 (3.8%)
Endocrine	3/26 (11.5%)	3/26 (11.5%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	3/26 (11.5%)	0/26 (0%)	0/26 (0%)
Sexual/Reproductive Function	2/26 (7.7%)	2/26 (7.7%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	1/26 (3.8%)	0/26 (0%)
Musculoskeletal/Soft Tissue	2/26 (7.7%)	1/26 (3.8%)	1/26 (3.8%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	1/26 (3.8%)	0/26 (0%)
Auditory/Ear	1/26 (3.8%)	1/26 (3.8%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	0/26 (0%)
Hepatobiliary/Pancreas	1/26 (3.8%)	0/26 (0%)	1/26 (3.8%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	0/26 (0%)
Vascular	1/26 (3.8%)	0/26 (0%)	0/26 (0%)	0/26 (0%)	1/26 (3.8%)	1/26 (3.8%)	0/26 (0%)	1/26 (3.8%)