



## Clinical trial results:

### Safety and Efficacy of BI 695500 in patients with moderately to severely active rheumatoid arthritis: an open-label extension trial

#### Summary

EudraCT number	2013-002622-23
Trial protocol	NL PT BG BE DE HU ES GR
Global end of trial date	08 November 2016

#### Results information

Result version number	v1 (current)
This version publication date	12 November 2017
First version publication date	12 November 2017

#### Trial information

##### Trial identification

Sponsor protocol code	1301.4
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01955733
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 8002430127, <a href="mailto:clintrriage.rdg@boehringer-ingelheim.com">clintrriage.rdg@boehringer-ingelheim.com</a>
Scientific contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 8002430127, <a href="mailto:clintrriage.rdg@boehringer-ingelheim.com">clintrriage.rdg@boehringer-ingelheim.com</a>

Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

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**Results analysis stage**

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Analysis stage	Final
Date of interim/final analysis	13 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 August 2015
Global end of trial reached?	Yes
Global end of trial date	08 November 2016
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

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Main objective of the trial:

Primary objective: To evaluate the long-term safety of BI 695500 in adult patients with moderate to severe active Rheumatoid Arthritis [RA] who have successfully completed treatment in Trial 1301.1. Secondary objective: To assess the long-term efficacy of BI 695500 in patients with moderately to severely active RA. These analyses will be displayed by the groups the patients were randomized in Trial 1301.1 as well as overall.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given. Close monitoring of all subjects was adhered to throughout the trial conduct. Rescue medication was allowed for all patients as required.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Bulgaria: 2
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Chile: 1
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Greece: 1
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Mexico: 9
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Poland: 9
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	United States: 63
Worldwide total number of subjects	97
EEA total number of subjects	23

Notes:

<b>Subjects enrolled per age group</b>	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	75
From 65 to 84 years	22
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

97 subjects were screened for eligibility to participate in this extension trial. 91 subjects met all inclusion and exclusion criteria and were assigned to receive treatment.

### Pre-assignment

Screening details:

All subjects were screened for eligibility to participate in the trial. Subjects attended specialist sites which would then ensure that they [the subjects] met all strictly implemented inclusion/exclusion criteria. Subjects were not to be randomised to trial treatment if any one of the specific entry criteria were violated.

### Period 1

Period 1 title	Period 1
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	BI 695500

Arm description:

The subjects were administered BI 695500, concentrate for solution for infusion, 10 mg/mL by Intravenous Infusion [IV]. Two 1000 mg infusions were separated by 2 weeks. Each patient was treated with BI 695500 on Days 1 and 15, with a possible further two infusions at Weeks 24 and 26 for eligible responders.

Arm type	Experimental
Investigational medicinal product name	BI 695500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The subjects were administered BI 695500, concentrate for solution for infusion, 10 mg/mL by IV infusion. Two 1000 mg infusions were separated by 2 weeks. Each patient was treated with BI 695500 on Days 1 and 15, with a possible further two infusions at Weeks 24 and 26 for eligible responders.

<b>Arm title</b>	Rituxan from 1301.1
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Arm description:

The Rituxan from 1301.1 [ClinicalTrials.gov identifier: NCT01682512] recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

Arm type	Experimental
Investigational medicinal product name	Rituxan from 1301.1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The Rituxan from 1301.1 [ClinicalTrials.gov identifier: NCT01682512] recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

<b>Arm title</b>	MabThera from 1301.1
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**Arm description:**

The MabThera from 1301.1 recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

Arm type	Experimental
Investigational medicinal product name	MabThera from 1301.1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intravenous use

**Dosage and administration details:**

The MabThera from 1301.1 recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

<b>Number of subjects in period 1</b>	BI 695500	Rituxan from 1301.1	MabThera from 1301.1
Started	33	29	29
Completed	32	29	29
Not completed	1	0	0
Lost to follow-up	1	-	-

**Period 2**

Period 2 title	Period 2
Is this the baseline period?	Yes <sup>[1]</sup>
Allocation method	Not applicable
Blinding used	Not blinded

**Arms**

Are arms mutually exclusive?	Yes
<b>Arm title</b>	BI 695500

**Arm description:**

The subjects were administered BI 695500, concentrate for solution for infusion, 10 mg/mL by Intravenous Infusion [IV]. Two 1000 mg infusions were separated by 2 weeks. Each patient was treated with BI 695500 on Days 1 and 15, with a possible further two infusions at Weeks 24 and 26 for eligible responders.

Arm type	Experimental
Investigational medicinal product name	BI 695500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

The subjects were administered BI 695500, concentrate for solution for infusion, 10 mg/mL by IV infusion. Two 1000 mg infusions were separated by 2 weeks. Each patient was treated with BI 695500 on Days 1 and 15, with a possible further two infusions at Weeks 24 and 26 for eligible responders.

<b>Arm title</b>	Rituxan from 1301.1
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**Arm description:**

The Rituxan from 1301.1 [ClinicalTrials.gov identifier: NCT01682512] recommended dose for use in

patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

Arm type	Experimental
Investigational medicinal product name	Rituxan from 1301.1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The Rituxan from 1301.1 [ClinicalTrials.gov identifier: NCT01682512] recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

<b>Arm title</b>	MabThera from 1301.1
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Arm description:

The MabThera from 1301.1 recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

Arm type	Experimental
Investigational medicinal product name	MabThera from 1301.1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The MabThera from 1301.1 recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: The results presented in the outcome measures are based on period 2. Thus, period 2 is selected as the baseline period.

<b>Number of subjects in period 2<sup>[2]</sup>[3]</b>	BI 695500	Rituxan from 1301.1	MabThera from 1301.1
Started	30	29	29
Completed	18	10	8
Not completed	12	19	21
Consent withdrawn by subject	1	3	2
Other not defined above	-	2	2
Physician decision	-	-	1
Adverse event, non-fatal	1	-	-
Study terminated by sponsor	8	14	15
Lost to follow-up	2	-	1

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Baseline characteristics are based on patients who were randomised after successfully completing the screening period and received at least one of the trial medications.

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: 2 subjects from 1301.1 safety run-in who also received treatment in 1301.4. Thus, the number of subjects in period 2 is 88.

## Baseline characteristics

### Reporting groups

Reporting group title	Period 2
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Reporting group description: -

Reporting group values	Period 2	Total	
Number of subjects	88	88	
Age categorical			
Units: Subjects			

Age Continuous			
Safety Randomized Analysis Set [SAFRD]: All subjects randomized in 1301.1 [excluding open-label safety run-in subjects of trial 1301.1] who receive at least one dose of trial medication and subjects will be classified according to treatment received in trial 1301.1. 2 subjects from 1301.1 safety run-in also received treatment in 1301.4, thus 88.			
Units: years			
arithmetic mean	55.9		
standard deviation	± 10.38	-	
Gender, Male/Female			
Units: Subjects			
Female	67	67	
Male	21	21	

## End points

### End points reporting groups

Reporting group title	BI 695500
Reporting group description: The subjects were administered BI 695500, concentrate for solution for infusion, 10 mg/mL by Intravenous Infusion [IV]. Two 1000 mg infusions were separated by 2 weeks. Each patient was treated with BI 695500 on Days 1 and 15, with a possible further two infusions at Weeks 24 and 26 for eligible responders.	
Reporting group title	Rituxan from 1301.1
Reporting group description: The Rituxan from 1301.1 [ClinicalTrials.gov identifier: NCT01682512] recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.	
Reporting group title	MabThera from 1301.1
Reporting group description: The MabThera from 1301.1 recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.	
Reporting group title	BI 695500
Reporting group description: The subjects were administered BI 695500, concentrate for solution for infusion, 10 mg/mL by Intravenous Infusion [IV]. Two 1000 mg infusions were separated by 2 weeks. Each patient was treated with BI 695500 on Days 1 and 15, with a possible further two infusions at Weeks 24 and 26 for eligible responders.	
Reporting group title	Rituxan from 1301.1
Reporting group description: The Rituxan from 1301.1 [ClinicalTrials.gov identifier: NCT01682512] recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.	
Reporting group title	MabThera from 1301.1
Reporting group description: The MabThera from 1301.1 recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.	

### Primary: The percentage of patients with drug related adverse events during the treatment phase

End point title	The percentage of patients with drug related adverse events during the treatment phase <sup>[1]</sup>
End point description: This outcome measure presents percentage of patients with drug related adverse events during the treatment phase. Treatment Emergent Adverse Events [TEAEs] were defined as AEs that started or worsened in severity on or after the first dose of trial medication in this extension study [1301.4] and prior to the last date of trial medication + 180 days [inclusive]. Drug-related events were those considered by the investigator to have a causal relationship to trial medication.	
End point type	Primary
End point timeframe: Week 48	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Statistical analysis evaluating this endpoint was purely for exploratory purposes.	



End point values	BI 695500	Rituxan from 1301.1	MabThera from 1301.1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30 <sup>[2]</sup>	29 <sup>[3]</sup>	29 <sup>[4]</sup>	
Units: Percentage of patients				
number (not applicable)	16.7	6.9	3.4	

Notes:

[2] - SAFRD.

[3] - SAFRD.

[4] - SAFRD.

## Statistical analyses

No statistical analyses for this end point

### Secondary: The change from baseline in trial 1301.1 in DAS28 [Disease Activity Score 28][Erythrocyte Sedimentation Rate [ESR] at Week 48 of Trial 1301.4

End point title	The change from baseline in trial 1301.1 in DAS28 [Disease Activity Score 28][Erythrocyte Sedimentation Rate [ESR] at Week 48 of Trial 1301.4
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End point description:

This outcome measure presents the change from baseline in trial 1301.1 in DAS28 ESR at Week 48 of Trial 1301.4. Assigned Set [ASD]: All subjects in the Enrolled Set [ENR set][All subjects who provide informed consent for this trial] who were assigned to trial medication in 1301.4 and who were randomized to trial medication in 1301.1 [initial randomization at Day 1] or entered in open-label safety run-in. Abbreviation used: CRP: C-Reactive Protein. ACR20: American College of Rheumatology 20% response criteria.

Full Analysis Set

[FAS]: Subjects from the ASD by excluding subjects from the open-label safety run-in in trial 1301.1, who received at least one dose of trial medication, and had data recorded for at least one DAS28 [ESR or CRP] or ACR20 during the trial.

End point type	Secondary
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End point timeframe:

Baseline and Week 48

End point values	BI 695500	Rituxan from 1301.1	MabThera from 1301.1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19 <sup>[5]</sup>	19 <sup>[6]</sup>	17 <sup>[7]</sup>	
Units: mm/h				
number (not applicable)	-2.0	-2.0	-1.6	

Notes:

[5] - FAS.

[6] - FAS.

[7] - FAS.

## Statistical analyses

No statistical analyses for this end point

### Secondary: The percentage of patients meeting the ACR20 [based on improvement since baseline in trial 1301.1] at Week 48 of trial 1301.4

End point title	The percentage of patients meeting the ACR20 [based on improvement since baseline in trial 1301.1] at Week 48 of trial 1301.4
End point description: This outcome measure presents the percentage of patients meeting the 20% ACR20 response criteria [based on improvement since baseline in trial 1301.1] at Week 48 of Trial 1301.4.	
End point type	Secondary
End point timeframe: Week 48	

End point values	BI 695500	Rituxan from 1301.1	MabThera from 1301.1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30 <sup>[8]</sup>	26 <sup>[9]</sup>	28 <sup>[10]</sup>	
Units: Percentage of patients				
number (not applicable)	10.0	7.7	7.1	

Notes:

[8] - FAS.

[9] - FAS.

[10] - FAS.

### Statistical analyses

No statistical analyses for this end point

### Secondary: The percentage of patients who meet the ACR/European League Against Rheumatism [EULAR] definition of remission [based on improvement since baseline in trial 1301.1] at Week 48 of trial 1301.4

End point title	The percentage of patients who meet the ACR/European League Against Rheumatism [EULAR] definition of remission [based on improvement since baseline in trial 1301.1] at Week 48 of trial 1301.4
End point description: This outcome measure presents the percentage of patients who meet the ACR/EULAR definition of remission [based on improvement since Baseline in Trial 1301.1] at Week 48 of Trial 1301.4.	
End point type	Secondary
End point timeframe: Week 48	

End point values	BI 695500	Rituxan from 1301.1	MabThera from 1301.1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30 <sup>[11]</sup>	26 <sup>[12]</sup>	28 <sup>[13]</sup>	
Units: Percentage of patients				
number (not applicable)	0.0	0.0	0.0	

Notes:

[11] - FAS.

[12] - FAS.

## Statistical analyses

No statistical analyses for this end point

### Secondary: The percentage of patients who meet the EULAR response [good response, moderate response, or no response] [based on DAS28 improvement since baseline in trial 1301.1] at Week 48 of trial 1301.4

End point title	The percentage of patients who meet the EULAR response [good response, moderate response, or no response] [based on DAS28 improvement since baseline in trial 1301.1] at Week 48 of trial 1301.4
End point description:	This outcome measure presents percentage of patients who meet the EULAR response [good response, moderate response, or no response] [based on DAS28 improvement since baseline in trial 1301.1] at Week 48 of trial 1301.4.
End point type	Secondary
End point timeframe:	Week 48

End point values	BI 695500	Rituxan from 1301.1	MabThera from 1301.1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30 <sup>[14]</sup>	26 <sup>[15]</sup>	28 <sup>[16]</sup>	
Units: Percentage of patients				
number (not applicable)				
Good response	0.0	0.0	0.0	
Moderate response	3.3	7.7	0.0	
No response	13.3	15.4	14.3	
Missing	43.3	15.4	14.3	

Notes:

[14] - FAS.

[15] - FAS.

[16] - FAS.

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Enter time frame here

Adverse event reporting additional description:

AEs are presented for the Safety Randomised Analysis Set [SAF] which consisted of all randomised subjects who received at least one dose of trial medication in this extension study [1301.4].

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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### Reporting groups

Reporting group title	BI 695500
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Reporting group description:

The subjects were administered BI 695500, concentrate for solution for infusion, 10 mg/mL by Intravenous Infusion [IV]. Two 1000 mg infusions were separated by 2 weeks. Each patient was treated with BI 695500 on Days 1 and 15, with a possible further two infusions at Weeks 24 and 26 for eligible responders.

Reporting group title	Rituxan from 1301.1
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Reporting group description:

The Rituxan from 1301.1 [ClinicalTrials.gov identifier: NCT01682512] recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

Reporting group title	MabThera from 1301.1
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Reporting group description:

The MabThera from 1301.1 recommended dose for use in patients with Rheumatoid Arthritis is 1000 mg by IV infusion followed by a second 1000 mg IV infusion 2 weeks later.

Serious adverse events	BI 695500	Rituxan from 1301.1	MabThera from 1301.1
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	2 / 29 (6.90%)	2 / 29 (6.90%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 30 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 30 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nervous system disorders</b>			
Cerebral microangiopathy			
subjects affected / exposed	0 / 30 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 29 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory, thoracic and mediastinal disorders</b>			
Pulmonary embolism			
subjects affected / exposed	0 / 30 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Cellulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 29 (0.00%)	2 / 29 (6.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metabolism and nutrition disorders</b>			
Hypoglycaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 29 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 29 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

<b>Non-serious adverse events</b>	BI 695500	Rituxan from 1301.1	MabThera from 1301.1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 30 (23.33%)	8 / 29 (27.59%)	9 / 29 (31.03%)
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 30 (6.67%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 29 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 29 (3.45%)	2 / 29 (6.90%)
occurrences (all)	1	1	2
Urinary tract infection			
subjects affected / exposed	3 / 30 (10.00%)	2 / 29 (6.90%)	4 / 29 (13.79%)
occurrences (all)	3	2	5
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 30 (10.00%)	2 / 29 (6.90%)	2 / 29 (6.90%)
occurrences (all)	3	2	2
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 29 (6.90%)	1 / 29 (3.45%)
occurrences (all)	1	2	1
Insomnia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Further development of BI 695500 has been stopped and the program was therefore prematurely discontinued on 3SEP2015. The decision was made by the Sponsor based on a strategic review of company's product portfolio and not due to any safety concern.
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Notes: