Roche	**SIX-MONTHLY SUSAR REPORT** **No. 1059272**
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Medicinal Product	MabThera®/ Rituximab/ RO0452294
Report Data	Blinded
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SSR approved by: See electronic signature manifestation below.

Name	**Reason for Signing**	**Date and Time** (UTC)
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During the current review period, 26 November 2013 to 25 May 2014 (inclusive), the Sponsor identified 55[1] potential Suspected Unexpected Serious Adverse Reactions (SUSARs) for rituximab and blinded rituximab. In addition, there were 37 non–company Investigational Medicinal Product (IMP) SUSARs and no potential non–company IMP blinded SUSARs in trials where rituximab is the primary IMP.

The reported SUSARs did not necessitate changes to rituximab study documentation during the current reporting interval.

After review of the clinical details of the reported SUSARs, the Sponsor concludes that no changes to the conduct of the ongoing clinical trials with rituximab are warranted. Based on the information presented in this report, the benefit-risk assessment of the use of rituximab in the indications under investigation remains favorable.

[1] In the appended line listing, AER No. 1332405 (PT: Productive cough) appears under two different indications namely, graft versus host disease and scleroderma. The correct indication for this case is cutaneous sclerosis. A non-significant data correction will be performed in the safety database to remove the "graft versus host disease" as an indication. Therefore, the event of productive cough has been counted only once as a SUSAR.

1. INTRODUCTION

This is a Six-Monthly Suspected Unexpected Serious Adverse Reaction (SUSAR) Report (SSR 1059272) prepared for rituximab in accordance with the European Union (EU) Clinical Trials Directive [1] and 'CT-3' guidance [2]. This SSR covers the reporting interval from 26 November 2013 to 25 May 2014, inclusive.

Methodology used to prepare this report is described in Section 4.

2. ACTIONS TAKEN IN THE REPORTING INTERVAL RELATED TO REPORTED SUSARS

2.1 CHANGES TO REFERENCE SAFETY INFORMATION

The reference safety information (RSI) in effect at the start of the reporting interval is the Investigator's Brochure (IB) version 12.0 dated May 2013 for autoimmune disease which incorporates the Developmental Core Safety Information (DCSI) version 3.0 dated February 2013.

In July 2013, an addendum no. 1 and in September 2013 addendum no. 2 were added to the IB version 12.0 for autoimmune disease.

For oncology indications, IB version 18.0 dated July 2013 containing DCSI version 6.0 dated July 2013 was used as the safety reference document.

The IB for rituximab subcutaneous formulation version 4.0 dated February 2013 which incorporates DCSI version 5.0 dated February 2013 was used as the safety reference document till February 2014. In February 2014, IB version 5.0 containing DCSI version 7.0 became available and was used as the safety reference document for the remaining review period.

The reported SUSARs did not necessitate changes to the rituximab IB and DCSI during the current reporting interval.

Prior to 1 April 2014, the Sponsor used the rituximab Core Data Sheet dated November 2013 as the RSI in trials where the Investigators use local label as the safety reference document. From 1 April 2014, the company uses rituximab EU Summary of Product Characteristics (SPC) to assess event listedness in such trials.

The following documents were used as the RSI for non-company Investigational Medicinal Product (IMP) SUSARs during the review interval:

- Cladribine, cyclophosphamide, chlorambucil, doxorubicin, prednisolone, vincristine EU SPCs were used to determine SUSARs to cladribine, cyclophosphamide, chlorambucil, doxorubicin, prednisolone, vincristine respectively

- Bendamustine IB was used to determine SUSARs to bendamustine.

2.2 CHANGES TO OTHER STUDY DOCUMENTATION

The reported SUSARs did not necessitate changes to other study documentation for rituximab during the current reporting period.

3. CONCLUSION

After review of the clinical details of the reported SUSARs, the Sponsor concludes that no changes to the conduct of the ongoing clinical trials with rituximab are warranted. Based on the information presented in this report, the benefit-risk assessment of the use of rituximab in the indications under investigation remains favorable.

4. METHODOLOGY

4.1 CASE INCLUSION

This report includes a line listing of all SUSAR cases submitted to the Investigators in the six-monthly reporting period outlined in Section 1, for a given Roche IMP (hereinafter referred to as the SSR drug), and/or any non-Roche IMPs used in clinical trials where the SSR drug is the primary IMP.

Roche expedites all initial SUSAR cases to the Investigators. In addition, follow-up SUSAR cases are submitted to the Investigators if a change in event seriousness, causality, preferred term, or expectedness for safety reference document occurs, or an additional (existing or new) event in the case qualifies for a SUSAR.

If two or more SUSAR case versions are submitted during the reporting period, only the version most recently submitted during the reporting period is presented in the report. SUSAR cases submitted during the reporting period that no longer qualify for a SUSAR in the most recently submitted version, or were logically deleted subsequent to submission, are not presented in the report.

4.2 LISTING PRESENTATION

The version of Medical Dictionary for Regulatory Activities used to generate the line listing is printed in the listing.

The line listing is sorted by indication coded by Medical Dictionary for Regulatory Activities preferred term. Under each indication, the reports are shown under two different sub-sections: “SUSARs” and “SUSARs to Other IMPs and Comparators”. Separate tables are produced for each indication.

If more than one indication is investigated in a study (e.g., refractory solid tumors or lymphoma) and the indication is not provided by the reporter, the company initially codes all study indications in the case. As a result, such a case appears in more than one indication table. This is taken into consideration when counting SUSARs to prevent over count.

All IMPs for which the event is a SUSAR are shown in bold – for the SSR drug and other Roche IMPs in the “SUSARs” table, and for non-Roche IMPs, in trials where the SSR drug is the primary IMP, in the “SUSARs to Other IMPs and Comparators” table. If the suspect medication column contains more than one SUSAR drug, then each SUSAR event is marked with the list of drug sequence numbers to which it is related.

Only SUSARs to the SSR drug and non-Roche IMPs in trials where the SSR drug is the primary IMP are counted in this report, because SUSARs to other Roche IMPs are counted in their respective SSRs.

Events in a SUSAR case that do not qualify for a SUSAR are not presented in the report.

4.3 CAUSALITY ASSESSMENT

Both the reporter and the company causality assessments are shown for each SUSAR. Roche’s medical assessment of causality is based on the information provided in the individual case safety report. This assessment does not represent a full evaluation of all similar cases and epidemiological data of the therapeutic population. The company assessment of causal relationship at the event level, within the safety database, is not intended to suggest, imply, or confirm the event in question is a reaction to the medicinal product. Rather this assessment fulfills a regulatory requirement to indicate a potential association between product and event.

Adverse events where the causal relationship to the IMP is assessed by the reporter, or the company, as unknown will be considered by Roche to be suspected adverse reactions for reporting purposes, and thus submitted to Investigators if meeting other SUSAR criteria. Submission of adverse events where the causal relationship to the IMP is not provided by the reporter is driven by the company causality assessment.

4.4 REFERENCE SAFETY INFORMATION

The RSI for Roche IMPs is primarily the IB, which incorporates the DCSI. The DCSI details which events are to be considered expected, and will be updated with only those events evaluated by the Sponsor and preliminarily identified as suspected Adverse Drug Reactions.

From 1 April 2014, the company uses EU SPC to assess event listedness in trials where the Investigators use local label as the reference safety document. Prior to this date, Core Data Sheet was used for this assessment.

The reference safety document for non-Roche IMPs is the EU SPC (or United Kingdom SPC if an EU SPC is not available), or the IB, as defined in the respective study protocols.

Expectedness (or listedness) for each SUSAR is determined based on reference safety document version in effect at the time of case entry.

5. REFERENCES

1. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
2. Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (2011/C 172/01)

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO25455 1177209(7.0) 2010-023407-95 235909 235909002 UNITED KINGDOM 63 Years Male	**1 # RHUPH20/ RITUXIMAB**	Subcutaneous --x1400mg / -- --	31DEC2012/ --	Constipation	HAEMATOMA (INJECTION SITE) Injection site haematoma (03JAN2013)	Related Related IB Recovered/resolved with se (06JAN2013)
	2 RITUXIMAB	Intravenous (not otherwise specified) -- Intravenous (not otherwise specified) --x750mg / -- --	31OCT2012/ -- 28NOV2012/ --			

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO25455 1206182(12.0) 2010-023407-95 236878 236878003 FRANCE 72 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x630mg / 1 Total	18APR2012/ 18APR2012	Chills Herpes zoster Vomiting Neutropenia Tinnitus	RECTAL CANCER Rectal cancer [SUSAR Drugs 1, 2] (03DEC2012)	Related Related IB Fatal
	2 # RHUPH20/ RITUXIMAB	Subcutaneous 1x1400mg / 1 Months Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- --	30MAY2012/ 29OCT2013 27JUN2012/ 27JUN2012 22AUG2012/ 22AUG2012 07NOV2012/ 07NOV2012			
BO22334 1249694(8.0) 2010-021377-36 205058 1319 ITALY 66 Years Female	**1 # RHUPH20/ RITUXIMAB**	Subcutaneous 2x---- / 1 Months	07JUL2011/ --	Asthenia Anxiety	PROBABLY CREUTZFELDT-JACOB DISEASE Creutzfeldt-Jakob disease [SUSAR Drugs 1, 2] (MAY2013) DYSARTHRIA Dysarthria [SUSAR Drugs 1, 2] (MAY2013) COGNITIVE DISTURBANCE Cognitive disorder [SUSAR Drugs 1, 2]	Related Related IB Fatal Related Related IB Recovered/resolved (13JUL2013) Related Related IB

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
					[SUSAR Drugs 1, 2] (MAY2013) NERVOUS SYSTEM DISORDER Nervous system disorder [SUSAR Drugs 1, 2] (MAY2013) CONCENTRATION IMPAIRMENT Disturbance in attention [SUSAR Drugs 1, 2] (MAY2013) MEMORY IMPAIRMENT Memory impairment [SUSAR Drugs 1, 2] (MAY2013)	IB Recovered/resolved (13JUL2013) Related Related IB Recovered/resolved (13JUL2013) Related Related IB Recovered/resolved (13JUL2013) Related Related IB Recovered/resolved (13JUL2013)
	2 # RITUXIMAB	Intravenous (not otherwise specified) --x375mg/m2 / -- --	-- --			
MO28457 1277004(4.0) 2012-003230-17 257287 257287005 INDONESIA 38 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x520mg / -- --	06SEP2013/ --	Ileus	UNEXPLAINED DEATH Death (14SEP2013)	Related Related IB Fatal

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21223 1300766(1.0) 2010-024132-41 256783 57855 JAPAN 58 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x625mL / 4 Weeks	01OCT2013/ --	Hypertension Hyperlipidaemia Hyperuricaemia Cerebral infarction Rash maculo-papular Nausea Febrile neutropenia	LIVER DYSFUNCTION Hepatic function abnormal (15OCT2013)	Related Related CDS Not recovered/not resolved
	2 BENDAMUSTINE	Intravenous (not otherwise specified) 1x150mg / 4 Weeks	02OCT2013/ --			
BO22334 1312440(4.0) 2010-021377-36 205663 1517 MEXICO 49 Years Female	**1 # RHUPH20/ RITUXIMAB**	Subcutaneous 1x1400mg / 2 Months	10APR2013/ --		HYDROCEPHALUS Hydrocephalus [SUSAR Drugs 1, 2] (28JAN2014)	Related Related IB Not recovered/not resolved
	2 # RITUXIMAB	Intravenous (not otherwise specified) --	-- --			

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO28457 1314200(0.0) 2012-003230-17 253442 253442001 GERMANY 56 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 2x638mg / 1 Days	21NOV2013/ --		MUCOSITIS Mucosal inflammation (01DEC2013)	Related Related IB Not Reported
	2 BENDAMUSTINE	Intravenous (not otherwise specified) 3x73.8mg / 1 Days	21NOV2013/ --			
MO25455 1318125(0.0) 2010-023407-95 245903 245903002 COLOMBIA 55 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x540mg / -- --	-- --	Radiotherapy	CELLULITE MEMBER LOWER LEFT Peau d'orange [SUSAR Drugs 1, 2] (06DEC2013)	Related Related IB Not recovered/not resolved
	2 # RHUPH20/ RITUXIMAB	Subcutaneous 1x1400mg / 8 Weeks	05APR2013/ --			

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO22334 1321331(3.0) 2010-021377-36 233731 3101 GERMANY 50 Years Male	**1 # RHUPH20/** **RITUXIMAB**	Subcutaneous --	19SEP2011/ --	Hepatic steatosis	ULCERATIVE COLITIS Colitis ulcerative [SUSAR Drugs 1, 2] (21NOV2013)	Related Related IB Recovered/resolved (20DEC2013)
	2 # RITUXIMAB	Intravenous (not otherwise specified) --x375mg/m2 / -- --	-- --			
BO21223 1329581(3.0) 2010-024132-41 207907 50258 BELGIUM 76 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 3 Weeks Intravenous (not otherwise specified) 1x---- / 12 Months Intravenous (not otherwise specified) 1x---- / 2 Months	25JUN2012/ 13NOV2012 03JAN2013/ -- 28NOV2013/ --	Gastrooesophageal reflux disease Hyperlipidaemia Fatigue Back pain Abdominal pain Abdominal distension Nausea Flatulence Constipation	CHOLECYSTITIS Cholecystitis (31DEC2013)	Related Related CDS Recovered/resolved (17JAN2014)
	2 BENDAMUSTINE	Intravenous (not otherwise specified) 1x---- / 4 Weeks	25JUN2012/ --			

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21223 1338066(7.0) 2010-024132-41 208744 53980 UNITED KINGDOM 70 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 2 Months	01MAY2013/ --	Hypertension Gastrooesophageal reflux disease	HEMOPHAGOCYTIC SYNDROME Histiocytosis haematophagic (16FEB2014)	Related Related CDS Fatal
	2 BENDAMUSTINE	Intravenous (not otherwise specified) 1x---- / 4 Weeks	01MAY2013/ --			
BO21223 1360598(0.0) 2010-024132-41 258797 61752 JAPAN 83 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 3 Weeks	17OCT2013/ --	Osteoporosis Hypertension Constipation Diabetes mellitus Hyperlipidaemia Haemorrhoids Deafness	SYNCOPE Syncope (05MAR2014)	Related Related CDS Recovering/resolving
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x1113mg / 3 Weeks	18OCT2013/ --			
	3 VINCRISTINE	Intravenous (not otherwise specified) 1x1mg / 3 Weeks	-- --			
	4 PREDNISONE	Oral 1x100mg / 3 Weeks	21OCT2013/ --			

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. AER No. (Ver. No.) EudraCT No. Site No. Patient No. Country Age Sex	**Suspect Medication # = SUSAR Drug**	**Route Regimen**	**Treatment Start/Stop or Duration**	**Medical History**	**SUSAR Reported Term Preferred Term (Onset Date)**	**Drug-Event Relationship: Reporter Causality Company Causality Ref. Doc. Event Outcome (Resolved Date)**
BO21223 1371968(0.0) 2010-024132-41 210303 50723 CZECH REPUBLIC 78 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 3 Weeks	14NOV2013/ --	Hypertension Oedema peripheral Hypokalaemia Cholecystectomy Meniscus operation Appendicectomy	DEEP VEIN THROMBOSIS Deep vein thrombosis (26FEB2014)	Related Related CDS Recovered/resolved (07MAR2014)
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	14NOV2013/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x---- / 3 Weeks	14NOV2013/ --			
	4 VINCRISTINE	-- 1x---- / 3 Weeks	-- --			
	5 PREDNISONE	Oral 1x---- / 3 Weeks	14NOV2013/ --			
MO25455 1389437(0.0) 2010-023407-95 245902 245902001 COLOMBIA 42 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x660mg / 4 Weeks	27MAR2014/ --		TUMOUR LYSIS Tumour lysis syndrome (14APR2014)	Related Related IB Fatal
	2 BENDAMUSTINE	Unknown --	27MAR2014/ --			

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21223 1391147(1.0) 2010-024132-41 255266 59054 CHINA 64 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 2 Months	29JUL2013/ --	Irritability Liver injury Neutropenia Leukopenia	INTESTINAL OBSTRUCTION Intestinal obstruction (24APR2014)	Related Related EU-SPC Not recovered/not resolved
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	30JUL2013/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x---- / 3 Weeks	30JUL2013/ --			
	4 VINCRISTINE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	-- --			
	5 PREDNISOLONE	Oral 1x---- / 3 Weeks	29JUL2013/ --			

RITUXIMAB; RHUPH20

Indication: B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21685 1398787(0.0) 2008-005859-16 240 71367 GERMANY 55 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x562mg / -- --	21FEB2011/ 17MAR2014		PSORIASIS ARTHRITIS Psoriatic arthropathy (17DEC2012)	Related Related EU-SPC Recovering/resolving
	2 BENDAMUSTINE	Intravenous (not otherwise specified) --x106mg / -- --	21FEB2011/ 30AUG2011			

Indication: B-CELL LYMPHOMA - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: CHRONIC GRAFT VERSUS HOST DISEASE - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML19922 1330258(0.0) 2008-004125-42 -- 33 NETHERLANDS 59 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x800mg / -- --	16DEC2013/ 23DEC2013	Mantle cell lymphoma Stem cell transplant	GUILLAIN BARRE LIKE Guillain-Barre syndrome (06JAN2014)	Related Related IB Not Reported
ML19922 1335997(1.0) 2008-004125-42 -- 32 NETHERLANDS 57 Years Male	**1 # RITUXIMAB** 2 NILOTINIB HYDROCHLORIDE	Intravenous (not otherwise specified) --x375mg/m2 / 4 Weeks Oral --x600mg / -- --	10DEC2013/ 03JAN2014 13JAN2014/ --		MYELOMA LESION IN OS ILIUM Plasma cell myeloma (18JAN2014)	Related Related IB Not Reported

Indication: CHRONIC GRAFT VERSUS HOST DISEASE - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 1039206(1.0) 2008-001140-39 203568 4 BELARUS 57 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x500mg/m2 / 4 Week	25APR2011/ --		POSTERIOR CERVICAL SYMPATHETIC SYNDROME Sympathetic posterior cervical syndrome (08FEB2012)	Related Related IB Not recovered/not resolved
	2 CLADRIBINE	Intravenous (not otherwise specified) --x0.12mg/kg / -- --	26APR2011/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x250mg/m2 / -- --	26APR2011/ --			
ML21283 1057398(6.0) 2008-001140-39 117920 9 POLAND 67 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x930mg / 1 Months	02JUN2010/ --		SQUAMOUS CELL CARCINOMA OF THE FIFTH FINGER RIGHT HAND Squamous cell carcinoma (JAN2012)	Related Related IB Recovered/resolved (17APR2012)
	2 CLADRIBINE	Intravenous (not otherwise specified) --x9mg / -- --	03JUN2010/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x465mg / -- --	03JUN2010/ --			

RITUXIMAB; RHUPH20

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 1083190(3.0) 2008-001140-39 203568 17 BELARUS 67 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x500mg/m2 / 1 Week	11OCT2011/ --		ACUTE LEUKEMIA Acute leukaemia (25JUN2012)	Related Related IB Recovered/resolved with se (06AUG2012)
	2 CLADRIBINE	Intravenous (not otherwise specified) --	12OCT2011/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --	12OCT2011/ --			
BO25341 1149644(4.0) 2010-021380-32 233507 2821 GERMANY 73 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x822.43mg / 4 Weeks	17SEP2012/ --	Hypertonia Type 2 diabetes mellitus Gastritis Hyperhidrosis Pain Hyperuricaemia Pyrexia Hypertension Back pain Herpes zoster Tenosynovitis	VERTIGO Vertigo (26OCT2012)	Related Related IB Recovered/resolved (07NOV2012)

RITUXIMAB; RHUPH20

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 730213(4.0) 2008-001140-39 117917 MK7 POLAND 67 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x940mg / -- --	27APR2010/ --	Chronic lymphocytic leukaemia	RICHTER'S SYNDROME Richter's syndrome (27SEP2010)	Related Related IB Recovered/resolved with se (22OCT2010)
	2 CLADRIBINE	Intravenous (not otherwise specified) --x10.8mg / -- --	28APR2010/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x470mg / -- --	28APR2010/ --			
ML21283 730362(3.0) 2008-001140-39 117917 13 POLAND 40 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x775mg / -- --	29MAR2010/ --	Chronic lymphocytic leukaemia	RICHTER'S SYNDROME Richter's syndrome (28SEP2010)	Not Reported Unknown IB Fatal
	2 CLADRIBINE	Intravenous (not otherwise specified) --x7.08mg / -- --	29MAR2010/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x387.5mg / -- --	29MAR2010/ --			

RITUXIMAB; RHUPH20

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 740996(2.0) 2008-001140-39 -- 117917WO27 POLAND 51 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x675mg / -- --	05OCT2010/ 09NOV2010	Chronic lymphocytic leukaemia	IMMUNE THROMBOCYTOPENIC PURPURA Immune thrombocytopenic purpura (19OCT2010)	Related Related IB Recovered/resolved (04JAN2011)
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x450mg / -- --	06OCT2010/ 03NOV2010			
	3 CLADRIBINE	Intravenous (not otherwise specified) --x8.04mg / -- --	06OCT2010/ 03NOV2010			
ML21283 755693(3.0) 2008-001140-39 117920 IM11 POLAND 68 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x1065mg / 1 Months	03DEC2010/ --	Chronic lymphocytic leukaemia	BRONCHOPNEUMONIA Bronchopneumonia (28FEB2011) NEUTROPENIA Neutropenia (28FEB2011)	Related Related IB Fatal Related Related IB Fatal
	2 CLADRIBINE	Intravenous (not otherwise specified) 3x10mg / 1 Months	04DEC2010/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 3x530mg / 1 Months	04DEC2010/ --			

RITUXIMAB; RHUPH20

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO22468 803910(15.0) 2009-012072-28 167240 1 FRANCE 84 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x620mg / -- --	16JUN2011/ 16SEP2011	Acute coronary syndrome	THROMBOPENIA Thrombocytopenia (13JUL2011)	Related Related IB Fatal
	2 BENDAMUSTINE	Intravenous (not otherwise specified) --x147.5mg / -- --	16JUN2011/ 16SEP2011			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 1039206(1.0) 2008-001140-39 203568 4 BELARUS 57 Years Female	1 RITUXIMAB	Intravenous (not otherwise specified) 1x500mg/m2 / 4 Week	25APR2011/ --		POSTERIOR CERVICAL SYMPATHETIC SYNDROME Sympathetic posterior cervical syndrome [SUSAR Drugs 2, 3] (08FEB2012)	Related Related EU-SPC Not recovered/not resolved
	2 # CLADRIBINE	Intravenous (not otherwise specified) --x0.12mg/kg / -- --	26APR2011/ --			
	3 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x250mg/m2 / -- --	26APR2011/ --			
ML21283 1057398(6.0) 2008-001140-39 117920 9 POLAND 67 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) 1x930mg / 1 Months	02JUN2010/ --		SQUAMOUS CELL CARCINOMA OF THE FIFTH FINGER RIGHT HAND Squamous cell carcinoma [SUSAR Drugs 2, 3] (JAN2012)	Related Related EU-SPC Recovered/resolved (17APR2012)
	2 # CLADRIBINE	Intravenous (not otherwise specified) --x9mg / -- --	03JUN2010/ --			
	3 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x465mg / -- --	03JUN2010/ --			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 1083190(3.0) 2008-001140-39 203568 17 BELARUS 67 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) 1x500mg/m2 / 1 Week	11OCT2011/ --		ACUTE LEUKEMIA Acute leukaemia (25JUN2012)	Related Related EU-SPC Recovered/resolved with se (06AUG2012)
	2 # CLADRIBINE	Intravenous (not otherwise specified) --	12OCT2011/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --	12OCT2011/ --			
MO22468 1384942(0.0) 2009-012072-28 168630 18 TUNISIA 57 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) 1x914.3mg / 1 Months	13JUN2012/ --		FEBRILE NEUTROPENIA Febrile neutropenia (11OCT2013)	Related Related EU-SPC Recovered/resolved (14OCT2013)
	2 # CHLORAMBUCIL	Oral 1x126mg / 1 Months	13JUN2012/ --			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 719884(1.0) 2008-001140-39 -- 11791711 POLAND 72 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) --x895mg / -- --	12APR2010/ --	Chronic lymphocytic leukaemia	ACUTE CHOLECYSTITIS Cholecystitis acute [SUSAR Drugs 2, 3] (28APR2010)	Unknown Not Related EU-SPC Recovered/resolved (05MAY2010)
	2 # CLADRIBINE	Intravenous (not otherwise specified) --x8.22mg / -- --	13APR2010/ --			
	3 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x447.5mg / -- --	13APR2010/ --			
ML21283 730213(4.0) 2008-001140-39 117917 MK7 POLAND 67 Years Female	1 RITUXIMAB	Intravenous (not otherwise specified) --x940mg / -- --	27APR2010/ --	Chronic lymphocytic leukaemia	RICHTER'S SYNDROME Richter's syndrome [SUSAR Drugs 2, 3] (27SEP2010)	Related Related EU-SPC Recovered/resolved with se (22OCT2010)
	2 # CLADRIBINE	Intravenous (not otherwise specified) --x10.8mg / -- --	28APR2010/ --			
	3 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x470mg / -- --	28APR2010/ --			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 730362(3.0) 2008-001140-39 117917 13 POLAND 40 Years Female	1 RITUXIMAB	Intravenous (not otherwise specified) --x775mg / -- --	29MAR2010/ --	Chronic lymphocytic leukaemia	RICHTER'S SYNDROME Richter's syndrome [SUSAR Drugs 2, 3] (28SEP2010)	Not Reported Unknown EU-SPC Fatal
	2 # CLADRIBINE	Intravenous (not otherwise specified) --x7.08mg / -- --	29MAR2010/ --			
	3 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x387.5mg / -- --	29MAR2010/ --			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 740996(2.0) 2008-001140-39 -- 117917WO27 POLAND 51 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) --x675mg / -- --	05OCT2010/ 09NOV2010	Chronic lymphocytic leukaemia	PURE RED CELL APLASIA Aplasia pure red cell [SUSAR Drugs 2, 3] (19OCT2010) IMMUNE THROMBOCYTOPENIC PURPURA Immune thrombocytopenic purpura [SUSAR Drugs 2] (19OCT2010)	Related Related EU-SPC Recovered/resolved (04JAN2011) Related Related EU-SPC Recovered/resolved (04JAN2011)
	2 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x450mg / -- --	06OCT2010/ 03NOV2010			
	3 # CLADRIBINE	Intravenous (not otherwise specified) --x8.04mg / -- --	06OCT2010/ 03NOV2010			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 755693(3.0) 2008-001140-39 117920 IM11 POLAND 68 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) 1x1065mg / 1 Months	03DEC2010/ --	Chronic lymphocytic leukaemia	BRONCHOPNEUMONIA Bronchopneumonia [SUSAR Drugs 2] (28FEB2011) NEUTROPENIA Neutropenia [SUSAR Drugs 2, 3] (28FEB2011) NEUTROPENIC FEVER Febrile neutropenia [SUSAR Drugs 3] (13JAN2011)	Related Related EU-SPC Fatal Related Related EU-SPC Fatal Related Related EU-SPC Not recovered/not resolved
	2 # CLADRIBINE	Intravenous (not otherwise specified) 3x10mg / 1 Months	04DEC2010/ --			
	3 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 3x530mg / 1 Months	04DEC2010/ --			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 780705(1.0) 2008-001140-39 205938 9 POLAND 61 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) --x735mg / -- --	06MAY2011/ --	Chronic lymphocytic leukaemia	SUBCUTANEOUS TISSUE INFLAMMATION Dermatitis (10MAY2011)	Related Related EU-SPC Recovered/resolved (19MAY2011)
	2 # CLADRIBINE	Intravenous (not otherwise specified) --x972mg / -- --	07MAY2011/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x490mg / -- --	07MAY2011/ --			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21283 789718(3.0) 2008-001140-39 205938 4 POLAND 51 Years Male	1 RITUXIMAB	Intravenous (not otherwise specified) --x980mg / -- --	16FEB2011/ 12APR2011	Chronic lymphocytic leukaemia	WEIGHT LOSS Weight decreased [SUSAR Drugs 2, 3] (11APR2011) MANY SMALL CHANGES IN THE LUNGS (UNK DIAGNOSIS) Lung disorder [SUSAR Drugs 2, 3] (11APR2011)	Unknown Related EU-SPC Recovered/resolved with se (07JUN2011) Unknown Related EU-SPC Recovered/resolved with se (07JUN2011)
	2 # CLADRIBINE	Intravenous (not otherwise specified) --x9.12mg / -- --	17FEB2011/ 15APR2011			
	3 # CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x490mg / -- --	17FEB2011/ 15APR2011			
ML21283 799972(2.0) 2008-001140-39 205938 KN17 POLAND -- Male	1 RITUXIMAB	Intravenous drip 1x1000mg / 1 Months	17JAN2011/ --	Chronic lymphocytic leukaemia	NEUTROPENIA Neutropenia (30AUG2011)	Related Related EU-SPC Recovered/resolved (02SEP2011)
	2 # CYCLOPHOSPHAMIDE	Intravenous bolus 3x500mg / 1 Months	18JAN2011/ --			

Indication: CHRONIC LYMPHOCYTIC LEUKAEMIA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO22468 803910(15.0) 2009-012072-28 167240 1 FRANCE 84 Years Female	1 RITUXIMAB	Intravenous (not otherwise specified) --x620mg / -- --	16JUN2011/ 16SEP2011	Acute coronary syndrome	THROMBOPENIA Thrombocytopenia (13JUL2011)	Related Related IB Fatal
	2 # **BENDAMUSTINE**	Intravenous (not otherwise specified) --x147.5mg / -- --	16JUN2011/ 16SEP2011			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21005 1250832(2.0) 2010-024194-39 231806 14906 CANADA 69 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x881.25mg / 3 Weeks	17MAY2013/ --	Cough Sleep apnoea syndrome Dyspnoea exertional Obesity	DEATH FROM UNKNOWN CAUSE Death (16JUL2013)	Related Related CDS Fatal
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x1762mg / 3 Weeks	17MAY2013/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x117.5mg / 3 Weeks	17MAY2013/ --			
	4 VINCRISTINE	Intravenous (not otherwise specified) 1x2mg / 3 Weeks	17MAY2013/ --			
	5 PREDNISONE	Oral 1x100mg / 3 Weeks	17MAY2013/ --			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. AER No. (Ver. No.) EudraCT No. Site No. Patient No. Country Age Sex	**Suspect Medication # = SUSAR Drug**	**Route Regimen**	**Treatment Start/Stop or Duration**	**Medical History**	**SUSAR Reported Term Preferred Term (Onset Date)**	**Drug-Event Relationship: Reporter Causality Company Causality Ref. Doc. Event Outcome (Resolved Date)**
MO18261 1303644(3.0) 2005-005229-68 421 353 GERMANY 69 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x375mg/m2 / -- --	03MAR2010/ --		HEMORRHAGIC CYSTITIS Cystitis haemorrhagic (10MAR2010)	Related Related CDS Recovered/resolved (31MAR2010)
	2 DOXORUBICIN	Intravenous (not otherwise specified) --x50mg/m2 / -- --	03MAR2010/ --			
	3 PREDNISOLONE	Oral --x100mg / -- --	03MAR2010/ --			
	4 VINCRISTINE	Intravenous (not otherwise specified) --x2mg / -- --	03MAR2010/ --			
	5 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x750mg/m2 / -- --	03MAR2010/ --			
MO28457 1312423(1.0) 2012-003230-17 252540 252540001 MALAYSIA 49 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 21 Days	08NOV2013/ --	Neutropenia Autoimmune haemolytic anaemia	RITUXIMAB INDUCED PNEUMONITIS Pneumonitis (29NOV2013)	Related Related IB Fatal

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. AER No. (Ver. No.) EudraCT No. Site No. Patient No. Country Age Sex	**Suspect Medication # = SUSAR Drug**	**Route Regimen**	**Treatment Start/Stop or Duration**	**Medical History**	**SUSAR Reported Term Preferred Term (Onset Date)**	**Drug-Event Relationship: Reporter Causality Company Causality Ref. Doc. Event Outcome (Resolved Date)**
BO21005 1330667(0.0) 2010-024194-39 264775 23701 JAPAN 66 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 3 Weeks	21NOV2013/ --		ANAL FISTULA Anal fistula (25DEC2013)	Related Related CDS Not recovered/not resolved
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	21NOV2013/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x---- / 3 Weeks	21NOV2013/ --			
	4 VINCRISTINE	Intravenous bolus 1x---- / 3 Weeks	21NOV2013/ --			
	5 PREDNISOLONE	Oral 1x---- / 3 Weeks	21NOV2013/ --			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21005 1333944(2.0) 2010-024194-39 253013 16562 CHINA 71 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 3 Weeks	30DEC2013/ --	Liver injury Gastric pH decreased Irritability	GASTRORRHAGIA Gastric haemorrhage (13JAN2014)	Related Related CDS Fatal
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x1245mg / 3 Weeks	31DEC2013/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x83mg / 3 Weeks	31DEC2013/ --			
	4 VINCRISTINE	-- 1x1.5mg / 3 Weeks	31DEC2013/ --			
	5 PREDNISONE	Oral 1x100mg / 3 Weeks	30DEC2013/ --			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO28107 1334176(0.0) 2012-000669-19 248944 248944008 COLOMBIA 63 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x660mg / -- --	22AUG2013/ --	Hypertension Hysterectomy Aspiration pleural cavity	ACUTE DIARRHEA Diarrhoea [SUSAR Drugs 1, 2] (28DEC2013)	Related Related IB Fatal
	2 # RHUPH20/ RITUXIMAB	Subcutaneous 1x1400mg / 21 Days	11SEP2013/ --			
	3 CYCLOPHOSPHAMIDE	Unknown 1x1320mg / 21 Days	22AUG2013/ 20DEC2013			
	4 DOXORUBICIN	Unknown 1x88mg / 21 Days	22AUG2013/ 20DEC2013			
	5 VINCRISTINE	Unknown 1x2mg / 21 Days	22AUG2013/ 20DEC2013			
	6 PREDNISONE	Unknown --	-- --			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO18261 1358788(0.0) 2005-005229-68 106 484 GERMANY 70 Years Male	**1 # RITUXIMAB**	Unknown --	09DEC2010/ --	Prostate cancer	SECOND CANCER PANKREAS Pancreatic carcinoma (21FEB2014)	Related Related CDS Not recovered/not resolved
	2 CYCLOPHOSPHAMIDE	Unknown --	09DEC2010/ --			
	3 DOXORUBICIN	Unknown --	09DEC2010/ --			
	4 VINCRISTINE	Unknown --	09DEC2010/ --			
	5 PREDNISOLONE	Unknown --	09DEC2010/ --			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21005 1369367(1.0) 2010-024194-39 230792 10413 CANADA 83 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 3 Weeks	24JAN2014/ --	Osteoporosis Exostosis Diarrhoea Scoliosis Atelectasis Tendonitis Constipation Urinary tract infection Hypokalaemia Pyrexia Oral herpes Patella fracture Hysterectomy Foot fracture	FAILURE TO THRIVE Failure to thrive (17MAR2014) DEHYDRATION Dehydration (17MAR2014)	Related Related CDS Not recovered/not resolved Related Related CDS Not recovered/not resolved
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	24JAN2014/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x---- / 3 Weeks	24JAN2014/ --			
	4 VINCRISTINE	Intravenous bolus 1x---- / 3 Weeks	24JAN2014/ --			
	5 PREDNISONE	Oral 1x---- / 3 Weeks	24JAN2014/ --			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21005 1374462(2.0) 2010-024194-39 254889 20402 PERU 56 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 3 Weeks	21MAR2014/ --		ENTERITIS Enteritis (27MAR2014)	Related Related EU-SPC Recovered/resolved (03APR2014)
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	21MAR2014/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x---- / 3 Weeks	21MAR2014/ --			
	4 VINCRISTINE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	21MAR2014/ --			
	5 PREDNISONE	Oral 1x---- / 3 Weeks	22MAR2014/ --			

RITUXIMAB; RHUPH20

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO28457 1386729(1.0) 2012-003230-17 256280 256280004 GUATEMALA 80 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x750mg / 3 Weeks	31MAR2014/ --	Hypertension	OROPHARYNGEAL CANDIDIASIS Oropharyngeal candidiasis (09APR2014)	Related Related IB Fatal
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x750mg / 3 Weeks	31MAR2014/ --			
	3 VINCRISTINE	Unknown --	-- --			
	4 PREDNISONE	Unknown --	-- --			

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO18261 1303644(3.0) 2005-005229-68 421 353 GERMANY 69 Years Female	1 RITUXIMAB	Intravenous (not otherwise specified) --x375mg/m2 / -- --	03MAR2010/ --		HEMORRHAGIC CYSTITIS Cystitis haemorrhagic [SUSAR Drugs 3, 4] (10MAR2010)	Related Related EU-SPC Recovered/resolved (31MAR2010)
	2 DOXORUBICIN	Intravenous (not otherwise specified) --x50mg/m2 / -- --	03MAR2010/ --			
	3 # **PREDNISOLONE**	Oral --x100mg / -- --	03MAR2010/ --			
	4 # VINCRISTINE	Intravenous (not otherwise specified) --x2mg / -- --	03MAR2010/ --			
	5 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x750mg/m2 / -- --	03MAR2010/ --			

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO18261 1312707(0.0) 2005-005229-68 370 560 GERMANY 79 Years Female	1 RITUXIMAB	Intravenous (not otherwise specified) --x560mg / -- --	24AUG2011/ --		REDUCED GENERAL CONDITION General physical health deterioration [SUSAR Drugs 2, 3, 4, 5] (06OCT2011) ANAEMIA Anaemia [SUSAR Drugs 5] (21SEP2011)	Related Related EU-SPC Recovered/resolved (03NOV2011) Related Related EU-SPC Recovered/resolved (22SEP2011)
	2 # DOXORUBICIN	Unknown --	-- --			
	3 # PREDNISOLONE	Unknown --	-- --			
	4 # VINCRISTINE	Unknown --	-- --			
	5 # CYCLOPHOSPHAMIDE	Unknown --	-- --			

Indication: DIFFUSE LARGE B-CELL LYMPHOMA - SUSARs to non-company IMPs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO18261 1358788(0.0) 2005-005229-68 106 484 GERMANY 70 Years Male	1 RITUXIMAB	Unknown --	09DEC2010/ --	Prostate cancer	SECOND CANCER PANKREAS Pancreatic carcinoma [SUSAR Drugs 2, 3, 4, 5] (21FEB2014)	Related Related EU-SPC Not recovered/not resolved
	2 # CYCLOPHOSPHAMIDE	Unknown --	09DEC2010/ --			
	3 # DOXORUBICIN	Unknown --	09DEC2010/ --			
	4 # VINCRISTINE	Unknown --	09DEC2010/ --			
	5 # PREDNISOLONE	Unknown --	09DEC2010/ --			

RITUXIMAB; RHUPH20

Indication: GRAFT VERSUS HOST DISEASE - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML27769 1332405(0.0) EVCT-999999-25 -- 204009 USA 26 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x375mg/m2 / 1 Week	10OCT2013/ 30OCT2013	Pneumonia fungal	PRODUCTIVE COUGH Productive cough (04JAN2014)	Related Related IB Recovering/resolving

Indication: GRAFT VERSUS HOST DISEASE - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: LYMPHOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
BO21223 1134338(7.0) 2010-024132-41 209184 50351 BELGIUM 51 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 2 Months	21OCT2011/ --	Hypertension Orthostatic hypotension Neutropenia Gastric ulcer Infection Constipation Pyrexia Nausea	ULCUS ON VAGINAL MUCOSA Vaginal ulceration (12AUG2012)	Related Related CDS Recovered/resolved (29JAN2013)
	2 BENDAMUSTINE	Intravenous (not otherwise specified) 1x---- / 4 Weeks	21OCT2011/ --			

Indication: LYMPHOMA - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: LYMPHOPLASMACYTOID LYMPHOMA/IMMUNOCYTOMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML21685 1396164(1.0) 2008-005859-16 -- 72216 AUSTRIA 62 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x787.5mg / -- --	17APR2014/ --		CIRCULATORY COLLAPSE Circulatory collapse (28APR2014)	Related Related EU-SPC Recovered/resolved (29APR2014)
	2 BENDAMUSTINE	Intravenous (not otherwise specified) 1x90mg/m2 / 28 Days	17APR2014/ --			
		Intravenous (not otherwise specified) --x189mg / -- --	18APR2014/ --			
		Intravenous (not otherwise specified) --x189mg / -- --	19APR2014/ --			

Indication: LYMPHOPLASMACYTOID LYMPHOMA/IMMUNOCYTOMA - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: MALIGNANT LYMPHOID NEOPLASM - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML22863 1315860(0.0) EVCT-999999-25 24 24442 GERMANY 48 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x375mg/m2 / -- --	09NOV2013/ --	Hyperthyroidism	APLASIA (NOT CONGENITAL) (BLOOD DISORDER) (UNK DIAGNOSIS) Blood disorder (03DEC2013)	Related Related IB Not recovered/not resolved
	2 DOXORUBICIN	Intravenous (not otherwise specified) --x50mg/m2 / -- --	10NOV2013/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x750mg/m2 / -- --	09NOV2013/ --			
	4 VINCRISTINE	Intravenous (not otherwise specified) --x2mg / -- --	09NOV2013/ --			
	5 ETOPOSIDE	Intravenous (not otherwise specified) --x100mg/m2 / -- --	09NOV2013/ --			
	6 PREDNISOLONE	Oral --x100mg / -- --	09NOV2013/ --			

Indication: MALIGNANT LYMPHOID NEOPLASM - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: NON-HODGKIN'S LYMPHOMA UNSPECIFIED HISTOLOGY INDOLENT - SUSARs

Protocol No. AER No. (Ver. No.) EudraCT No. Site No. Patient No. Country Age Sex	**Suspect Medication # = SUSAR Drug**	**Route Regimen**	**Treatment Start/Stop or Duration**	**Medical History**	**SUSAR Reported Term Preferred Term (Onset Date)**	**Drug-Event Relationship: Reporter Causality Company Causality Ref. Doc. Event Outcome (Resolved Date)**
MO25455 1302713(3.0) 2010-023407-95 236897 236897003 ROMANIA 68 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x566mg / -- --	24JUL2013/ --	Tuberculosis	SEPSIS Sepsis [SUSAR Drugs 1, 2] (30OCT2013)	Related Related IB Fatal
	2 # RHUPH20/ RITUXIMAB	Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- --	21AUG2013/ 30OCT2013 18SEP2013/ --			
BO21223 1309212(5.0) 2010-024132-41 210314 52829 HUNGARY 75 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 4 Weeks	25SEP2013/ --	Gastrooesophageal reflux disease Hypertension Hyperthyroidism	RESPIRATORY FAILURE Respiratory failure (21NOV2013)	Related Related EU-SPC Fatal
	2 BENDAMUSTINE	Intravenous (not otherwise specified) 1x---- / 4 Weeks	25SEP2013/ --			

RITUXIMAB; RHUPH20

Indication: NON-HODGKIN'S LYMPHOMA UNSPECIFIED HISTOLOGY INDOLENT - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO25455 1329626(2.0) 2010-023407-95 235519 235519011 UNITED KINGDOM 75 Years Female	**1 # RHUPH20/ RITUXIMAB** **2 # RITUXIMAB**	Subcutaneous 1x1400mg / 8 Weeks Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- -- Subcutaneous --x1400mg / -- -- Subcutaneous 1x1400mg / 8 Weeks Intravenous (not otherwise specified) --x590mg / -- --	23MAR2013/ -- 24MAY2013/ -- 21JUN2013/ -- 07AUG2013/ -- 16SEP2013/ -- 07OCT2013/ -- 13DEC2013/ -- 03MAY2013/ -- 21MAR2013/ --	Emphysema Hypertension Angina pectoris Hyperuricaemia Constipation Anaemia	PNEUMONIA Pneumonia [SUSAR Drugs 1, 2] (29DEC2013)	Related Related IB Fatal

RITUXIMAB; RHUPH20

Indication: NON-HODGKIN'S LYMPHOMA UNSPECIFIED HISTOLOGY INDOLENT - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
MO25455 1365857(1.0) 2010-023407-95 252002 252002005 UNITED KINGDOM 69 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --	Anaemia Constipation Lower respiratory tract infection Oropharyngeal pain C-reactive protein increased Back pain Neck pain Pyrexia	SKIN REACTION Skin reaction [SUSAR Drugs 1, 2] (16FEB2014)	Related Related IB Not recovered/not resolved
	2 # RHUPH20/ RITUXIMAB	Subcutaneous --x1400mg / -- --	12FEB2014/ --			
	3 BENDAMUSTINE	Intravenous (not otherwise specified) --x145mg / -- --	15JAN2014/ --			

Indication: NON-HODGKIN'S LYMPHOMA UNSPECIFIED HISTOLOGY INDOLENT - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: RENAL TRANSPLANT - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML28426 1325450(0.0) EVCT-999999-25 -- -- USA 57 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x700mg / -- --	12SEP2013/ --	Renal failure chronic Atrial fibrillation Focal segmental glomerulosclerosis Renal transplant Biopsy kidney	ELEVATED CREATININE Blood creatinine increased (10DEC2013)	Not Reported Unknown IB Not Reported
	2 VALGANCICLOVIR HYDROCHLORIDE	Oral --	-- --			

Indication: RENAL TRANSPLANT - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: RHEUMATOID ARTHRITIS - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML20580 1314831(2.0) 2009-015950-39 107182 12812123 GERMANY 53 Years Male	**1 # RITUXIMAB** **(Blinded)**	Intravenous (not otherwise specified) -- Intravenous (not otherwise specified) --	20DEC2012/ 20DEC2012 03JAN2013/ 03JAN2013		GASTRO INTESTINAL STROMA TUMOR Gastrointestinal stromal tumour (12FEB2014) GASTRIC TUMOR Gastric neoplasm (14OCT2013)	Related Related CDS Recovered/resolved (26FEB2014) Related Related CDS Recovered/resolved (16OCT2013)

Indication: RHEUMATOID ARTHRITIS - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB; RHUPH20

Indication: SCLERODERMA - SUSARs

Protocol No. **AER No. (Ver. No.)** **EudraCT No.** **Site No.** **Patient No.** **Country** **Age** **Sex**	**Suspect Medication** **# = SUSAR Drug**	**Route** **Regimen**	**Treatment** **Start/Stop** **or Duration**	**Medical** **History**	**SUSAR** **Reported Term** **Preferred Term** **(Onset Date)**	**Drug-Event** **Relationship:** **Reporter Causality** **Company Causality** **Ref. Doc.** **Event Outcome** **(Resolved Date)**
ML27769 1332405(0.0) EVCT-999999-25 -- 204009 USA 26 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x375mg/m2 / 1 Week	10OCT2013/ 30OCT2013	Pneumonia fungal	PRODUCTIVE COUGH Productive cough (04JAN2014)	Related Related IB Recovering/resolving

Indication: SCLERODERMA - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

Dataset Parameters	
Dataset Name	25MAY2014_SSR_1059272
Date range (Informed Date)	from 26NOV2013 to 25MAY2014
Report Parameters	
SSR Drug	RITUXIMAB;RITUXIMAB HALOZYME
Unblinded Report?	No

Current MedDRA Version: v.17.0

Report ID: SSR02 v1.1.1.0