Roche	**SIX-MONTHLY SUSAR REPORT** **No. 1067169**
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Interval Covered by This Report	18 May 2015 to 17 November 2015 (inclusive)

SSR approval date: See last date in electronic signature manifestation below.

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Name	**Reason for Signing**	**Date and Time** (UTC)
Banzet,Sophie	Safety Science Cluster Head	14-Dec-2015 13:34:36

During the current review period, 18 May 2015 to 17 November 2015 (inclusive), the Sponsor submitted 51 Suspected Unexpected Serious Adverse Reactions (SUSARs) for rituximab. There were no non–company Investigational Medicinal Product SUSARs in trials where rituximab is the primary Investigational Medicinal Product.

The reported SUSARs did not necessitate changes to the 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 and formulations under investigation remains favorable.

1. INTRODUCTION

This is a Six-Monthly Suspected Unexpected Serious Adverse Reaction (SUSAR) Report (SSR 1067169) 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 18 May 2015 to 17 November 2015, 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

For autoimmune indications (intravenous (IV) formulation), the reference safety information (RSI) in effect at the start of the reporting interval was the Investigator's Brochure (IB) version 14.0 dated May 2015 which incorporates the Section 6 "Guidance for the Investigator (Reference Safety Information)".

For oncology indications, the IB for rituximab oncology subcutaneous (SC) formulation, version 6.0 dated February 2015 which incorporates the Section 6 "Guidance for the Investigator (Reference Safety Information)" was used as the safety reference document for the SC formulation and; theIB for rituximab oncology IV formulation, version 20.0 dated July 2015 containing Section 6 "Guidance for the Investigator (Reference Safety Information)" was used as the safety reference document for the IV formulation.

The Sponsor used the rituximab EU Summary of Product Characteristics (SPC) as the RSI in trials where the Investigators use local label as the safety reference document.

The reported SUSARs from all indications/formulations did not necessitate any changes to the rituximab IBs during the current reporting interval.

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 and formulations 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 Investigational Medicinal Product (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 MedDRA used to generate the line listing is printed in the listing.

The line listing is sorted by indication coded by MedDRA 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 relevant IB for the indication/formulation, which details those events that are to be considered expected. The IB 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

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)**
ML28881 1472472(4.0) 2013-000647-12 259725 2597251241 ITALY 63 Years Male	**1 # RITUXIMAB**	Subcutaneous 1x1400mg / 21 Days	24JUL2014/ --		KPC RESISTANT KLEBSIELLA INFECTION Klebsiella infection (19SEP2014)	Related Related IB Fatal
	2 CYCLOPHOSPHAMIDE	Unknown --	-- --			
	3 DOXORUBICIN	Unknown --	-- --			
	4 VINCRISTINE	Unknown --	-- --			
	5 PREDNISONE	Unknown --	-- --			
MO25455 1638210(0.0) 2010-023407-95 237875 237875002 ARGENTINA 88 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	07JAN2014/ --	Dyspnoea Arrhythmia Nausea	CLARK 5 MELANOMA Malignant melanoma [SUSAR Drugs 1, 2] (31AUG2015)	Related Related IB Not recovered/not resolved
	2 # RITUXIMAB	Subcutaneous 1x1400mg / 8 Weeks	--/ 23SEP2015			

RITUXIMAB

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)**
GO29044 1659699(0.0) 2013-003541-42 266058 31152 FRANCE 77 Years Male	**1 # POLATUZUMAB VEDOTIN**	Intravenous (not otherwise specified) 1x---- / 21 Days	01JUL2015/ --	Aortic stenosis Intervertebral disc protrusion Decreased appetite Dysphonia Dyspnoea Anxiety Hypercholesterolaemia Dysphagia Ventricular extrasystoles Mucosal inflammation Hypothyroidism Thyroidectomy	MALNUTRITION Malnutrition [SUSAR Drugs 1, 2] (08NOV2015)	Related Not Related IB Not recovered/not resolved
	2 # RITUXIMAB	Intravenous (not otherwise specified) 1x---- / 21 Days	30JUN2015/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x---- / 21 Days	30JUN2015/ --			
	4 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x---- / 21 Days	30JUN2015/ --			
	5 PREDNISONE	Oral 1x100mg / 21 Days	25JUN2015/ --			

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

NO SUSARS WERE IDENTIFIED

RITUXIMAB

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 1604602(0.0) 2008-004125-42 -- 47 NETHERLANDS 58 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x375mg/m2 / 1 Week Intravenous (not otherwise specified) 1x---- / 1 Weeks Intravenous (not otherwise specified) 1x---- / 1 Weeks	18JUN2015/ -- 25JUN2015/ -- 02JUL2015/ --	Acute myeloid leukaemia Stem cell transplant	PLEURAL EFFUSION Pleural effusion (03JUL2015)	Related Related IB Not Reported

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

NO SUSARS WERE IDENTIFIED

RITUXIMAB

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)**
ML18429 1279759(4.0) EVCT-999999-25 116506 4 VENEZUELA, BOLIVARIAN REPUBLIC OF 69 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x375mg / 1 Days	23AUG2013/ --	Diabetes mellitus	FEBRILE NEUTROPENIA Febrile neutropenia (18SEP2013)	Related Related IB Fatal
					NOSOCOMIAL PNEUMONIA Pneumonia (28SEP2013)	Related Related IB Fatal
	2 BENDAMUSTINE	Unknown --	-- --			
BO21004 1400124(2.0) 2009-012476-28 202502 6824 ITALY 78 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x910mg / 28 Days	24OCT2011/ --		MYELODYSPLASTIC SECONDARY SYNDROME Myelodysplastic syndrome (08MAR2014)	Related Related EU-SPC Fatal
	2 CHLORAMBUCIL	-- 1x36mg / 2 Weeks	24OCT2011/ --			
	3 FLUDARABINE	Unknown --	02MAY2013/ 02OCT2013			
	4 CYCLOPHOSPHAMIDE	Unknown --	02MAY2013/ 02OCT2013			

RITUXIMAB

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)**
BO25341 1621923(0.0) 2010-021380-32 205493 1352 SPAIN 72 Years Male	**1 # RITUXIMAB**	Subcutaneous --x1600mg / -- --	14FEB2012/ 14FEB2012		THERAPY-RELATED MYELODYSPLASTIC SYNDROME Myelodysplastic syndrome [SUSAR Drugs 1, 2] (04AUG2015)	Related Related IB Not recovered/not resolved
	2 # RITUXIMAB	Intravenous (not otherwise specified) --	-- --			
	3 FLUDARABINE	Unknown --	-- --			
	4 CYCLOPHOSPHAMIDE	Unknown --	-- --			

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

NO SUSARS WERE IDENTIFIED

RITUXIMAB

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 1232241(11.0) 2012-000669-19 249881 249881003 NETHERLANDS 62 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x800mg / -- --	14MAY2013/ --	Candida infection Abdominal pain Osteoarthritis Tachycardia	MULTI ORGAN FAILURE Multi-organ failure [SUSAR Drugs 1, 2] (04JUN2013)	Related Related IB Fatal
	2 # RITUXIMAB	Subcutaneous --x1400mg / -- --	28MAY2013/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x1600mg / -- --	28MAY2013/ --			
		Intravenous (not otherwise specified) --x1600mg / -- --	14MAY2013/ --			
	4 DOXORUBICIN	Intravenous (not otherwise specified) --x105mg / -- --	28MAY2013/ --			
		Intravenous (not otherwise specified) --x105mg / -- --	14MAY2013/ --			
	5 VINCRISTINE SULFATE	Intravenous (not otherwise specified) --x1mg / -- --	28MAY2013/ --			
		Intravenous (not otherwise specified) --x1.4mg/m2 / -- --	14MAY2013/ --			

RITUXIMAB

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)**
	6 PREDNISONE	Unknown --x500Unit Not Reported / -- -- Unknown --	14MAY2013/ -- 28MAY2013/ --			
MO28107 1249783(10.0) 2012-000669-19 249401 249401010 TURKEY 78 Years Female	**1 # RITUXIMAB**	Subcutaneous 1x1400mg / 21 Days	17MAY2013/ 15JUL2013	Cerebrovascular disorder Atrial fibrillation	LUNG INFECTION Lung infection (15JUL2013)	Related Related IB Fatal
	2 RITUXIMAB	Intravenous (not otherwise specified) --x520mg / -- --	26APR2013/ --			
	3 CYCLOPHOSPHAMIDE	Unknown 1x1035mg / 21 Days	26APR2013/ 15JUL2013			
	4 DOXORUBICIN	Unknown 1x70mg / 21 Days	26APR2013/ 15JUL2013			
	5 VINCRISTINE	Unknown 1x2mg / 21 Days	26APR2013/ 15JUL2013			
	6 METHYLPREDNISOLONE	Unknown 1x80mg / 21 Days	26APR2013/ 15JUL2013			

RITUXIMAB

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)**
ML28881 1441041(2.0) 2013-000647-12 259187 2591871404 ITALY 49 Years Female	**1 # RITUXIMAB**	Subcutaneous 1x1400mg / 21 Days	11JUL2014/ 28AUG2014	Cholelithiasis	ACUTE CHOLECYSTITIS Cholecystitis acute (22JUL2014) MYELODYSPLASTIC SYNDROME Myelodysplastic syndrome (28AUG2014)	Related Related IB Recovered/resolved (27AUG2014) Related Related IB Unknown
	2 CYCLOPHOSPHAMIDE	Unknown --	-- --			
	3 DOXORUBICIN HYDROCHLORIDE	Unknown --	-- --			
	4 VINCRISTINE	Unknown --	-- --			
	5 PREDNISONE	Unknown --	-- --			

RITUXIMAB

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)**
ML28881 1464934(3.0) 2013-000647-12 258260 2582601303 ITALY 61 Years Male	**1 # RITUXIMAB**	Subcutaneous 1x1400mg / 21 Days	13AUG2014/ --		CHYLOTHORAX Chylothorax (09SEP2014)	Related Related IB Recovering/resolving
	2 CYCLOPHOSPHAMIDE	Unknown --	-- --			
	3 DOXORUBICIN	Unknown --	-- --			
	4 VINCRISTINE SULFATE	Unknown --	-- --			
	5 PREDNISONE	Unknown --x25mg / -- -- Unknown --x12.5mg / -- --	09SEP2014/ 09SEP2014 10SEP2014/ 10SEP2014			

RITUXIMAB

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 1648490(0.0) 2010-024194-39 250711 15466 JAPAN 77 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x517mL / -- --	30APR2014/ --	Interstitial lung disease Haemorrhoids Constipation	COLON CANCER Colon cancer (13OCT2015)	Related Related EU-SPC Not recovered/not resolved
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --	01MAY2014/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) --x51.67mg / -- --	01MAY2014/ --			
	4 VINCRISTINE	Intravenous (not otherwise specified) --x1.93mg / -- --	01MAY2014/ --			
	5 PREDNISONE	Oral --x100mg / -- --	30APR2014/ --			

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

NO SUSARS WERE IDENTIFIED

RITUXIMAB

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)**
MO17244 GNE249727(2.0) EVCT-000000-16 495 495209 FRANCE 75 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x375mg/m2 / -- --	-- --	Arteritis Myocarditis Ulcer Myocardial infarction	IMPAIRMENT OF HEALTH STATUS General physical health deterioration (24SEP2007)	Related Related IB Not recovered/not resolved
	2 INTERFERON ALFA-2A	Unknown 1x50mg / 1 Weeks	01JUN2007/ 24SEP2007			

Indication: LYMPHOMA - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB

Indication: MANTLE 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)**
MO17244 1572427(2.0) EVCT-000000-16 134 209 GERMANY 73 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x375mg/m2 / -- --	-- --		BLEEDING FROM SQUAMOUS CELL CARCINOMA OF THE LUNG Tumour haemorrhage (15MAR2005)	Related Related IB Not recovered/not resolved

RITUXIMAB

Indication: MANTLE 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)**
MO17244 1572617(0.0) EVCT-999999-25 151 228 GERMANY 75 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) -- Intravenous (not otherwise specified) --	-- -- 25MAR2011/ --	Hypertension Arrhythmia Renal failure Prostatectomy Stent placement	HEMIPARESIS LEFT Hemiparesis (01APR2011)	Related Not Related IB Recovered/resolved (--)
	2 CYCLOPHOSPHAMIDE	Unknown -- Unknown --	-- -- 26MAR2011/ 30MAR2011			
	3 VINCRISTINE	Unknown -- Unknown --	-- -- 26MAR2011/ 30MAR2011			
	4 DOXORUBICIN	Unknown -- Unknown --	-- -- 26MAR2011/ 30MAR2011			
	5 PREDNISOLONE	Unknown -- Unknown --	-- -- 26MAR2011/ 30MAR2011			

RITUXIMAB

Indication: MANTLE 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)**
MO17244 1573077(0.0) EVCT-999999-25 087 265 GERMANY 72 Years Female	**1 # RITUXIMAB**	Unknown --x600mg / -- --	14JUL2011/ --		EXCISION OF BASALIOMA Skin neoplasm excision (13JUN2012)	Related Related IB Recovered/resolved (18JUN2012)
MO17244 1573303(0.0) EVCT-000000-16 494 238 NETHERLANDS 73 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x600mg / -- --	06MAY2009/ 12APR2012		PNEUMONIA Pneumonia (21FEB2013)	Related Related IB Fatal

RITUXIMAB

Indication: MANTLE 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)**
MO17244 1573315(0.0) EVCT-999999-25 494 220 GERMANY 77 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x680mg / -- --	02APR2007/ --		SIGMOID STENOSIS Large intestinal stenosis (21JUN2007)	Related Related IB Recovered/resolved (18JUL2007)
	2 FLUDARABINE	Intravenous (not otherwise specified) --x54mg / -- --	02APR2007/ --			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x460mg / -- --	02APR2007/ --			

RITUXIMAB

Indication: MANTLE 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)**
MO17244 1573337(0.0) EVCT-000000-16 494 209 NETHERLANDS 77 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	17DEC2008/ 17DEC2008		MYOCARDIAL INFARCTION Myocardial infarction (17FEB2009) SPUTUM RETENTION Sputum retention (--) PULMONAL BLEEDING Pulmonary haemorrhage (--) DECOMPENSATION CORDIS Cardiac failure (--)	Related Not Related IB Fatal Related Not Related IB Not Reported Related Not Related IB Not Reported Related Not Related IB Not Reported

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MO17244 1573347(0.0) EVCT-000000-16 494 267 NETHERLANDS 86 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) -- Intravenous (not otherwise specified) --	-- -- 20OCT2009/ --	Myocardial infarction	UPPER DIGESTIVE TRACT BLEEDING Upper gastrointestinal haemorrhage (08SEP2009)	Related Related IB Unknown
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --x140mg / -- --	20AUG2009/ 20AUG2009			
	3 DOXORUBICIN	Intravenous (not otherwise specified) --x90mg / -- --	20AUG2009/ 20AUG2009			
	4 VINCRISTINE	Intravenous (not otherwise specified) --x2mg / -- --	20AUG2009/ 20AUG2009			
	5 PREDNISOLONE	Oral --x100mg / -- --	20AUG2009/ 24AUG2009			

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MO17244 1573373(0.0) EVCT-999999-25 494 290 NETHERLANDS 68 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	08SEP2010/ --	Anxiety disorder Hypercholesterolaemia	GI BLEEDING Gastrointestinal haemorrhage (10SEP2010)	Related Not Related IB Recovering/resolving
	2 FLUDARABINE	Intravenous (not otherwise specified) --	08SEP2010/ 09SEP2010			
	3 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) --	08SEP2010/ 09SEP2010			
MO17244 1573749(0.0) EVCT-000000-16 -- 270 NETHERLANDS 71 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --	Pneumonitis	CIRCULATORY COLLAPSE Circulatory collapse (31OCT2010)	Related Not Related IB Recovered/resolved (01NOV2010)
	2 PEGINTERFERON ALFA-2B	Unknown 1x---- / 1 Weeks	29MAR2010/ --			

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MO17244 1573752(0.0) EVCT-999999-25 -- 246 NETHERLANDS 73 Years Male	**1 # RITUXIMAB**	Unknown --	-- --	Hypertension Type 2 diabetes mellitus	MELENA Melaena (24JUL2008)	Related Related IB Recovered/resolved (--)
MO17244 1573759(0.0) EVCT-999999-25 599 204 GERMANY 71 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) -- Intravenous (not otherwise specified) --	19JUL2010/ -- 28FEB2011/ --	Hypertension Cerebrovascular disorder Cholelithiasis	BILIARY PANCREATITIS Pancreatitis (13AUG2010) VISUAL DISTURBANCE Visual impairment (07MAR2011)	Related Not Related IB Unknown Related Not Related IB Unknown
MO17244 1573761(0.0) EVCT-000000-16 548 201 GERMANY 78 Years Male	**1 # RITUXIMAB** 2 INTERFERON ALFA-2A 3 IBUPROFEN	Intravenous (not otherwise specified) -- Unknown -- Unknown -- Unknown -- Unknown --	-- -- 02JUL2008/ -- -- -- -- -- -- --		CIRCULATORY COLLAPSE Circulatory collapse (--)	Related Not Related IB Recovered/resolved (--)

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Indication: MANTLE 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)**
MO17244 1573789(0.0) EVCT-000000-16 21 203 GERMANY 67 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --	Atrial fibrillation Cerebral ischaemia	HEMOTHORAX Haemothorax (10JUN2007)	Related Not Related IB Recovering/resolving
MO17244 1573792(0.0) EVCT-999999-25 034 234 GERMANY 75 Years Female	**1 # RITUXIMAB**	Unknown --	-- --		CEREBRAL CANDIDIASIS Candida infection (21FEB2011)	Related Related IB Fatal
					SECONNDARY MYELODYSPLASTIC SYNDROME Myelodysplastic syndrome (21FEB2011)	Related Related IB Fatal
	2 FLUDARABINE	Unknown --	-- --			
	3 CYCLOPHOSPHAMIDE	Unknown --	-- --			

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Indication: MANTLE 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)**
MO17244 1573803(0.0) EVCT-000000-16 120 293 GERMANY 67 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	23SEP2008/ --		RESPIRATORY FAILURE Respiratory failure (03AUG2009)	Related Not Related IB Fatal
MO17244 1573816(0.0) EVCT-000000-16 486 208 DENMARK 69 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --		PHLEBITIS Phlebitis (29APR2008) PNEUMONIA Pneumonia (--)	Related Related IB Recovered/resolved (08MAY2008) Related Related IB Fatal
MO17244 1573825(0.0) EVCT-999999-25 486 209 DENMARK 70 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --		FREQUENT URINATION Pollakiuria (21JAN2009)	Related Related IB Recovered/resolved (19FEB2009)

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Indication: MANTLE 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)**
MO17244 1573840(0.0) EVCT-999999-25 274 208 GERMANY 70 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x375mg/m2 / -- --	-- --		HYPERKALAEMIA Hyperkalaemia (27NOV2007)	Related Related IB Recovered/resolved (28NOV2007)
	2 VINCRISTINE	Unknown --x2mg / -- --	26NOV2007/ 27NOV2007			
	3 DOXORUBICIN	Unknown --x94mg / -- --	26NOV2007/ 27NOV2007			
	4 CYCLOPHOSPHAMIDE	Unknown --x1400mg / -- --	26NOV2007/ 27NOV2007			
	5 METHYLPREDNISOLONE SODIUM SUCCINATE	Unknown --x75mg / -- --	26NOV2007/ 27NOV2007			

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Indication: MANTLE 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)**
MO17244 1573926(0.0) EVCT-999999-25 486 213 GERMANY 76 Years Not specified	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --		DEAFNESS TRAUMATIC Deafness traumatic (20AUG2009)	Related Not Related IB Not recovered/not resolved
	2 CYCLOPHOSPHAMIDE	Unknown --x1695mg / -- --	-- --			
	3 DOXORUBICIN	Unknown --x113mg / -- --	-- --			
	4 VINCRISTINE	Unknown --x2mg / -- --	-- --			
	5 PREDNISONE	Unknown --	-- --			
MO17244 1573946(0.0) EVCT-000000-16 517 206 CZECH REPUBLIC 76 Years Not specified	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --	Angiogram	EPISODE OF UNCONSCIOUSNESS Loss of consciousness (19MAY2009)	Related Related IB Recovered/resolved (22MAY2009)

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Indication: MANTLE 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)**
MO17244 1573955(0.0) EVCT-999999-25 486 209 GERMANY 70 Years Not specified	**1 # RITUXIMAB**	Unknown --	-- --		INCREASED LIVER ENZYMES Hepatic enzyme increased (13MAY2009) INCREASED BILIRUBIN Blood bilirubin increased (13MAY2009)	Related Not Related IB Not recovered/not resolved Related Not Related IB Not recovered/not resolved
MO17244 1573958(0.0) EVCT-000000-16 494 205 NETHERLANDS 82 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --		CARDIOMYOPATHY Cardiomyopathy (15FEB2006)	Related Not Related IB Unknown
MO17244 1575875(0.0) EVCT-999999-25 21 203 GERMANY 69 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --	-- --		INFRARENAL ABDOMINAL AORTIC ANEURYSM Aortic aneurysm (10NOV2009)	Related Not Related IB Unknown

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

NO SUSARS WERE IDENTIFIED

RITUXIMAB

Indication: NON-HODGKIN'S 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 1601071(0.0) 2010-023407-95 236853 236853003 FRANCE 69 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x375mg/m2 / -- --	-- --	Hypertension Gastritis Blood cholesterol	SECOND MALIGNANCY DLBCL Diffuse large B-cell lymphoma [SUSAR Drugs 1, 2] (23JUN2015)	Related Related IB Not recovered/not resolved
	2 # RITUXIMAB	Subcutaneous 1x1400mg / 2 Months	06AUG2012/ --			
	3 BENDAMUSTINE	Intravenous (not otherwise specified) --x90mg/m2 / -- --	07AUG2012/ --			
ML21685 1643689(0.0) 2008-005859-16 250 71424 GERMANY 60 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x860mg / 8 Weeks	10MAR2014/ 30SEP2015		SEVERE ELEVATION OF LIVER ENZYMES Hepatic enzyme increased (03AUG2015) HEPATITIS OF UNKNOWN CAUSE Hepatitis (03AUG2015)	Unknown Related EU-SPC Recovering/resolving Unknown Related EU-SPC Recovering/resolving

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

NO SUSARS WERE IDENTIFIED

RITUXIMAB

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)**
BO21223 1646095(0.0) 2010-024132-41 252963 58606 CHINA 69 Years Male	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 1x---- / 2 Months	25JUN2013/ --	Diabetes mellitus Hypertension	SECOND PRIMARY TUMORS (LUNG ADENOCARCINOMA) Lung adenocarcinoma (10OCT2015)	Related Related EU-SPC Not recovered/not resolved
	2 CYCLOPHOSPHAMIDE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	26JUN2013/ --			
	3 DOXORUBICIN	Intravenous (not otherwise specified) 1x---- / 3 Weeks	26JUN2013/ --			
	4 VINCRISTINE	Intravenous (not otherwise specified) 1x---- / 3 Weeks	-- --			
	5 PREDNISONE	Oral 1x---- / 3 Weeks	26JUN2013/ --			

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

NO SUSARS WERE IDENTIFIED

RITUXIMAB

Indication: PRODUCT USED FOR UNKNOWN INDICATION - 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)**
MO17244 1573902(2.0) EVCT-000000-16 486 205 DENMARK 65 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) --x375mg/m2 / -- --	-- --	Asthma Hypothyroidism	DEHYDRATION Dehydration (30SEP2006)	Related Not Related IB Recovered/resolved (06OCT2006)

Indication: PRODUCT USED FOR UNKNOWN INDICATION - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

RITUXIMAB

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)**
WA17044 GNE233905 (19.0) 2005-002396-33 53875 8704 UNITED KINGDOM 56 Years Female	**1 # RITUXIMAB**	Intravenous (not otherwise specified) 2x500mg / 15 Days	11OCT2006/ 10JAN2007		HYPOXIA Hypoxia (08DEC2006)	Related Related IB Recovered/resolved with se (10JAN2007)
	2 METHOTREXATE	Oral 1x20mg / 1 Weeks	05APR2004/ DEC2006			

Indication: RHEUMATOID ARTHRITIS - SUSARs to non-company IMPs

NO SUSARS WERE IDENTIFIED

Dataset Parameters	
Dataset Name	17NOV2015_SSR_1067169
Date range (Informed Date)	from 18MAY2015 to 17NOV2015
Report Parameters	
SSR Drug	RITUXIMAB (FORM UNKNOWN);RITUXIMAB (IV);RITUXIMAB (SC)
Unblinded Report?	No

Current MedDRA Version: v.18.1

Report ID: SSR02 v1.1.1.0