Appendix A6.1.5.3 SAE ICSRs

This appendix lists all individual case safety reports for serious adverse events which occurred during the course of completed and ongoing clinical studies and reported until 30-April-2016.

List of Tables

Table 1 List of SAE Individual Case Safety Reports.....2

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Table 1 List of SAE Individual Case Safety Reports

Safety Case #	Study code	Preferred term, Latest Update, Date	Case Status
PMI000007	ZRHM-REXA-08-US	Diabetic ketoacidosis, Sinusitis, Follow-up 4, 26 Feb 2015	Closed
PMI000350	ZRHR-ERS-09-US	Metastases to small intestine, Anaemia, Follow-up 4, 17 Feb 2016	Closed
PMI000360	ZRHR-ERS-09-US	Urosepsis, Pyelonephritis acute, Nephrolithiasis, Follow-up 4, 12 Feb 2016	Closed
PMI000369	ZRHR-ERS-09-US	Papillary thyroid cancer, Follow-up 3, 5 Feb 2016	Further information expected
PMI000385	ZRHR-ERS-09-US	Vertebral osteophyte, Cervical myelopathy, Follow-up 1, 25 Jan 2016	Closed
PMI000452	ZRHR-ERS-09-US	Alcohol abuse, Follow-up 3, 22 Apr 2016	Closed
PMI000463	ZRHR-ERS-09-US	Loss of consciousness, Head injury, Seizure, Follow-up 2, 22 Apr 2016	Closed
PMI000466	ZRHR-ERS-09-US	Head injury, Follow-up 1, 29 Jan 2016	Further information expected
PMI000467	ZRHR-ERS-09-EXT-US	Cellulitis staphylococcal, Follow-up 4, 22 Apr 2016	Closed
PMI000470	ZRHR-ERS-09-EXT-US*	Laceration, Initial, 25 Jan 2016	Further information expected
PMI000482	ZRHR-ERS-09-EXT-US	Breast cancer, Follow-up 2, 31 Mar 2016	Further information expected
PMI000500	ZRHR-ERS-09-EXT-US	Costochondritis, Follow-up 1, 24 Mar 2016	Closed
PMI000507	ZRHR-ERS-09-US	Suicidal ideation, Follow-up 1, 5 Apr 2016	Further information expected
PMI000511	ZRHR-ERS-09-US	Pneumonia mycoplasmal, Initial, 3 Mar 2016	Further information expected
PMI000514	ZRHR-ERS-09-US	Grief reaction, Initial, 7 Mar 2016	Further information expected
PMI000518	ZRHR-ERS-09-EXT-US	Epiglottitis, Follow-up 2, 22 Apr 2016	Further information expected

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Safety Case #	Study code	Preferred term, Latest Update, Date	Case Status
PMI000551	ZRHR-ERS-09-EXT-US	Influenza, Follow-up 1, 22 Apr 2016	Further information expected
PMI000553	ZRHR-ERS-09-US	Tooth infection, Follow-up 1, 22 Apr 2016	Closed
PMI000559	ZRHR-ERS-09-EXT-US	Blood triglycerides increased, Follow-up 1, 27 Apr 2016	Further information expected
PMI000627	ZRHR-ERS-09-EXT-US	Appendicitis, Initial, 02 May 2016**	Further information expected

* Case PMI000470 was reported during ZRHR-ERS-09-EXT-US study but occurred apparently during ZRHR-ERS-09-US study

**Case was initially reported by the Investigator on 22 Apr 2016 (D0) and the initial Medwatch report was produced on 02 May 2016

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