LUITPOLD PHARMACEUTICALS, INC

US Post Marketing Commitments

Product Compound	Description of Commitment	NDA Number	Agreement Date	Project Completion Date	Status
INJECTAFER (ferric carboxymaltose injection). 50mg/mL	Identify an optimal dose of INJECTAFER (ferric carboxymaltose injection) for the pediatric patient population. Conduct one or more pharmacokinetic (PK) and pharmacodynamic (PD) trials in pediatric patients aged 1 to <17 years with iron deficiency anemia sufficient to justify and to characterize the dose to be tested in a confirmatory clinical trial of safety and efficacy. Identify the most relevant PD endpoints to measure (PMR 2064-1).	203565	7/25/2013	7/31/2017	Ongoing
INJECTAFER (ferric carboxymaltose injection). 50mg/mL	Determine the safety and efficacy of INJECTAFER (ferric carboxymaltose injection) in pediatric patients aged 1 to <17 years with iron deficiency anemia by conducting a randomized, active-controlled clinical trial (PMR 2064-2)	203565	7/25/2013	1/31/2021	Not started
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Observational study to collect long-term safety data in at least 50 pediatric patients with chronic kidney disease on erythropoietin-stimulating agent (ESA) therapy who require iron maintenance treatment for iron deficiency anemia (PMR-1926-1).	21-135	9/21/2012	6/30/2017	Ongoing

Product Compound	Description of Commitment	NDA Number	Agreement Date	Project Completion Date	Status
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	An adequate and well-controlled clinical trial of safety and efficacy of Venofer in the treatment of iron deficiency in children (aged 2 to 12 years) who are on hemodialysis and receive epoetin (Use of an active control, such as an oral iron, or dose ranging comparison should be considered in designing this study). PMC was subsequently renumbered as PMC 428-3	21-135	11/6/2000 and 6/17/2005	9/21/2012	Fulfilled
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Deferred pediatric study under PREA for a pharmacokinetic study of Venofer administration to adolescent non-dialysis-dependent chronic kidney disease (NDD-CKD) patients greater than or equal to 12 years to less than 16 years of age, receiving or not receiving erythropoietin. PMR was subsequently renumbered as PMR 852-1	21-135	11/6/2000 and 6/17/2005	9/21/2012	Fulfilled
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Deferred pediatric study under PREA for the treatment of iron deficiency anemia in non-dialysis-dependent chronic kidney disease (NDD-CKD) pediatric patients ages greater than or equal to two years to less than 12 years receiving or not receiving erythropoietin. (PMR was subsequently renumbered as PMR 852-2)	21-135	11/6/2000 and 6/17/2005	9/21/2012	Fulfilled

Product Compound	Description of Commitment	NDA Number	Agreement Date	Project Completion Date	Status
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Deferred pediatric study under PREA for the treatment of iron deficiency anemia [sic]for hemodialysis dependent-chronic kidney disease (HDD-CKD) patients receiving an erythropoietin in pediatric patients. (PMR was subsequently renumbered as PMR 428-6)	21-135	12/31/2010	9/21/2012	Fulfilled
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Examine the worldwide safety database for Venofer® for occurrence of adverseevents in pediatric patients by age group (neonates, infants, children, adolescents).Attempt to obtain further information on the 5 reported cases of necrotizingenterocolitis in infants, including examination of the safety database for othersimilar cases. No study of Venofer® in neonates and infants is requested at thistime. However, you should address possible need for and risks involved withVenofer® use in very young pediatric patients;	21-135	11/6/2000	12/6/2001	Fulfilled
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Conduct a study to provide additional safety date (e.g., incidence of allergic or anaphylactic reactions, cross-reactivity with other parenteral iron preparations);	21-135	11/6/2000	08/7/2003	Fulfilled
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Develop an in vitro release test for Venofer® and propose specifications.	21-135	11/6/2000	11/2/2004	Fulfilled
Venofer® (Iron Sucrose Injection, USP), 20 mg/mL	Conduct a single-dose, pharmacokinetics study of Venofer following intravenous administration to adolescent hemodialysis patients on epotein	21-135	11/6/2000	12/16/2003	Fulfilled