Press Release

Vifor Pharma and American Regent announce settlement of Injectafer® patent litigation

- **Abbreviated New Drug Application (ANDA) disputes regarding Injectafer® (ferric carboxymaltose) have now been settled**

St. Gallen, Switzerland, and Shirley, N.Y, 20 December 2021 – Vifor Pharma Group and its partner American Regent, Inc., a Daiichi Sankyo Group company, today announced that they have reached settlement agreements with Mylan Laboratories Ltd., and Sandoz, Inc., that resolve the patent litigation brought in response to Abbreviated New Drug Applications seeking approval by the U.S. Food and Drug Administration to market a generic version of Injectafer®.

Under the terms of the settlements, Vifor Pharma and American Regent will grant Mylan Laboratories Ltd., and Sandoz, Inc., licenses to market generic ferric carboxymaltose products in the United States beginning 1 July 2026 (subject to U.S. FDA approval). Details of all settlements are confidential.

“We are pleased to have settled all outstanding patent litigations regarding Injectafer®,” commented Dr. Oliver P. Kronenberg, Group General Counsel of Vifor Pharma. “With these agreements in place, we can continue to focus on addressing the significant remaining unmet medical need to diagnose and appropriately treat iron deficiency anemia to improve lives of U.S. patients, together with our partner American Regent.”

“Injectafer® is an important treatment option for patients with iron deficiency anemia”, said Gretchen Fritz, Chief Legal Officer of American Regent. “American Regent is proud of the innovation and decades of hard work that made this treatment option possible and available to patients in the U.S. We are pleased to resolve the burdens of litigation, and excited for future results of our ongoing robust clinical program for Injectafer®.”

In the US, more than 1.7 million patients have been treated for iron deficiency anemia. Injectafer® has been studied in more than 40 clinical trials that included over 8,800 patients worldwide. Injectafer® has been approved in 83 countries since initial European Union (EU) approval in 2007 and is the most extensively studied intravenous iron.

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About Vifor Pharma Group
Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The

company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).
For more information, please visit viforpharma.com.

About American Regent, Inc.
American Regent, Inc., a Daiichi Sankyo Group company, is a top-10 injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing, and supplying quality generic and branded injectables for healthcare providers. For nearly 20 years, we have been a leader in IV iron therapy. American Regent is committed to U.S.-based manufacturing. In 2018, more than 99% of units supplied were formulated, filled, and finished at our U.S.-based facilities, making us uniquely positioned to quickly mobilize to respond to shortages or changes in market needs. Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need. For more information, please visit www.americanregent.com.

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