

Press  
Release

# VFMCRRP announces positive results of phase-III clinical trial of Velphoro® in China

- Met primary efficacy endpoint of non-inferiority versus sevelamer carbonate
- Velphoro® effective in lowering and maintaining serum phosphorus level
- Safety profile of Velphoro® confirmed
- Submission to the Chinese Center for Drug Evaluation (CDE) anticipated for the end of 2021

**St. Gallen, Switzerland, 30 April 2021** –Vifor Fresenius Medical Care Renal Pharma (VFMCRRP) today announced positive results from a phase-III study in China (PA-CL-CHINA-01), evaluating the efficacy of Velphoro® (PA21) compared to sevelamer carbonate in lowering and maintaining serum phosphorus in adult Chinese patients with chronic kidney disease (CKD) on dialysis after 12 weeks of treatment. The study met its primary endpoint demonstrating non-inferiority versus sevelamer carbonate in the change from baseline in serum phosphorus levels at week 12.

Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma Group commented, “We are delighted by the positive results from the PA-CL-CHINA-01 study, which confirm previous data generated in the US and Europe, and reinforce the potential of Velphoro® as an important new treatment option for dialysis patients with hyperphosphatemia in China where there is a high prevalence of CKD<sup>1</sup>. This is another important step in our geographic expansion and will further strengthen the position of Velphoro® as a global leader in the calcium-free phosphate binder market<sup>2</sup>.”

Importantly, patients who received Velphoro® experienced additional benefits compared to those in the sevelamer control group: Serum phosphorus levels in patients treated with Velphoro® declined faster than in the sevelamer group and the average number of tablets taken daily (3.23) was significantly lower than with sevelamer carbonate (6.31). Safety results were consistent with the known safety profile of Velphoro® with no new safety signal observed in Chinese CKD patients with hyperphosphataemia.

VFMCRRP intends to submit the Chinese New Drug Application to the National Medical Products Administration’s CDE at the end of 2021.

## About the PA-CL-CHINA-01 study

This phase-III study was designed to demonstrate non-inferiority of the change from baseline at week 12 in serum phosphorus between PA21 (Velphoro®) and sevelamer carbonate, and support market expansion of Velphoro® to China. PA-CL-CHINA-01 was an open-label, active-controlled, parallel group, multicenter study with a total of 286 patients randomized: 142 in the Velphoro® arm and 144 in the sevelamer arm. No major protocol deviation related to COVID-19 were reported and no patients were excluded from the Per Protocol Set (PPS) due to COVID-19.

## About Velphoro®

Velphoro® is a non-calcium, iron-based, chewable phosphate binder approved for the control of phosphate levels in the blood of adults with CKD on dialysis. Velphoro® has been launched in over 30 countries, with more than 100,000 patients estimated to use the drug on a yearly basis. In 2020, Velphoro® became a global leader by value in the calcium-free phosphate binder market<sup>2</sup>.

## References:

<sup>1</sup> Zhang et al. Lancet. 2012 Mar 3;379(9818):815-22; Guo et al. Int J Environ Res Public Health 2016; 13: E770; Guo et al. Curr Cardiol Rev. 2013 May; 9(2): 112–122.

<sup>2</sup> Monthly IQVIA MIDAS panel, INSIGHT Health & DN, GERS, DLI, Farminform | 03.2020.

Contact and further information:

**Media Relations**

Nathalie Ponnier  
Global Head Corporate Communications  
+41 79 957 96 73  
[media@viforpharma.com](mailto:media@viforpharma.com)

**Investor Relations**

Julien Vignot  
Head of Investor Relations  
+41 58 851 66 90  
[investors@viforpharma.com](mailto:investors@viforpharma.com)

**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](http://viforpharma.com).