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Vifor Pharma updates PIVOTAL trial results

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The re-analysis of the data revealed a statistically significant improvement in the treatment effects of a higher dose of Venofer® (i.v. iron sucrose) compared with a lower dose.

No difference in the infection rate Further to the announcement on 29 October 2018, Vifor Pharma provides an update to the results of the Proactive IV irOn Therapy in haemodiALysis patients (PIVOTAL) trial. This update was necessitated by identification of a programming error in the original analysis by the investigators.

Re-analysis of the PIVOTAL data by the investigators has revealed that proactive, high-dose Venofer® compared to reactive, low-dose Venofer® resulted in:

• Superiority and statistically significant reduction in the risk of death or major cardiovascular events (P=0.04)

• Fewer myocardial infarctions or fewer hospitalisations for heart failure

• Reduction in recurrent cardiovascular events

• Lower need/use of erythropoiesis-stimulating agents and a lower incidence of blood transfusion

The re-analysis of the data revealed a statistically significant improvement in the treatment effects of a higher dose of Venofer® (i.v. iron sucrose) compared with a lower dose. These results supersede those presented at the High-Impact Clinical Trial session at ASN Kidney Week 2018 and published on The New England Journal of Medicine website, NEJM.org,

on 26 October 2018. The updated results can be viewed on: www.NEJM.org (DOI: 10.1056/NEJMoa1810742). In the updated results, the primary endpoint ? which was the composite of nonfatal myocardial infarction, nonfatal stroke, hospitalisation for heart failure, or death – reached statistically significant superiority (P=0.04) for the proactive, high-dose Venofer® regimen compared with the low-dose Venofer® group. Similarly, the rates of the individual components of fatal or non-fatal myocardial infarction and hospitalisation for heart failure were lower among patients receiving high-dose i.v. iron. Results on deaths, as well as all safety endpoints (vascular access thrombosis, hospitalisation for any cause and for infection), reduction in ESA dose requirements and number of blood transfusions did not differ between the two treatment arms. “The PIVOTAL trial was the first trial to assess optimal dosing strategy of intravenous iron in patients undergoing haemodialysis and demonstrated that exposing those patients to higher doses of iron over time significantly reduced the risk of mortality or major nonfatal cardiovascular events.” said Stefan Schulze, President of the Executive Committee and COO of Vifor Pharma Group. Francesco Locatelli, Professor of Nephrology, Hospital Alessandro Manzoni, Lecco, Italy said, “PIVOTAL was a long-awaited landmark study in nephrology and the results mark a significant milestone in the treatment of Page 2/3 haemodialysis patients. It is expected that the results from this study will impact guidelines and clinical practice for the benefit of these patients.” Javed Butler, Professor of Cardiology, University of Mississippi, Jackson, MS, USA added that “the effect of iron levels on cardiovascular events in haemodialysis patients has previously been given little recognition. The PIVOTAL trial has demonstrated the significant benefits of effective treatment with intravenous iron by improving major cardiovascular outcome parameters in this high risk population.”