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Triferic (ferric pyrophosphate citrate) Clinical Update

Clinical Update: FDA Approves Triferic AVNU (ferric pyrophosphate citrate), Intravenous Formulation of Triferic for Replacement of Iron and Maintenance of Hemoglobin in Hemodialysis Patients.

FDA approval date: March 27, 2020

Triferic is the only FDA-approved therapy in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients during each dialysis treatment. Triferic has a unique and differentiated mechanism of action which has the potential to benefit patients and health care economics. Triferic represents a potential innovative medical advancement in hemodialysis patient iron management– with the potential to become the future standard of care. The Company has two FDA-approved formulations of Triferic (1) Triferic Dialysate and (2) Triferic AVNU. Triferic delivers between 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin). Triferic donates iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood and is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no reports of anaphylaxis in over 1,000,000 patient administrations, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESRD patients.

The U.S. Food and Drug Administration ("FDA") has approved New Drug Application ("NDA") for intravenous formulation of Triferic, Triferic AVNU. With this approval, Triferic AVNU joins Triferic Dialysate as the only FDA-approved products indicated to replace iron and maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. Triferic is a novel, physiologic iron maintenance therapy that provides bioavailable iron to replace iron lost during every dialysis treatment and maintain hemoglobin. While Triferic Dialysate is designed to be administered via liquid bicarbonate, Triferic AVNU is designed for direct intravenous infusion, which provides hemodialysis patients with greater access to the Triferic platform and expands administration options for clinicians. Triferic AVNU can be administered regardless of a dialysis center's mode of bicarbonate delivery. Many dialysis centers in international markets and an increasing number of dialysis centers in the U.S. have converted to the use of dry bicarbonate cartridges or bags and on-line dialysate generation, which is not compatible with Triferic Dialysate. Clinical trials have demonstrated that patients treated with Triferic receive steady and consistent bioavailable iron to replace the iron that is lost at every dialysis treatment and hemoglobin is maintained. Now, even in clinics where delivering Triferic through the dialysate is not operationally possible, Triferic AVNU is an option.