



Hematide™/peginesatide

Hematide™/peginesatide is an investigational (not yet approved for use) erythropoiesis-stimulating agent (ESA) that has been tested in Phase 3 clinical trials for the treatment of anemia associated with chronic renal failure (CRF). The investigational therapy was co-developed by Affymax (Palo Alto, CA) and Takeda (Osaka, Japan).

In contrast to the current standard of care, recombinant protein-based ESAs, Hematide is a novel, synthetic peptide-based ESA that is immunologically distinct from endogenous human erythropoietin (EPO), a protein produced by the kidneys to stimulate the production of oxygen-transporting red blood cells. The most advanced portion of Hematide's clinical development program, the Phase 3 program, consisted of four studies (two in dialysis, two in non-dialysis) involving approximately 2,600 patients across almost 400 clinical sites in U.S. and Europe. These and other well-designed studies in patients with CRF not only evaluated Hematide's ability to manage patients' Hgb with monthly dosing, but also the ability of Hematide to maintain patients' Hgb between the range of 11 to 12 g/dL in non-dialysis patients and 10-12 g/dL in dialysis patients.

While the development of pure red cell aplasia (PRCA) is listed as a potential adverse reaction to currently approved ESAs, Phase 2 Hematide data have shown that Hematide has the potential to increase and maintain Hgb levels in patients who have developed PRCA as a result of ESA use. PRCA is a rare condition in which the body develops neutralizing antibodies to recombinant ESAs that negate the effects of the ESA as well as the body's naturally produced EPO. PRCA often leaves patients severely anemic and reliant on regularly administered blood transfusions and/or immunosuppressant therapy.

Takeda and Affymax are collaborating on the development of Hematide and plan to co-commercialize the product in the United States. The product, upon approval, will be commercialized in the European Union and Japan by Takeda.

Peginesatide is the USAN or nonproprietary name for the compound.