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Therapeutic Class Report Overview - Hemophilia

https://marketpublishers.com/r/T9FB7A2FE8DEN.html
Date: February 2013
Pages: 47
Price: US$ 2,000.00 (Single User License)
ID: T9FB7A2FE8DEN

Abstracts

Hemophilia is an inherited (X-linked recessive trait), lifelong bleeding disorder that prevents blood from clotting due to insufficient or lack of adequate amount of clotting factors – Factor VIII (FVIII) and Factor IX (proteins in blood that control bleeding). Plasma-derived FVIII and FIX proteins were used in the 70's for treating these disorders but transmission of contaminating viruses reduced its use. In 1999, recombinant FVIIIs and FIX, free of viral, animal, or human proteins became the standard of care (SoC). However, frequent injections used for prophylaxis resulted in development of antibodies (called inhibitors – acquired hemophilia or neutralizing abs) to FVIII or FIX. The presence of inhibitors complicated treatment of hemophilia A and B- ~30% in hemophilia A and up to 3 to 5% in hemophilia B pts. The high cost of treatment, frequent dosing, and infusion related adverse events are other concerns.

To address these limitations, companies are developing next generation clotting factors which are more potent – Short Acting or Long Acting Recombinant Factors. These potentially could result in fewer injections, reduce the inhibitor level, and improve compliance. Several of these pipeline products are now poised for approval and launch in the next two-three years. At present, Baxter, Bayer/ CSL, Pfizer, Novo Nordisk dominate the current ~$10b hemophilia market. In this report, we have analyzed the clinical efficacy, safety, and commercial prospects of the late-stage products in development and expect the long acting products that have best clinical and safety data to lead by offering patients better Cost per Quality Adjusted Life Year (QALY).

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