**THE SOLUTION**

This human activated recombinant blood coagulation factor VII (rFVIIa), is a glycoprotein with 406 amino acids and molecular weight of about 50KDa. It is produced in Baby Hamster Kidney cell line (BHK) via recombinant technology and is highly purified to be acceptable as an injectable human drug. This biosimilar medicine is produced under strict cGMP standards and has been fully characterized at the molecular level by several parties, including regulatory and other third party laboratories. It has been found very high bioequivalence to other forms of Factor VII in the market.

Clinical trials conducted with patients suffering from congenital factor VII deficiency showed that there was there was no significant difference in baseline characteristics between two arms in any of the trials. Clinical trials and results were totally comparable with other forms of Factor VII in incrementing serum level of FVII, reducing bleeding events, reducing severity of bleeding and occurrence of adverse events. This was also seen in clinical trials on hemophilia patients with inhibitors; results were again comparable with other forms of Factor VII, based on Kavaki global response scoring system, bleeding episodes, increment in serum level of FVII and occurrence of adverse events.

**COMMERCIAL OPPORTUNITY**

The global bleeding disorder market\(^1\) generated USD8.5 billion in sales in 2011, and is expected to grow to USD11.4 billion by 2016, mainly due to increased use of prophylaxis in developed countries, as well as pharmaceutical companies’ expansion of markets into underserved countries. The bleeding disorder market in the US is dominated by eight pharmaceutical companies. The bleeding disorder market\(^2\) is expected to be able to support some new products, and it’s expected to grow almost 6% yearly—about $500 million—over the next five to ten years. The broader hemophilia market\(^3\) will grow at an average 5.9% rate over the next five years, from $8.5 billion in 2011 to $11.4 billion in 2016. Combined product sales\(^2\) of the three classes of recombinant coagulation factors used in hemophilia treatment was at USD7.172 million in 2012. The pipeline of new recombinant coagulation factors is maturing and the first molecules are under regulatory review by the FDA and the EMA and many have entered pivotal clinical studies. There are 46 different molecules and R&D approaches for novel recombinant coagulation factors for hemophilia A and B in the pipeline of which 24 are in clinical development of under regulatory review.

1 “New Factor Concentrates, The Future is Now!” – Hemophilia of Georgia, August 2013
2 “Recombinant Coagulation Factors 2013 – The Race to Market and for Market Shares: Technology & Pipeline Assessment and Corporate Benchmarking Analysis”
3 "The Hemophilia Market" - Morningstar Healthcare Observer, January 2013

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**SNAPSHOT**

Factor VII is a serine protease class enzyme that is one of the proteins that causes blood to clot in the coagulation cascade. It initiates the process of coagulation in conjunction with tissue factor III (TF III). Recombinant factor VIIa is used for people with hemophilia who have developed inhibitors against replacement coagulation factor. Recombinant human factor VII while initially looking promising in intracerebral hemorrhage failed to show benefit following further study and this is no longer recommended.

The team has thus developed a biosimilar Factor VII that has very promising bioequivalence to the naturally occurring Factor VII.

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