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Recombinant Coagulation Factors 2013 - The Race to Market and for Market Shares: A Technology & Pipeline Assessment and Corporate Benchmarking Analysis

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Abstracts

The report “Recombinant Coagulation Factors 2013 – The Race to Market and for Market Shares: Technology & Pipeline Assessment and Corporate Benchmarking Analysis” of June 2013 describes a market forecast based on growth of historical sales of recombinant coagulation factors. The report evaluates reasons for failures of novel recombinant coagulation factors and provides detailed profiles of active recombinant coagulation factors in clinical development. Preclinical projects are valued on the basis of the underlying technologies. Emerging alternative therapeutic approaches are described and assessed. The detailed target pipeline assessments put emphasis on the competitive situation regarding stage of development, inhibitor profile, half-life, administration frequency, clinical success and especially time to approval/market. The pipelines of the clinically active companies are described and their competitive position assessed in light of the key success factors. Sources of information are LMP’s proprietary database, scientific literature (abstracts, papers), corporate information (press releases, presentations, reports, SEC filings). All information is referenced.

Combined product sales of the three classes olf recombinant coagulation factors used in hemophilia were US$ 7.172 mln 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. Given this tight competition, time-to-market will be an important success. This report will explain the potential development and approval timelines of

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each of the advanced molecules.

What will you find in this report?

Historical sales data of the recombinant coagulation factors VIII, IX, VIIa and II;

Historical growth rates and a 5-year sales forecast of each class of recombinant factors;

Reasons for failure and profiles of failed recombinant coagulation factors;

Detailed profiles of clinical stage recombinant coagulation factors;

Technologies used for creation of novel recombinant coagulation factors;

Preclinical stage recombinant coagulation factors;

New approaches: alternative procoagulants / adjuncts and gene therapy;

Pipeline analysis and assessment for each recombinant coagulation factor class;

Comparative data on clinical inhibitor formation and discussion of its relevance;

Comparison of half-life prolongation and its impact on administration frequency;

Comparison of the time to approval for each clinical stage recombinant coagulation factor;

Company pipeline and competitive position of each major player in the field

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About

Baxter reported total recombinant Factor VIII product sales in 2012 of US$ 2,234 mln for Advate and Recombinate combined. This represents a growth of 1% at actual growth rates compared with the previous year (US$ 2,212 mln). Total 2012 sales of recombinant and plasma-derived hemophilia products of Baxter were US$ 3.2 bln. Additional sales of US$ 0.7 bln were generated by biosurgery products including hemostats and tissue sealants containing human plasma-derived thrombin and/or fibrinogen.

With the 2012 regulatory approval in China, Advate is now available in more than 50 countries worldwide. Sales growth of Advate/Recombinate in 2011/2012 was driven primarily by strong U.S. demand for ADVATE. Sales growth was partially offset by lower tender sales in Australia in 2012 and in the United Kingdom in 2011.

Bayer HealthCare Pharmaceuticals achieved 2012 worldwide sales of Kogenate of € 1,182 mln with a growth of 10% compared with the previous year. US sales were € 332 mln. Growth was mainly driven by good performance in ex-U.S. markets, especially by higher volumes due to tender business in Australia. For 2013, Bayer targets low single-digit sales growth.

Kogenate sales include sales of active ingredient to CSL which has marketing and distribution rights for recombinant F. VIII under its own brand Helixate until 2017. The percentage of Bayer’s Kogenate sales to CSL of total Kogenate sales was 25 % in 2007 and 30 % in 2006. CSL posted calendar year 2012 sales of US$ 501 mln compared with US$ 496 mln in 2011 (+1% vs. previous year).

Pfizer’s recombinant factor VIII known as Xyntha in the US and Refacto in the EU, achieved 2012 sales of US$ 584 mln, 15% higher than in 2011.

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