

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

https://marketpublishers.com/r/RAD4D26BE10EN.html

Date: June 2013

Pages: 129

Price: US\$ 2,767.00 (Single User License)

ID: RAD4D26BE10EN

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



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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Contents

1 EXECUTIVE SUMMARY

2 RECOMBINANT COAGULATION FACTOR MARKETS

- 2.1 Recombinant Factor VIII (rFVIII) Market
 - 2.1.1 rFVIII Product Sales
 - 2.1.2 rFVIII Market Dynamic
- 2.2 Recombinant Factor IX (rFIX) Product Sales and Market Dynamics
- 2.3 Recombinant Factor VII (rFVII) Product Sales and Market Dynamics
- 2.4 Market Size & Dynamics of Recombinant Coagulation Factors in Hemophilia
- 2.5 Total Recombinant Coagulation Factors Market

3 PIPELINE CHANGES & DRUG PROFILES

- 3.1 Discontinued Development of Recombinant Coagulation Factors
 - 3.1.1 BAY 86-6150
 - 3.1.2 Vatreptacog alfa; NN1731; NNC 0078-0000-0007; rFVIIa-DVQ
 - 3.1.3 N7-GP; NN7128 (SC) / NN7129 (IV); NNC 0128-0000-2011; LA-rFVIIa
 - 3.1.4 BAX 499; ARC19499
- 3.2 Active Clinical Development of Recombinant Coagulation Factors
 - 3.2.1 Recombinant factor XIII
 - 3.2.2 Recombinant von Willebrand factor
 - 3.2.3 Wild-type and Biosimilar Recombinant Factor VIII
 - 3.2.4 Long-acting Recombinant factor VIII
 - 3.2.5 Wild-type and Biosimilar Recombinant Factor IX
 - 3.2.6 Long-acting Recombinant Factor IX
 - 3.2.7 Wild-type Recombinant factor VIIa
 - 3.2.8 Long-acting Recombinant factor VIIa
- 3.3 Non-Clinical Development of Recombinant Coagulation Factors
- 3.4 Technologies and preclinical stage recombinant coagulation factors
 - 3.4.1 Conjugation Technologies
 - 3.4.2 Drug Delivery
 - 3.4.3 Fusion Protein Technologies
 - 3.4.4 Protein Engineering Technologies
 - 3.4.5 Manufacturing & Cell Line Technologies
 - 3.4.6 Biosimilar Recombinant Coagulation Factors
- 3.5 Alternative Procoagulants & Adjuncts



- 3.5 Gene & Cell Therapy of Hemophilia
 - 3.5.1 Hemophilia B Gene Therapy
 - 3.5.2 Hemophilia A Gene Therapy

4 COMPARATIVE TARGET PIPELINE ANALYSIS & ASSESSMENT

- 4.1 Recombinant Factor VIII Pipeline
 - 4.1.1 Clinical Pipeline of Novel Recombinant Factor VIII Molecules
 - 4.1.2 Preclinical Pipeline of Novel Recombinant Factor VIII Molecules
- 4.2 Recombinant Factor IX Pipeline
- 4.3 Recombinant Factor VII Pipeline
- 4.4 Recombinant Fibrinogen and Thrombin Pipeline
- 4.5 Recombinant von Willebrand Factor Pipeline
- 4.6 Recombinant Factor XIII
- 4.7 Alternative Procoagulants & Adjuncts Pipeline
- 4.8 Gene Therapy of Hemophilia

5 CORPORATE BENCHMARK ANALYSIS

- 5.1 Stakeholder Overview
- 5.2 Stakeholders per Company

Baxter

Bayer HealthCare Pharmaceuticals

Biogen Idec

Cangene

Chugai (Roche)

CSL

Green Cross

LFB (rEVO Biologics)

Novo Nordisk

Octapharma

OPKO Health (PROLOR Biotech)

Pfizer

Pharmstandard

5.3 Key Success & Failure Factors

5.4 Opportunities

6 REFERENCES



7 TABLES



Tables

TABLES

- Table 1 Calendar Year Sales of Advate/Recombinate from Baxter
- Table 2 Calendar year Sales of Kogenate (FS) from Bayer
- Table 3 Calendar Year Sales of Helixate from CSL
- Table 4 Calendar Year Sales of ReFacto (AF)/Xyntha from Pfizer
- Table 5 Market Shares of Recombinant Factor VIII Products
- Table 6 Growth of the Recombinant Factor VIII Market
- Table 7 rFVIII Market and Product Growth Rates 2005-2012
- Table 8 Sales of BeneFIX in US\$ mln
- Table 9 Sales of NovoSeven
- Table 10 Total Market Size (US\$ mln) of Rec Coagulation Factors in Hemophilia
- Table 11 Sales of Recothrom
- Table 12 Market Shares of Recombinant Coagulation Factor Classes Tables in the Text
- Table 13 Overview of Competitive Situation of Recombinant Coagulation Factors and
- Novel Therapeutic Approaches for Hemophilia
- Table 14 Pipeline of rFVIII Molecules in Clinical Development
- Table 15 Inhibitor Formation with Clinical Stage rFVIII Molecules
- Table16 Half-life and Administration Frequency of Clinical Stage rFVIII Molecules
- Table 17 Clinical Success of rFVIII Treatment and Prophylaxis
- Table 18 Calculation of Approval Dates of Clinical Stage rFVIII Molecules
- Table 19 Approval Dates of Clinical Stage rFVIII Molecules
- Table 20 Preclinical Stage recombinant Factor VIII Molecules
- Table 21 Clinical Stage Recombinant Factor IX Molecules
- Table 22 Inhibitor Formation with Clinical Stage rFIX Molecules
- Table 23 Half-life and Administration Frequency of Clinical Stage rFIX Molecules
- Table 24 Clinical Success of rFIX Treatment and Prophylaxis
- Table 25 Calculation of Approval Dates of Clinical Stage rFIX Molecules
- Table 26 Approval Dates of Clinical Stage rFIX Molecules
- Table 27 Preclinical Stage recombinant Factor IX Molecules
- Table 28 Clinical Stage Recombinant Factor VIIa Molecules
- Table 29 Half-life and Administration Frequency of Clinical Stage rFVIIa Molecules
- Table 30 Calculation of Approval Dates of Clinical Stage rFIX Molecules
- Table 31 Preclinical Stage recombinant Factor VIIa Molecules
- Table 32 Pipeline of Recombinant Fibrinogen and Thrombin
- Table 33 Pipeline of Recombinant von Willebrand Factor
- Table 34 Pipeline of Recombinant Factor XIII



Table 35 Alternative Procoagulants & Adjuncts

Table 36 Pipeline of Gene Therapy of Hemophilia B

Table 37 Pipeline of Gene Therapy of Hemophilia A

Table 38 Comparative Clinical Portfolio Overview of Major Stakeholders

Table 39 Baxter Coagulation Pipeline

Table 40 Bayer Coagulation Pipeline

Table 41 Biogen Idec Coagulation Pipeline

Table 42 Cangene Coagulation Pipeline

Table 43 Chugai (Roche) Coagulation Pipeline

Table 44 CSL Coagulation Pipeline

Table 45 Green Cross

Table 46 LFB (rEVO Biologics) Coagulation Pipeline

Table 47 Novo Nordisk Coagulation Pipeline

Table 48 Octapharma Coagulation Pipeline

Table 49 OPKO Health (PROLOR Biotech) Coagulation Pipeline

Table 50 Pfizer Coagulation Pipeline

Table 51 Pharmstandard Coagulation Pipeline



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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