Hemophilia A and B Recombinant Factor Replacement Therapy - 5EU Drug Forecast and Market Analysis to 2024

Summary

Congenital Hemophilia A and B are bleeding disorders that are caused by genetic X-linked deficiencies in the blood clotting Factors VIII and IX, respectively. Hemophilia manifests as mild, moderate, or severe inability to form clots, depending upon the endogenous levels of circulating factor in an individual patient. The mainstay of treatment for hemophilia is to replace the missing FVIII or FIX, produced using plasma-derived or recombinant methods. Some patients develop inhibitors to FVIII or FIX treatment and need a bypassing agent, such as FVIIa, to resolve bleeds. Patients of hemophilia A or B often require lifelong treatment to prevent and control bleeding episodes, and this therefore represents a lucrative sales opportunity.

The total market for recombinant hemophilia treatment in the 5EU is expected to grow from approximately $2.08 billion in 2014 to $2.36 billion in 2024. This growth will be driven by increasing rates of recombinant factor replacement therapies across the 5EU countries; in Italy and Spain in particular, where the current rate of prophylactic treatment is relatively low, an increasing proportion of adult patients are getting prophylactic treatments. GlobalData expects moderate and high rates of adoption of the long-acting rFVIII and rFIX therapies, respectively, over the forecast period. However, GlobalData’s primary research indicates that the high annual cost of therapy is of great concern among physicians and regulators in Europe and therefore the opportunities for premium pricing for new therapies will be limited during the forecast period.

*This is an on-demand report and will be delivered within 24 hrs. (excluding weekends) of the
purchase.

Scope

- Overview of Hemophilia A and B including epidemiology, etiology, symptoms, diagnosis, pathology and treatment guidelines as well as an overview on the competitive landscape.
- Detailed information on the key drugs in 5EU including product description, safety and efficacy profiles as well as a SWOT analysis.
- Sales forecast for the top drugs in 5EU from 2014-2024.
- Analysis of the impact of key events as well the drivers and restraints affecting 5EU Hemophilia A and B market.

Reasons to buy

- Understand and capitalize by identifying products that are most likely to ensure a robust return
- Stay ahead of the competition by understanding the changing competitive landscape for Hemophilia A and B.
- Effectively plan your M&A and partnership strategies by identifying drugs with the most promising sales potential
- Make more informed business decisions from insightful and in-depth analysis of drug performance
- Obtain sales forecast for drugs from 2014-2024 in 5EU.

Table Of Contents:

1 Table of Contents
1.1 List of Tables
1.2 List of Figures
2 Introduction
2.1 Catalyst
2.2 Related Reports
2.3 Upcoming Related Reports
3 Disease Overview
3.1 Etiology and Pathophysiology
3.1.1 Etiology
3.1.2 Pathophysiology
3.1.3 Prognosis and Quality of Life
3.2 Symptoms
3.2.1 Hemophilia A and B
3.2.2 Inhibitors
4 Disease Management
4.1 Treatment Overview
4.1.1 Hemophilia A and B Diagnosis
4.1.2 Hemophilia A and B Treatment
4.1.3 Diagnosis of Inhibitors
4.1.4 Treatment of Inhibitors
4.2 France
4.2.1 Clinical Practice
4.3 Germany
4.3.1 Clinical Practice
4.4 Italy
4.4.1 Clinical Practice
4.5 Spain
4.5.1 Clinical Practice
4.6 UK
4.6.1 Clinical Practice
5 Competitive Assessment
5.1 Overview
5.2 Strategic Competitive Assessment
5.3 Product Profiles - Hemophilia A
5.3.1 Advate (Octocog Alfa)
5.3.2 Kogenate FS/Helixate FS (Octocog Alfa)
5.3.3 Xyntha/ReFacto AF (Moroctocog Alfa)
5.3.4 Recombinate (Octocog Alfa)
5.3.5 Eloctate (Efmoroctocog Alfa)
5.3.6 NovoEight (Turoctocog Alfa)
5.3.7 Nuwiq (Simoctocog Alfa)
5.4 Product Profiles - Hemophilia B
5.4.1 BeneFIX (Nonacog Alfa)
5.4.2 Alprolix (Eftrenonacog Alfa)
5.4.3 Rixubis (Nonacog Gamma)
5.4.4 IXinity (Trenonacog Alfa)
5.5 Product Profiles - Hemophilia A and B with Inhibitors
5.5.1 NovoSeven RT (Eptacog Alfa)
6 Unmet Need and Opportunity
6.1 Overview
6.2 Opportunity Analysis
6.2.1 Longer-Lasting Recombinant Factors
6.2.2 Lower-Cost Recombinant Replacement Therapies
6.2.3 Lower Risk of Inhibitor Formation in Previously Untreated Patients
6.2.4 More Convenient Drug Administration
6.3 Unmet Needs Gap Analysis
6.3.1 Long-Acting FVIII Replacement Therapies
6.3.2 Gene Therapy Treatments for Hemophilia A and B

7 Pipeline Assessment

7.1 Overview

7.2 Late-Stage Development Candidates - Hemophilia A

7.2.1 Kovaltry (Octocog Alfa; BAY 81-8973)

7.2.2 Adynovate (BAX-855)

7.2.3 BAY 94-9027 (Damocctog Alfa Pegol)

7.2.4 N8-GP (Turoctog Alfa Pegol)

7.2.5 CSL-627 (rFVIII-SC)

7.2.6 GreenGene F (Berocctocog Alfa; GC1101C)

7.3 Late-Stage Development Candidates - Hemophilia B

7.3.1 CSL-654 (rIX-FP; Albutrepenacog Alfa)

7.3.2 N9-GP (NN-7999; Nonacog Beta Pegol)

7.4 Late-Stage Development Candidates - Hemophilia A and B Bypassing Agents (Patients with Inhibitors)

7.4.1 BAX-817 (rFVIIa BI)

7.4.2 LR-769 (rhFVIIa)

7.4.3 CSL-689 (rVIIa-FP)

7.5 Promising Drugs in Early-Stage Development

7.5.1 Alternative Coagulation Promoters

7.5.2 Gene Therapies

8 Market Outlook

8.1 France

8.1.1 Clinical Practice

8.2 Germany

8.2.1 Clinical Practice

8.3 Italy

8.3.1 Clinical Practice

8.4 Spain

8.4.1 Clinical Practice

8.5 UK

8.5.1 Clinical Practice

9 Appendix

9.1 Bibliography

9.2 Abbreviations

9.3 Methodology

9.4 Forecasting Methodology

9.4.1 Diagnosed Hemophilia Patients

9.4.2 Percent Drug-Treated Patients

9.4.3 Drugs Included in Each Therapeutic Class
9.4.4 Launch Dates
9.4.5 General Pricing Assumptions
9.4.6 Individual Drug Assumptions
9.4.7 Pricing of Pipeline Agents
9.5 Primary Research - KOLs Interviewed for this Report
9.6 Primary Research - Prescriber Survey
9.7 Real-World Data
9.8 About the Authors
9.8.1 Analyst
9.8.2 Therapy Area Director
9.8.3 Epidemiologists
9.8.4 Global Head of Healthcare
9.9 About GlobalData
9.10 Disclaimer

1.1 List of Tables
Table 1: Symptoms of Hemophilia A and B
Table 2: Most Prescribed Hemophilia A and B Drugs in the Global Markets, 2015
Table 3: Country Profile - France, 2014
Table 4: Country Profile - Germany, 2014
Table 5: Country Profile - Italy, 2014
Table 6: Country Profile - Spain, 2014
Table 7: Country Profile - UK, 2014
Table 8: Leading Recombinant Replacement Therapies for Hemophilia A and B and Patients with Inhibitors, 2015
Table 9: Product Profile - Advate
Table 10: Advate SWOT Analysis, 2015
Table 11: Global Sales Forecast ($m) for Advate, 2014-2024
Table 12: Product Profile - Kogenate FS/Helixate FS
Table 13: Kogenate FS/Helixate FS SWOT Analysis, 2015
Table 14: Global Sales Forecast ($m) for Kogenate FS/Kogenate Bayer, 2014-2024
Table 15: Global Sales Forecast ($m) for Helixate FS/Helixate NexGen, 2014-2024
Table 16: Product Profile - Xyntha/ReFacto AF
Table 17: Xyntha/ReFacto AF SWOT Analysis, 2015
Table 18: Global Sales Forecast ($m) for Xyntha/ReFacto AF, 2014-2024
Table 19: Product Profile - Recombinate
Table 20: Recombinate SWOT Analysis, 2015
Table 21: Global Sales Forecast ($m) for Recombinate, 2014-2024
Table 22: Product Profile - Eloctate
Table 23: Eloctate SWOT Analysis, 2015
Table 24: Global Sales Forecast ($m) for Eloctate, 2014-2024
Table 25: Product Profile - NovoEight
Table 26: NovoEight SWOT Analysis, 2015
Table 27: Global Sales Forecast ($m) for NovoEight, 2014-2024
Table 28: Product Profile - Nuwiq
Table 29: Nuwiq SWOT Analysis, 2015
Table 30: Global Sales Forecast ($m) for Nuwiq, 2014-2024
Table 31: Product Profile - BeneFIX
Table 32: BeneFIX SWOT Analysis, 2015
Table 33: Global Sales Forecast ($m) for BeneFIX, 2014-2024
Table 34: Product Profile - Alprolix
Table 35: Alprolix SWOT Analysis, 2015
Table 36: Global Sales Forecast ($m) for Alprolix, 2014-2024
Table 37: Product Profile - Rixubis
Table 38: Rixubis SWOT Analysis, 2015
Table 39: Global Sales Forecast ($m) for Rixubis, 2014-2024
Table 40: Product Profile - IXinity
Table 41: IXinity SWOT Analysis, 2015
Table 42: Global Sales Forecast ($m) for IXinity, 2014-2024
Table 43: Product Profile - NovoSeven RT
Table 44: NovoSeven RT SWOT Analysis, 2015
Table 45: Overall Unmet Needs - Current Level of Attainment
Table 46: Hemophilia A - Phase III Pipeline, 2015
Table 47: Product Profile - Kovaltry
Table 48: Kovaltry SWOT Analysis, 2015
Table 49: Global Sales Forecast ($m) for Kovaltry, 2014-2024
Table 50: Product Profile - Adynovate
Table 51: Adynovate SWOT Analysis, 2015
Table 52: Global Sales Forecast ($m) for Adynovate, 2014-2024
Table 53: Product Profile - BAY 94-9027
Table 54: Efficacy of BAY 94-9027 in the PROTECT VIII study
Table 55: BAY 94-9027 SWOT Analysis, 2015
Table 56: Global Sales Forecast ($m) for BAY 94-9027, 2014-2024
Table 57: Product Profile - N8-GP
Table 58: N8-GP SWOT Analysis, 2015
Table 59: Global Sales Forecast ($m) for N8-GP, 2014-2024
Table 60: Product Profile - CSL-627
Table 61: CSL-627 SWOT Analysis, 2015
Table 62: Global Sales Forecast ($m) for CSL-627, 2014-2024
Table 64: Product Profile - GreenGene F
Table 65: GreenGene F SWOT Analysis, 2015
Table 66: Global Sales Forecast ($m) for GreenGene F, 2014-2024
Table 67: Hemophilia B - Phase III Pipeline, 2015
Table 68: Product Profile - CSL-654
Table 69: CSL-654 SWOT Analysis, 2015
Table 70: Global Sales Forecast ($m) for CSL-654, 2014-2024
Table 71: Product Profile - N9-GP
Table 72: N9-GP SWOT Analysis, 2015
Table 73: Global Sales Forecast ($m) for N9-GP, 2014-2024
Table 74: Hemophilia A and B with Inhibitors - Phase III Pipeline, 2015
Table 75: Product Profile - BAX-817
Table 76: BAX-817 SWOT Analysis, 2015
Table 77: Global Sales Forecast ($m) for BAX-817, 2014-2024
Table 78: Product Profile - LR-769
Table 79: LR-769 SWOT Analysis, 2015
Table 80: Global Sales Forecast ($m) for LR-769, 2014-2024
Table 81: Product Profile - CSL-689
Table 82: CSL-689 SWOT Analysis, 2015
Table 83: Global Sales Forecast ($m) for CSL-689, 2014-2024
Table 84: Alternative Coagulation Promoters - Early-Stage Pipeline, 2015
Table 85: Hemophilia A and B Gene Therapies - Early-Stage Pipeline, 2015
Table 86: Country Profile - France, 2014
Table 87: Country Profile - Germany, 2014
Table 88: Country Profile - Italy, 2014
Table 89: Country Profile - Spain, 2014
Table 90: Country Profile - UK, 2014
Table 91: Key Launch Dates
Table 92: Physicians Surveyed

1.2 List of Figures
Figure 1: Competitive Assessment of Late-Stage Pipeline Agents in Hemophilia A, 2014-2024
Figure 2: Competitive Assessment of Late-Stage Pipeline Agents in Hemophilia B, 2014-2024
Figure 3: Competitive Assessment of Late-Stage Pipeline Agents for Hemophilia A and B Patients with Inhibitors, 2014-2024

License Types:

Single User License (PDF)

- This license allows for use of a publication by one person.
• This person may print out a single copy of the publication.
• This person can include information given in the publication in presentations and internal reports by providing full copyright credit to the publisher.
• This person cannot share the publication (or any information contained therein) with any other person or persons.
• Unless a Enterprise License is purchased, a Single User License must be purchased for every person that wishes to use the publication within the same organization.
• Customers who infringe these license terms are liable for a Global license fee.

**Site License (PDF)**

• This license allows for use of a publication by all users within one corporate location, e.g. a regional office.
• These users may print out a single copy of the publication.
• These users can include information given in the publication in presentations and internal reports by providing full copyright credit to the publisher.
• These users cannot share the publication (or any information contained therein) with any other person or persons outside the corporate location for which the publication is purchased.
• Unless a Enterprise License is purchased, a Site User License must be purchased for every corporate location by an organization that wishes to use the publication within the same organization.
• Customers who infringe these license terms are liable for a Global license fee.

**Global License (PDF)**

• This license allows for use of a publication by unlimited users within the purchasing organization e.g. all employees of a single company.
• Each of these people may use the publication on any computer, and may print out the report, but may not share the publication (or any information contained therein) with any other person or persons outside of the organization.
• These employees of purchasing organization can include information given in the publication in presentations and internal reports by providing full copyright credit to the publisher.

*If Applicable.

---

**Source URL:** https://www.marketresearchreports.com/globaldata/hemophilia-and-b-recombinant-fator-replacement-therapy-5eu-drug-forecast-and-market
Links
[1] https://www.marketresearchreports.com/countries/europe