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info@marketpublishers.com

Charting the Biosimilar and Biobetter Development Pipeline (2013)

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Abstracts

If you need to understand the important biosimilar and biobetter drug developments worldwide then this report is critical.

The promise of biosimilars has been great but beyond the first wave of products progress has been slow. With a number of high-value biologics, particularly monoclonal antibodies such as Herceptin, Avastin, Remicade and Humira, losing patent expiry in the coming years the potential for biosimilars remains high. With greater clarity on regulatory approval and the demand of health payers for low cost medicines, the drive to develop a viable biosimilar market will continue to grow.

Who are the companies involved? What does their portfolio look like? What stage are they at? Which products offer the best potential in terms of competitor development? Critical questions needing robust answers. That is where Charting the Biosimilar and Biobetter Development Pipeline (2013) comes in.

Scope

Charting the Biosimilar and Biobetter Development Pipeline (2013) will help you to:

Understand the landscape of biosimilar/biobetter development through pipeline analysis of all known biosimilar developers worldwide

Drill down to discover the levels of potential biosimilar and biobetter competition by therapy area, drug class, development status, and country

Establish the level of biosimilar/biobetter competition to leading brands

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Learn which biosimilar developers are potential future competitors or collaborators

Interrogate the development portfolio of over 300 companies and discover which are the leaders in biosimilar/biobetter development

Identify development hotspots and know where research is taking place

NEW FULLY UPDATED EDITION INCLUDES ANALYSIS AND DATAFILE

The massively expanded second edition of this leading drug intelligence report provides a complete, practical and highly-detailed insight into the status of 868 biosimilar/biobetter drugs in development from over 300 companies worldwide. Widely considered to be the most comprehensive analysis of its type, Charting the Biosimilar and Biobetter Development Pipeline (2013) is delivered in two modules:

1. Biosimilar Datafile – New this edition!

Enjoy the practical benefits of a Microsoft Excel file containing data on biosimilar and biobetter drugs currently marketed or known to be in clinical development worldwide. Each drug can be seen in the context of data on their biologic reference products and content can readily be filtered on key indicators such as:

Product Name/Development Code

Developer(s)

HQ Location

Reference Product

Originator Company

Product Type

Stage of Development (US)

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Stage of Development (EU)

Therapy Area

EU Patent Expiry

US Patent Expiry

Brand Name (reference products)

Sales Value (reference products)

Using the tables provided you can effortlessly drill down into the content to identify biosimilars/biobetters in development by country, company, ATC classification, stage of development therapeutic area. Better still, the data can easily be exported to your own analytics or competitive intelligence system.

2. Biosimilar Development Analysis Report

This completely updated and expanded report volume utilises the Datafile content to produce more than 200 clear tables, charts, graphs and maps to provide “at a glance” insights into high-level trends and significant developments. Areas covered include:

Leading biosimilar companies - number of biosimilar products in portfolio

Geographic distribution of biosimilar/biobetter research

Biosimilar development pipelines by 14 compound class and therapy areas

Biosimilar development pipelines by therapy area

Biobetter developments by compound class and therapy area

Biobetters in development by 13 therapy areas

Who should read this report?

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Product managers at pharma/biotech companies with original biologics:

Identify how many biosimilars versions of your products are being developed and by whom

Product managers at biosimilar developers:

Know how many biosimilars are being developed in different therapy areas or of different originator products so that you can identify opportunity gaps/areas with less competition

Heads of licensing at pharma/biotech companies: Use the database to identify biosimilars developers that may want to license in/out their products – whilst also assessing the competitive environment for any products that they may currently license.

Investment managers at venture capital firms, seed funding bodies and investment banks:

Assess the investment potential of companies and their development pipelines: the risks are high but potential reward is great for those that bring product to market.

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About

Patent data shows that in the US 20 reference biologics have already lost patent protection, which would allow for potential market entry of biosimilars as soon as the pathway is completely finalised. This would allow for as many as 98 biosimilars which are in development to enter the market.

Harvest Moon Pharmaceuticals based in the US has the largest number of biosimilars in development. It specialises in licensing-in biosimilar products from other players based in the emerging markets and then gaining approval for them in regulated markets where they are licensed-out to local players – effectively making it a ‘middle man’.

Currently no biosimilar insulins have been approved in the EU, although there are many in development with involvement of some of Pharma’s largest companies including Eli Lilly and Pfizer. Only one company has so far filed for marketing approval of a biosimilar insulin in the EU but it was unsuccessful: Marvel LifeSciences filed for approval in 2007 claiming that its product was similar to Eli Lilly’s Humulin; the application was withdrawn after the EMA raised several questions relating to trial design and practice.

Anti-anaemic preparations has the joint greatest number of biosimilars in development of all the ATC classes (with the Gonadotropins (G03GD)), with 65 biosimilars in development or already marketed. The majority of the reference products in this ATC class have already lost patent protection and within the EU the first biosimilar erythropoietins were approved for marketing in the EU in August 2007 with three epoetin alfas from Sandoz, Hexal and Medice Arzneimettel gaining approval.

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