+357 96 030922
info@marketpublishers.com

The Future of Biobetters

https://marketpublishers.com/r/FBAF50A4467EN.html
Date: March 2017
Pages: 0
Price: US$ 2,245.00 (Single User License)
ID: FBAF50A4467EN

Abstracts

Strategies for success in the biobetter market

How can you successfully position biobetter products in the increasingly crowded branded biologic/biosimilar space?

With the prospect of improving patient adherence, meeting unmet clinical need and increasing revenues, investment in the biobetter pipeline has grown rapidly. Yet biobetter products need to bring some serious clinical and cost saving advantages if they are to get stakeholder support and make a return on investment. Success depends on navigating an undefined regulatory pathway, avoiding IP minefields and ultimately persuading stakeholders that the benefits are worth the cost.

Report Overview

In The Future of Biobetters, senior industry experts from leading pharma companies and organisations identify the challenges facing this emerging sector and provide practical and actionable insights for achieving commercial success.

Report Features

- Unique insights from US and EU experts in companies such as Takeda, Eisai and MedImmune
- Table showing the technologies that can be applied in biobetter development
- Graph illustrating EU5+US sales of key biologics scheduled to lose patent protection in 2015-2020

+357 96 030922
info@marketpublishers.com

Chart demonstrating how biobetter development requires more analytical capabilities versus originator biologic development

Case Study: Developing a biobetter before an originator's patent expiry: lessons from Roche

Case Study: Pulling potential biobetters out of the freezer: Takeda Oncology using advanced technology to reinvigorate a failed biologic projects

Case Study: Competition between biobetters: Amgen and Teva go head-to-head

Case Study: How overpricing of biobetters can make stakeholders lose trust in a company: Vertex Pharmaceuticals Orkambi experience

At-a-glance summaries of all the key takeaways.

Key Benefits

Identify the advantages of biobetters, the value they present, and their competitive position in the branded biologic/biosimilar market

Examine how biobetters can meet unmet clinical need and improve patient outcomes

Understand the current regulatory situation and how this is impacting biobetter development

Investigate potential intellectual property issues that may challenge the sector

Critically appraise biobetter pricing and identify factors that will deliver optimum returns

Assess the potential for advances in technology and analytical tools to reinvigorate previously failed biologic projects

What's in a name?

+357 96 030922
info@marketpublishers.com

No one can agree exactly what a biobetter is. For some, it is a better safety profile, for others it is improved formulations and dosages that improve patient convenience and compliance. Biosuperior protein therapeutics is a definition preferred by others. Despite being sandwiched between originator biologics and biosimiliars, and with no standardised regulatory definition, the biobetter sector is carving out a significant market niche and attracting considerable investment and interest.

Key Questions Answered By This Report

Biobetters: what does “better” actually mean?

Timing: when is the optimum time to launch a biobetter for maximum market traction?

Targeting: What are the therapy areas of high unmet clinical need for biobetters to target?

Pricing: What are the critical clinical and patient benefits biobetters must have to command wide adoption and premium prices?

Old dog, new trick: How did Millennium Pharmaceuticals (Takeda Oncology) use advanced technology to create Entyvio (vedolizumab) from a previously failed biologic research project?

IP minefield: What IP issues should developers of biobetters be alert to?

Regulation: How is the lack of a standardised definition and regulatory guidelines negatively impacting biobetter sector progress?

Expert Views

Each industry expert has been carefully selected for their practical experience and detailed current knowledge of the biobetter sector.

Durgaprasad Annavajjula serves as the Senior Vice President of Stelis Biopharma in the Bengaluru area of India. He is a biopharma research and development senior leader and scientist, with over 25 years of extensive experience in R&D of biopharmaceuticals

+357 96 030922
info@marketpublishers.com

Manfred Kurz is responsible for Global Regulatory Affairs (EU) development at Eisai EMEA, based in the UK. He manages the development and regulatory approval of new anti-cancer medicines

Dr. Matt Cooper is the Business Development & Marketing Director at the National Institute for Health Research (NIHR,) Clinical Research Network (CRN), Coordinating Centre in the UK

Phil Morton, Science Director of Bioprocess Characterisation with Albumedix, in the UK, has over 20 years experience in the biopharmaceutical industry within process and product development

Dr. T. Shantha Raju currently holds the position of Senior Director at MedImmune, Maryland, as the Head of Global Bioassay and Quality. His most significant contribution is his research conducted to develop leading cancer therapeutics, such as Rituxan, Herceptin, Avastin, Remicade, and Simponi

Theresa O'Keefe is the Chief Scientific Officer and Co-Founder at Mend Therapeutics in Massachusetts. Dr. O'Keefe has over 15 years of biotechnology and pharma drug development experience, as well as 10 years in academic research

Oleksandr Karpenko, Consultant Global Safety Lead (Medical Director) based at Takeda Pharmaceuticals in London.

Anonymous. After having worked for over 20 years in a major pharmaceutical company that developed biobetters, this contributor is now a Director of an International Consultancy company on Biopharmaceuticals

Anonymous. The analytics lead at a leading biopharmaceutical company.

3 Key Quotes

"If the company developing the biobetter has correctly identified the unmet need associated with the originator, and the unmet need is seen as a significant failing by either the healthcare provider or the patients, then biobetters can be seen as a significantly differentiated product. Market share will depend very much on the improvements and safety profile of the biobetter versus the originator. If these are significant then it may be possible to take a very high market share."Phil Morton, Science Director of Bioprocess Characterisation at Albumedix

+357 96 030922
info@marketpublishers.com

“For example, a patient may be given a once-daily biologic in the first line therapy, a choice that is made because the biologic is well established and has a long history of use. If the first line biologic does not work, it will be unlikely that patients will be given the biobetter version since it has the same mechanism of action. As such, unless the biobetter offers enough to displace the use of the innovator original, then it will be a commercial struggle” Anonymous,Analytics Lead at a leading biopharmaceutical company

“They are two different businesses. Their target markets and pricing strategies can differ. In the biosimilar business, the main criterion is to increase the treatment accessibility by reducing the cost. Emerging markets and the Rest-of-the-World are the markets that biosimilars have good potential to grow, whereas regulated markets such as the US, Europe, Japan, Australia and New Zealand have good potential for biobetters. There is a business opportunity for both, separately” Durgaprasad Annavajjula ,Senior Vice President at Stelis Biopharma

Who Would Benefit from This Report?

Managers planning biobetter development programmes

HEOR teams building evidence of value for biobetter therapies

MSL teams needing to demonstrate the clinical advantages of biobetters to physicians

Commercial teams negotiating price and formulary position with payers

Regulatory professionals needing to navigate the as yet undefined submission and review pathways

Research managers designing biobetter clinical trials

Corporate managers needing to make strategic investment decisions in the biobetter market

Content Highlights

+357 96 030922
info@marketpublishers.com

Executive Summary & Experts interviewed

The emergence of biobetters

The biosimilar struggle

Introducing biobetters

Biobetters vs. biosimilars

The biobetter advantage

Marketing acceptance of biobetters

Key Insights

Expanding treatment options

Delivering convenience to patients

The risk for increased safety issues

Formulary preference for cheaper biologic alternatives

The implications of competing with originators and biosimilars

Key Insights

Biobetters versus originators

An opportunity to lower healthcare cost versus originators

An opportunity to generate manufacturing efficiency and quicker time-to-market for drug developers

More robust pre-trial analytical capabilities are required

Biobetters versus biosimilars

+357 96 030922
info@marketpublishers.com

Competing in terms of price will be a challenge

Addressing different patient types and populations

Timing the market entrance of a biobetter with respect to biosimilars

Challenges in biobetter development and uptake

Key Insights

Lack of a standardised definition and regulatory guidelines

The potential rise of intellectual property (IP) issues and competitor biobetters

The impact of market perception on clinical trial recruitment

Limited resources and the pressure to excel in the market

Putting a price on the value of biobetters

Key Insights

The issue of expensive pricing

A premium price for significant improvements in efficacy and safety

Lowered cost and other considerations during the valuation process

Strategies for future opportunities in the biobetter space

Key Insights

Seeking to address an unmet need

Mapping the safety data and the clinical trial design

Partnerships with biotech firms and research organisations

Early engagement with stakeholders: KOLs, Clinicians and Payers

+357 96 030922
info@marketpublishers.com

Predictions for biobetter development

Key Insights

About FirstWord

FirstWord is an innovative industry intelligence leader serving over 240,000 Pharma and MedTech professionals worldwide. FirstWord offers a range of products and services designed to help your company gain a competitive edge by making key business decisions with speed and confidence.

FirstWord Pharma PLUS is a personalised and comprehensive intelligence service delivering up-to-the-minute pharma news, insight, analysis and expert views of importance to your company’s success.

FirstWord Reports deliver timely, need-to-know intelligence about your products, your competitors and your markets. Covering biosimilars, market access, medical affairs, sales & marketing, technology and therapy areas, FirstWord Reports provide expert views and intelligence on the challenges facing pharma today.

+357 96 030922
info@marketpublishers.com

Contents

1. EXECUTIVE SUMMARY

2. EXPERTS INTERVIEWED

3. THE LANDSCAPE OF BIOLOGICAL MEDICINES

3.1 The case for biological alternatives
3.2 Introducing biobetters
3.3 Biobetters vs. biosimilars
3.4 The biobetter advantage

4. MARKETING ACCEPTANCE OF BIOBETTERS

4.1 Key Insights
4.2 Expanding treatment options
4.3 Delivering convenience to patients
4.4 The risk for increased safety issues
4.5 Formulary preference for cheaper biologic alternatives

5. SWOT ANALYSIS

6. THE IMPLICATIONS OF COMPETING WITH ORIGINATORS AND BIOSIMILARS

6.1 Key Insights
6.2 Biobetters versus biologics
  6.2.1 An opportunity to lower healthcare cost versus originators
  6.2.2 An opportunity to generate manufacturing efficiency and quicker time to-market for drug developers
  6.2.3 More robust pre-trial analytical capabilities are required
6.3 Biobetters versus biosimilars
6.4 Competing in terms of price will be a challenge
6.5 Addressing different patient types and populations
6.6 Timing the market entrance of a biobetter with respect to biosimilars

7. CHALLENGES IN BIOBETTER DEVELOPMENT AND UPTAKE

7.1 Key Insights

+357 96 030922
info@marketpublishers.com

7.2 Lack of a standardised definition and regulatory guidelines
7.3 The potential rise of issues relating to intellectual property (IP)
7.4 The impact of market perception on clinical trial recruitment
7.5 Limited resources and the pressure to excel in the market

8. PUTTING A PRICE ON THE VALUE OF BIOBETTERS

8.1 Key Insights
8.2 The issue of expensive pricing
8.3 A premium price for significant improvements in efficacy and safety
8.4 Lowered cost and other considerations during the valuation process

9. FUTURE OPPORTUNITIES IN THE BIOBETTER SPACE

9.1 Key Insights
9.2 Seeking to address an unmet need
9.3 Mapping the safety data and the clinical trial design
9.4 Partnerships with biotech firms and research organisations
9.5 Early engagement with stakeholders
  9.5.1 KOLs
  9.5.2 Clinicians
  9.5.3 Payers

10. PREDICTIONS FOR BIOBETTER DEVELOPMENT

10.1 Key Insights

11. CONCLUSION

12. APPENDIX

+357 96 030922
info@marketpublishers.com

I would like to order

Product name: The Future of Biobetters

Product link: https://marketpublishers.com/r/FBAF50A4467EN.html

Price: US$ 2,245.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:
info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page https://marketpublishers.com/r/FBAF50A4467EN.html