

# **Biobetters: Major Players and Market Prospects (2nd edition)**

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## **Abstracts**

Marketing gimmick or natural evolution?

For some, biobetters—drugs similar but superior to the branded reference product—are little more than the natural outcome of a drug's life-cycle management strategy.

Even so, interest in biobetters is increasing, since they can and will command higher prices while providing a significant improvement to the reference drug. At the forefront of those turning to biobetters are branded pharma, biotech and large generic companies who have already established themselves in the biosimilars industry. But will the emerging biobetter industry prove to be more lucrative than has been the case for biosimilars?

## **Scope**

In *Biobetters: Major Players and Market Prospects (2nd edition)*, FirstWord describes the biobetters market and how interest has mounted in what is still a very young market. The report reviews the role biosimilars have played, presents the rationale behind biobetters and how interest is stirring in their development. In addition, the report concisely outlines how companies are evolving biobetters, the areas of greatest potential and reviews the 'Achilles Heel' of immunogenicity. Based on frontline expert interviews, the report addresses the question of approval pathways, who the major players are and, perhaps most importantly, offers a compelling picture of biobetters' future prospects.

## **Highlights**

A comprehensive overview of the nascent biobetters market and where it is going

An outline of what biobetters are, how they are being developed and what their likely targets are

A discussion of the regulatory landscape

An insight into the biobetters manufacturers of tomorrow

An overview of optimal strategies for success

### **Purchase Reasons**

Access to top expert opinion and insights

Compelling overview of the biobetters industry

Frontline reporting on how it's evolving and who will be the industry leaders

### **Key Questions Asked**

How do second generation biologics vary from biobetters proper?

Will biobetters go through an abbreviated or full new drug approval pathway?

Who will be the pioneers of the biobetter industry and what is spurring their success?

How is interest by third-party manufacturers affecting the development of superior biosimilars?

How is the risk of immunogenicity affecting the case for branded biotech?

What areas of improvement exist for creating improved biobetters?

## Who Should Read This Report

Licensing and Business Development Managers

Sales and Marketing Executives

Strategic Management

Medical Affairs

Regulatory Affairs

New Product Development Managers

Marketing Research

Preclinical and Clinical Development Executives

Intellectual Property Executives

Pricing and Reimbursement Heads

Market Access Executives

## Key quotes

“I think it was just natural to start reminding people that rather than developing a biosimilar and trying to capture a small fraction of a much larger, more established market, take it one better and develop a biologic that has superior properties.”

– David Szymkowski, Senior Director, Biotherapeutics, Xencor Inc

“Anything that includes a modification of an innovator molecule is, by definition, a biobetter. However, it has to have a real therapeutic benefit to the patient. It has to have a significant advantage over its predecessor to be really classified as a biobetter.”

– Jesus Zurdo, Head of Innovation, Lonza Biologics

“Some products that are described as biobetters may be indistinguishable from a completely novel product. The concept of a specific abbreviated pathway intended for

biobetters does not make sense to regulators.”

– Dr Sandy Eisnen, former Chief Medical Officer, Teva

## **Expert Views**

Dr Sandy Eisnen, formerly Chief Medical Officer at Teva

Dr Jesus Zurdo, Head of Innovation at Lonza Biologics

Dr David Szymkowski, Senior Director of Biotherapeutics at Xencor Inc.

Ronald A. Rader, President of Biotechnology Information Institute

In addition to an Indian Biotech executive, an executive at a major US generic company, a Development Director of a specialist Biotech company, and a Senior Manager at a biotech manufacturer.

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‘Biobetters’ already on the market

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- Half-life extension and pegylation

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- Monoclonal antibodies could be improved upon

- Oncology could be a growth area for biobetters

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- Prediction is a risky game

- Clinical trials as the current gold-standard for immunogenicity testing

Biobetters – the route to market

- The full approval pathway beckons for biobetters

- Data package requirements could vary

- Clinical trial requirements likely to be biobetter specific

  - The bar for regulatory approval could be higher

  - ...but the risks are lower

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Manufacturing costs will have minimal impact on biobetter success

Stakeholder distrust in the short-term could restrict Asian biobetter success

## **CONCLUSION**

## **ACKNOWLEDGEMENTS**

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