

## Risk – Reward of Developing a Herceptin Biosimilar – A Thorough Assessment

Description: Herceptin exclusivity is expiring in major geographies and many Biosimilar players (both experienced and new entrant) are looking to have a share of this potential \$6billion pie. Herceptin sales are critical to Roche as it comprise about 15% of its cumulative Pharma sales. While eyeing for this potential lucrative opportunity, there are several risks and barriers that Biosimilar players should be aware. The report – “Risk – Reward of Developing a Herceptin biosimilar – A thorough assessment” looks into several aspects of potential opportunity size for Biosimilar players, with regard to:

- European Experience of Biosimilars
- Current market positioning of Herceptin across geography
- Different technologies deployed by biosimilar players
- Competition – Pipeline of Biosimilar and Biobetters targeting Herceptin
- Potential Market Expansion post expiry of Market Exclusivity
- Defense Strategies deployed by Roche
- Ongoing Clinical trials and their impact on Market Opportunity
- Global Regulatory Process and Hurdles
- Risk/Reward profile of developing Herceptin biosimilar

Contents:

1. Executive Summary
2. European experience of Biosimilar launch
  - Pricing
  - Market share dynamics
3. Introduction- Herceptin
  - Geography-wise Sales Forecast until patent expiry
  - Patent expiries in major geographies
  - Pricing in major geographies
  - Penetration in major emerging markets
  - Expected market expansion post patent expiry
  - Ongoing Clinical trials on Herceptin
4. About the biosimilar space
  - Different technologies deployed by biosimilar players
  - Partnering deals in biosimilar
  - Cost of developing biosimilar/biobetter
  - Comparison USFDA and EUROPE biosimilar guideline
  - Requirement of Analytical methods
  - Interchangeability and substitution
  - Regulatory review process for biosimilar- Principle and Concepts
  - Bridging Studies- A way to reduce the launch timeline in multiple geographies
  - Importance of post-marketing safety in Non-ICH countries
  - A brief on biosimilar approval guidelines in geographies other than US and Europe
5. Pipeline of Herceptin Biosimilar and Biobetters
  - Ongoing Clinical trials on Herceptin biosimilar/biobetter
  - A brief on companies developing Herceptin biosimilar

- Financial capability
- Technical capability

## 6. Opportunities and Threats for Herceptin Biosimilar

- Defense strategy by Roche to woo away biosimilar threat in global markets and Emerging markets
- Major clinical trials on Herceptin- potential impact on its future sales
- Physician's and Payers adaptation for using Biosimilar Mab
- Competitive threats - Upcoming biobetters and novel biologics in HER2+ve Breast cancer and Gastric cancer

## 7. Our view on Risk/Reward profile of developing Herceptin Biosimilar

### 8. About the biosimilar space

- Different technologies deployed by biosimilar players
- Partnering deals in biosimilar
- Cost of developing biosimilar/biobetter
- Comparison USFDA and EUROPE biosimilar guideline
- Requirement of Analytical methods
- Interchangeability and substitution
- Regulatory review process for biosimilar- Principle and Concepts
- Bridging Studies- A way to reduce the launch timeline in multiple geographies
- Importance of post-marketing safety in Non-ICH countries
- A brief on biosimilar approval guidelines in geographies other than US and Europe

### 9. Pipeline of Herceptin Biosimilar and Biobetters

- Ongoing Clinical trials on Herceptin biosimilar/biobetter
- A brief on companies developing Herceptin biosimilar
- Financial capability
- Technical capability

Ordering:

Order Online - <http://www.researchandmarkets.com/reports/2228908/>

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,  
Guinness Centre,  
Taylors Lane,  
Dublin 8,  
Ireland.

## Fax Order Form

To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit

<http://www.researchandmarkets.com/contact/>

## Order Information

Please verify that the product information is correct and select the format(s) you require.

Product Name: Risk – Reward of Developing a Herceptin Biosimilar – A Thorough Assessment  
Web Address: <http://www.researchandmarkets.com/reports/2228908/>  
Office Code: OC8DIRROLTVTVZ

## Product Formats

Please select the product formats and quantity you require:

	Quantity	
Electronic (PDF) - Single User:	<input type="checkbox"/>	€1,490
Electronic (PDF) - Site License:	<input type="checkbox"/>	€2,979
Electronic (PDF) - Enterprisewide:	<input type="checkbox"/>	€4,469

## Contact Information

Please enter all the information below in **BLOCK CAPITALS**

Title: Mr  Mrs  Dr  Miss  Ms  Prof

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Email Address: \* \_\_\_\_\_

Job Title: \_\_\_\_\_

Organisation: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

Postal / Zip Code: \_\_\_\_\_

Country: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

\* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)

**Payment Information**

Please indicate the payment method you would like to use by selecting the appropriate box.

- Pay by credit card:
  - American Express
  - Diners Club
  - Master Card
  - Visa

Cardholder's Name \_\_\_\_\_

Cardholder's Signature \_\_\_\_\_

Expiry Date \_\_\_\_\_ | \_\_\_\_\_

Card Number \_\_\_\_\_

CVV Number \_\_\_\_\_

Issue Date \_\_\_\_\_ | \_\_\_\_\_

(for Diners Club only)

- Pay by check:

Please post the check, accompanied by this form, to:

Research and Markets,  
Guinness Center,  
Taylors Lane,  
Dublin 8,  
Ireland.

- Pay by wire transfer:

Please transfer funds to:

Account number	833 130 83
Sort code	98-53-30
Swift code	ULSBIE2D
IBAN number	IE78ULSB98533083313083
Bank Address	Ulster Bank, 27-35 Main Street, Blackrock, Co. Dublin, Ireland.

If you have a Marketing Code please enter it below:

Marketing Code: \_\_\_\_\_

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at <http://www.researchandmarkets.com/info/terms.asp>

**Please fax this form to:**  
**(646) 607-1907 or (646) 964-6609 - From USA**  
**+353-1-481-1716 or +353-1-653-1571 - From Rest of World**