**Profitability Assessment of Branded Generic Inhalers**

**Description:**
This analysis examines the extent to which order of market entry influences the prospects of achieving a satisfactory return on investment for companies developing branded generic and generic inhaled products. The analysis shows that, in some cases, sufficiently attractive financial gains cannot be expected beyond the first few market entrants, as indicated by the appearance of negative net present values for later entrants. This emphasizes the importance of developers paying close attention to, and making frank assessments of, their ability to reach the market ahead of their competitors.

This report addresses the following questions:

- What are the regulatory requirements for approval of generic inhaled products in Europe and the US?
- What market share can manufacturers of generic inhaled products expect to achieve depending on their order of market entry?
- Which branded inhaled products should generic manufacturers target in order to achieve commercial success?
- What factors should generic inhaled product manufacturers assess when deciding on the economic viability of a new product?

An absence of head-to-head trials, along with biosimilar launches, provide payers with leverage to demand favorable pricing for branded products in exchange for formulary access.

This report addresses the following questions:

- What access controls are payers imposing on interleukins in psoriatic arthritis?
- What discounts and market access levers will be required to drive uptake of interleukins and second-generation TNFalpha inhibitors?
- How do US and European payers view the launch of oral small molecules in psoriatic arthritis?
- What impact will biosimilar entry have on pricing and reimbursement of branded biologics?

**Contents:**

1. Executive Summary

2. Introduction
   - Bibliography

3. Regulatory Landscape Review
   - Regulatory pathway in Europe
   - Regulatory pathway in the US
   - Regulatory pathway summary
   - Bibliography

4. Forecasting and Economic Assessment
   - Forecasting approach
   - US: Advair forecast
   - EU: Symbicort and Advair forecast
   - Profit and loss analysis
   - Economic appraisal
   - Bibliography

5. Conclusion

Appendix 1
Appendix 2
Biographies

List of Figures:
Figure 1: Patient flow diagram
Figure 2: Potential uptake curves diagram
Figure 3: Forecast assumptions for Advair Gx/BGx
Figure 4: Forecast assumptions for Symbicort BGx
Figure 5: Forecast assumptions for Advair BGx

List of Tables:
Table 1: Clinical trials conducted to support the approvals of AirFluSal Forspiro, DuoResp Spiromax, and Bufomix Easyhaler
Table 2: FDA guidance for bioequivalent AB-rated Advair generics
Table 3: Comparison of development pathway for Mylan MGR001 vs Teva FS Spiromax
Table 4: Comparison of development pathway for Teva ProAir Spiromax vs SkyePharma Flutiform
Table 5: Zipf market share distribution
Table 6: Clinical trial costs per patient, by phase
Table 7: Costs for clinical trials conducted by Teva for DuoResp Spiromax
Table 8: Device development: a review of respiratory device transactions
Table 9: Advair Gx/BGx US: summary P&L
Table 10: Advair BGx EU: summary P&L
Table 11: Symbicort BGx EU: summary P&L

Ordering:
Order Online - [http://www.researchandmarkets.com/reports/3445974/](http://www.researchandmarkets.com/reports/3445974/)

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: Profitability Assessment of Branded Generic Inhalers
Web Address: http://www.researchandmarkets.com/reports/3445974/
Office Code: SC2G81EK

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Format</th>
<th>Single User Price</th>
<th>Enterprise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF)</td>
<td>USD 5000</td>
<td>USD 17500</td>
</tr>
</tbody>
</table>

* The price quoted above is only valid for 30 days. Please submit your order within that time frame to avail of this price as all prices are subject to change.

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: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ 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