Asthma Pricing, Reimbursement, and Access

Description: Growth in the asthma market will be fueled by the introduction of new and expensive biologics, but companies will have to navigate access restrictions imposed by payers concerned about budget impact.

This report addresses the following questions:

- What pricing benchmarks will European payers use in price negotiations for IL-5 inhibitors?
- What access levers will be used for IL-5 inhibitors in each of the five major EU markets and how will they impact their uptake?
- What attributes of future biologic entrants could secure a higher price and which ones are not valued by payers?
- What are the EU and US payers’ and physicians’ opinions on generic ICS/LABA inhalers?
- What discounts and market access levers will be required to drive uptake of generic ICS/LABA inhalers?

Contents:

EXECUTIVE SUMMARY

MARKET CONTEXT

- Traditional branded drugs facing patent expiry are expected to decrease the asthma market size, but pipeline biologics will fuel growth
- Marketed asthma products in the US, Japan, and five major EU markets
- Pipeline asthma products in late-stage development
- Bibliography

GLOBAL PAYER INSIGHTS

- Insights and strategic recommendations
- Nucala and other IL-5 inhibitors are viewed positively, but cost is a worry
- Unclear product differentiation among branded inhaled products is driving price competition
- Low adherence to inhaler therapy is a major treatment challenge for both payers and Physicians
- Longer clinical trials with clinically significant results favored by both US and EU payers

US PRICING

- ICS/LABA combination inhalers have annual treatment costs of around $3,0
- Expensive price tags for biologics like Nucala are a worry for payers
- Bibliography

US PAYER INSIGHTS

- Insights and strategic recommendations
- Strict prior authorization criteria used for IL-5 inhibitors but conditions may vary
- Payers will welcome generic ICS/LABA inhalers, but physicians are more sceptical
- Bibliography

US REIMBURSEMENT

- Insights and strategic recommendations
- Trends in asthma drug expenditure
- Asthma treatment guideline GINA is widely used across the US, Japan, and five major EU Markets
- Formulary placement
- Prior authorization is reserved for asthma biologics
- Generic Advair entry to the US market is a real threat for GlaxoSmithKline
- Bibliography
JAPAN
- Price premiums are awarded for added benefit or innovation
- Pricing of launched asthma treatments
- Bibliography

FIVE MAJOR EU MARKETS PRICING

FIVE MAJOR EU MARKETS PAYER INSIGHTS
- Insights and strategic recommendations
- Inhaler spend is one of the top budget items for European payers with high visibility
- Access to asthma inhalers relatively unrestricted in the five major EU markets
- Breo Ellipta not well received by EU payers
- Entry of biologic IL-5 inhibitors is a key event in 2016

GENERIC ICS/LABA INHALERS IN THE FIVE MAJOR EU MARKETS
- Insights and strategic recommendations
- Generic versions of Advair and Symbicort struggle to gain market share
- Generic versions of Advair have received limited approval and continue to see low market penetration in the EU
- Generic Symbicort DuoResp gains traction in the EU
- Bibliography

FRANCE
- Insights and strategic recommendations
- ASMR rating has an impact on pricing
- Branded generic versions of Advair and Symbicort have been reviewed by the TC
- Bibliography

GERMANY
- Insights and strategic recommendations
- Positive assessment from the G-BA will impact price negotiations
- Sickness funds tender for branded combination ICS/LABAs; uptake of generics remain low
- Asthma medications are subject to indicative budget limits but relevance of this restriction may change under ongoing reforms
- Nucala's prospect remains unclear as Germany undergoes new regulatory changes
- Bibliography

ITALY
- Insights and strategic recommendations
- AIFA is responsible for pricing and reimbursement decisions
- Delays in inclusion on regional formularies hamper access to recently launched inhalers
- Access to Xolair is tightly controlled, with a price-volume agreement in place
- IL-5 inhibitors are likely to have stringent access criteria in place, with price-volume agreements or risk-sharing possible
- In the absence of restrictions from AIFA and regional decision-makers, the choice between branded vs generic combination inhaler is left to the physician
- Bibliography

SPAIN
- Insights and strategic recommendations
- National reimbursement decision is not a major access barrier in Spain, 56.Breo Ellipta is the only asthma product assessed by IPTs so far
- Regional assessments and formulary decisions
- Spanish payers place more importance on GÉNESIS regional reports than IPTs
- Regional therapeutic reports cause further delays after national product launches
- Access conditions for IL-5 inhibitors will be based on detailed analyses of clinical trial results
UK

- Insights and strategic recommendations
- NICE approval is a key access barrier in the UK
- Xolair, the only asthma drug appraised by NICE, received a positive recommendation
- Access to IL-5 inhibitors will be determined by NICE, with additional restrictions likely
- NICE recommends the most economical option for ICS or ICS/LABA combinations, with the ultimate choice made by regional commissioners.
- UK physicians prefer using BTS/SIGN guidelines for asthma

METHODOLOGY

- Primary research
- Price assumptions
- Exchange rates
- Bibliography

Ordering: Order Online - http://www.researchandmarkets.com/reports/3797428/

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.

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Asthma Pricing, Reimbursement, and Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web Address:</td>
<td><a href="http://www.researchandmarkets.com/reports/3797428/">http://www.researchandmarkets.com/reports/3797428/</a></td>
</tr>
<tr>
<td>Office Code:</td>
<td>SC</td>
</tr>
</tbody>
</table>

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

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic (PDF) - Single User:</td>
<td>☐</td>
<td>USD 7500</td>
<td></td>
</tr>
<tr>
<td>Electronic (PDF) - Enterprise-wide:</td>
<td>☐</td>
<td>USD 26250</td>
<td></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

<table>
<thead>
<tr>
<th>Title:</th>
<th>Mr ☐</th>
<th>Mrs ☐</th>
<th>Dr ☐</th>
<th>Miss ☐</th>
<th>Ms ☐</th>
<th>Prof ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email Address: *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Job Title:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postal / Zip Code:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax Number:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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:

<table>
<thead>
<tr>
<th>Account number</th>
<th>833 130 83</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sort code</td>
<td>98-53-30</td>
</tr>
<tr>
<td>Swift code</td>
<td>ULSBIE2D</td>
</tr>
<tr>
<td>IBAN number</td>
<td>IE78ULSB98533083313083</td>
</tr>
<tr>
<td>Bank Address</td>
<td>Ulster Bank, 27-35 Main Street, Blackrock, Co. Dublin, Ireland.</td>
</tr>
</tbody>
</table>

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