Product Profiles: COPD – Novel Combinations Race to the Finish

Description: Key unmet needs in the COPD market are driving development. While Spiriva (Boehringer Ingelheim) and Advair (GlaxoSmithKline) have market dominance, a number of pipeline products threaten their position.

COPD is a growing market with a dynamic pipeline aiming to address unmet needs. A number of pipeline products threaten established drug classes. Once-daily bronchodilator combinations in particular are expected to offer a novel treatment option with high clinical and commercial potential and a number of companies are racing to be the first to reach the market.

Scope
- Access Datamonitor's independent clinical and commercial assessment of marketed brands and key pipeline agents for COPD.
- Understand what it takes to differentiate a product in COPD treatment and how the pipeline threatens current market leaders.
- Assess how pipeline products compare to each other and how they will compete with established therapies.
- Review important clinical developments for key pipeline agents with analysis of the latest clinical trial data.

Highlights
- As the first once-daily LAMA, Spiriva (tiotropium; Boehringer Ingelheim) has become the clear gold-standard monotherapy for COPD, with widespread use across all disease severities. A number of novel LAMAs are being developed, but these will struggle to compete with Spiriva, which has had years to develop a loyal physician and patient base.

- Significant developments are expected during 2012 as numerous promising candidates are close to reaching the COPD market. Almirall's LAMA Eklira (aclidinium) is under review in the US and EU with a decision expected later in 2012. If successful, Eklira could pose the first direct threat to Spiriva (tiotropium; Boehringer Ingelheim).

- GlaxoSmithKline and Novartis are set to go head-to-head in a number of key drug classes for COPD, including the first once-daily ICS/LABA and LABA/LAMA combinations. With Phase III trials complete and plans to file in mid-2012, GlaxoSmithKline's Relovair (fluticasone furoate/vilanterol) is on track to become the first approved once-daily ICS/LABA.

Reasons to Purchase
- How do marketed treatments of COPD compare to one another and where will pipeline agents fit in?
- How are key players like Boehringer Ingelheim and GlaxoSmithKline protecting their market position in the face of increasing competition?
- Which pipeline products will need to compete with currently established treatments, and which can be positioned as add-on therapies?
- How is COPD treatment expected to change as novel therapies move through the pipeline?

Contents:

OVERVIEW
- Catalyst
- Summary

EXECUTIVE SUMMARY
- Strategic scoping and focus
- Datamonitor key findings
- Related reports

MARKET DEFINITION AND OVERVIEW
MARKETED PRODUCT PROFILES
- Advair (fluticasone/salmeterol; GlaxoSmithKline)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Product positioning
  - Clinical and commercial attractiveness
- Spiriva (tiotropium; Boehringer Ingelheim)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Product positioning
  - Clinical and commercial attractiveness
- Symbicort (budesonide/formoterol; AstraZeneca)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Product positioning
  - Clinical and commercial attractiveness
- Daliresp (roflumilast; Takeda)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Product positioning
  - Clinical and commercial attractiveness
- Arcapta Neohaler (QAB149, indacaterol; Novartis)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Product positioning
  - Clinical and commercial attractiveness
- Other marketed drugs for COPD
  - Combivent (salbutamol/ipratropium; Boehringer Ingelheim)

PIPELINE PRODUCT PROFILES
- Eklira (aclidinium; Almirall)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Satisfaction of unmet needs
  - Clinical and commercial attractiveness
- Relovair (fluticasone furoate/vilanterol; GlaxoSmithKline)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Satisfaction of unmet needs
  - Clinical and commercial attractiveness
- GSK573719/vilanterol (GlaxoSmithKline/Theravance)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Satisfaction of unmet needs
  - Clinical and commercial assessment
- QVA149 (indacaterol/glycopyrronium bromide; Novartis)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Satisfaction of unmet needs
  - Clinical and commercial assessment

- Olodaterol/tiotropium (Boehringer Ingelheim)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Satisfaction of unmet needs
  - Clinical and commercial assessment

- PT003 (formoterol/glycopyrrolate; Pearl Therapeutics)
  - Drug profile
  - Development overview
  - SWOT analysis
  - Satisfaction of unmet needs
  - Clinical and commercial attractiveness

- Other pipeline candidates for COPD
  - Seebri Breezhaler (glycopyrronium bromide; Sosei/Novartis)
  - Vilanterol (GlaxoSmithKline)
  - GSK573719 (GlaxoSmithKline)
  - LAS40464 (aclidinium/formoterol; Almirall)
  - QMF149 (mometasone/indacaterol; Novartis)

BIBLIOGRAPHY
- Journal papers
- Websites

APPENDIX
- Contributing experts
- Conferences attended
- Datamonitor drug assessment scorecard methodology

TABLES
Table: Summary of the ICD-10 codes used to define COPD, 2012
Table: Key marketed and pipeline products for COPD, 2012
Table: Advair (fluticasone/salmeterol; GlaxoSmithKline) - drug profile, 2012
Table: Overview of pivotal trial data for Advair Diskus in COPD, 2012
Table: Datamonitor’s drug assessment summary of Advair (fluticasone/salmeterol; GlaxoSmithKline) for COPD, 2012
Table: Spiriva (tiotropium; Boehringer Ingelheim) - drug profile, 2012
Table: Outcomes of Spiriva’s UPLIFT trial, 2008
Table: Datamonitor’s drug assessment summary of Spiriva (tiotropium; Boehringer Ingelheim) for COPD, 2012
Table: Symbicort (budesonide/formoterol; AstraZeneca) - drug profile, 2012
Table: Overview of pivotal trial data for Symbicort in COPD, 2012
Table: Datamonitor’s drug assessment summary of Symbicort (budesonide/formoterol; AstraZeneca) for COPD, 2012
Table: Daliresp (roflumilast; Nycomed) - drug profile, 2012
Table: Pooled safety analysis of Daliresp, 2010
Table: Datamonitor’s drug assessment summary of Daliresp (roflumilast; Nycomed) for COPD, 2012
Table: Arcapta (indacaterol; Novartis) - drug profile, 2012
Table: Arcapta (indacaterol): Phase III crossover study results
Table: Datamonitor’s drug assessment summary of Arcapta (indacaterol; Novartis) for COPD, 2012
Table: Combivent (salbutamol/ipratropium; Boehringer Ingelheim) - drug profile, 2012
Table: Eklira (aclidinium; Almirall) - drug profile, 2012
Table: Datamonitor’s drug assessment summary of Eklira (aclidinium; Almirall) for COPD, 2012
RESEARCH AND MARKETS

Table: Relovair (fluticasone furoate/vilanterol; GlaxoSmithKline) - drug profile, 2012
Table: Phase III asthma and COPD programs for Relovair
Table: Phase II/Ib clinical abstracts for Relovair components from the European Respiratory Society 2010 Annual Congress
Table: Fluticasone furoate: Phase Ib trial results
Table: Datamonitor's drug assessment summary of Relovair (fluticasone furoate/vilanterol) for COPD, 2012
Table: GSKS73719/GSK642444 (GlaxoSmithKline) - drug profile, 2012
Table: Phase III COPD programs for GSKS73719/vilanterol
Table: Datamonitor's drug assessment summary of GSKS73719/vilanterol for COPD, 2012
Table: QVA149 (indacaterol/glycopyrronium bromide; Novartis) - drug profile, 2012
Table: Phase III program for QVA149 (indacaterol/glycopyrronium bromide)
Table: Datamonitor's drug assessment summary of QVA149 (indacaterol/glycopyrronium; Novartis) for COPD, 2012
Table: Oloclaterol/tiotropium (Boehringer Ingelheim) - drug profile, 2012
Table: Phase III program for oloclaterol/tiotropium
Table: Datamonitor's drug assessment summary of oloclaterol/tiotropium (Boehringer Ingelheim) for COPD, 2012
Table: PT003 (formoterol/glycopyrrolate; Pearl Therapeutics) - drug profile, 2012
Table: Datamonitor's drug assessment summary of PT003 (formoterol/glycopyrrolate; Pearl Therapeutics) for COPD, 2012
Table: Seebri Breezhaler (glycopyrronium bromide; Novartis) - drug profile, 2012
Table: Vilanterol (GlaxoSmithKline) - drug profile, 2012
Table: GSKS73719 (GlaxoSmithKline) - drug profile, 2012
Table: LAS40464 (aclidinium/formoterol; Almirall/Forest) - drug profile, 2012
Table: QMF149 (mometasone/indacaterol; Novartis) - drug profile, 2012
Table: Datamonitor drug assessment parameters for COPD, 2012

FIGURES

Figure: Datamonitor's drug assessment summary for COPD, 2012
Figure: Advair - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of Advair (fluticasone/salmeterol; GlaxoSmithKline) for COPD, 2012
Figure: Phase IV trial comparing Spiriva with Serevent, 2011
Figure: Phase III trial comparing Spiriva Respimat with Spiriva HandiHaler
Figure: Spiriva - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of Spiriva (tiotropium; Boehringer Ingelheim) for COPD, 2012
Figure: Symbicort - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of Symbicort (budesonide/formoterol; AstraZeneca) for COPD, 2012
Figure: Daliresp (roflumilast): pooled results from HERMES and AURA Phase III trials
Figure: Daliresp - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of Daliresp (roflumilast; Nycomed) for COPD, 2012
Figure: Arcapta (indacaterol): INVOLVE study results
Figure: Arcapta (indacaterol): INHANCE study results
Figure: Arcapta (indacaterol): INLIGHT-1 study results
Figure: Arcapta (indacaterol): INLIGHT-2 study results
Figure: Phase III INSIST trial data of indacaterol versus salmeterol
Figure: Arcapta - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of Arcapta (indacaterol; Novartis) for COPD, 2012
Figure: ACCORD COPD 1: Phase III results for aclidinium
Figure: Eklira (aclidinium): results from two Phase III trials
Figure: Eklira - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of Eklira (aclidinium; Almirall) for COPD, 2012
Figure: Phase II COPD trial results for Relovair
Figure: Relovair component compounds: Phase Ib summary results
Figure: Relovair - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of Relovair (fluticasone furoate/vilanterol) for COPD, 2012
Figure: Forecast launch dates for Relovair and generic fluticasone/salmeterol in the US and EU, 2011-14
Figure: GSKS73719/vilanterol - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of GSKS73719/vilanterol for COPD, 2012
Figure: QVA149 (indacaterol/glycopyrronium bromide): results from a Phase II trial
Figure: QVA149 - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of QVA149 (indacaterol/glycopyrronium; Novartis) for COPD, 2012
Figure: Olodaterol/tiotropium - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of olodaterol/tiotropium (Boehringer Ingelheim) for COPD, 2012
Figure: Phase IIb trial results for PT003, 2011
Figure: PT003 - SWOT analysis for COPD, 2012
Figure: Datamonitor's drug assessment summary of PT003 (formoterol/glycopyrrolate; Pearl Therapeutics) for COPD, 2012

Ordering:
Order Online - http://www.researchandmarkets.com/reports/2158999/
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: Product Profiles: COPD – Novel Combinations Race to the Finish
Web Address: http://www.researchandmarkets.com/reports/2158999/
Office Code: SCD2I3UG

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

<table>
<thead>
<tr>
<th>Product Format</th>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF) - Single User</td>
<td></td>
<td>USD 11400</td>
</tr>
<tr>
<td>Electronic (PDF) - Enterprisewide</td>
<td></td>
<td>USD 28500</td>
</tr>
</tbody>
</table>

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