

# Chronic Obstructive Pulmonary Disorder (COPD) - KOL Insight and Consensus Outlook

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## Abstracts

The prevalence of Chronic Obstructive Pulmonary Disorder (COPD) is increasing globally, its impact on the wider health economy is significant and there remains considerable unmet clinical need. Valued at US\$10 billion and with a 5 year CAGR of 7.1% this high growth sector is set for radical change as new products and combinations are introduced changing both the treatment and competitive landscapes.

The cosy carve up of the market between Pfizer's Spiriva (tiotropium) and GSK's Advair/Seretide (fluticasone propionate/salmeterol), which currently account for 75% of sales globally, will be challenged by new entrants that provide better patient adherence, improve lung function, tackle inflammation and reduce exacerbations of the disease.

Why is COPD causing such excitement?

There is considerable industry and investor excitement about COPD treatment developments. Which of the new products will find favour with clinicians? What regulatory hurdles must they overcome? Do they offer a real clinical improvement over current therapies? Stripping away the hype and harnessing the real world insights from leading US and European KOL's, this Therapy Trends analysis critically examines the products and research and exposes the real potential. For example:

In September 2013, Novartis' Ultibro (glycopyrronium/indacaterol) was the first once daily fixed-dose LABA/LAMA to be approved, with promising research results and positive KOL opinion. However, approved dosages of the indacaterol element may be lower in the US, which could affect efficacy and take up. Regulatory delay with the FDA is likely to hand the advantage to GSK, Boehringer Ingelheim and Almirall/Forest all of whom are likely to bring

LABA/LAMA combinations to the US market before Novartis.

In May 2013, GlaxoSmithKline's Breo/Relvar (fluticasone furoate/vilanterol), the first once-daily ICS/LABA was approved, but there are questions over whether it offers clinical value compared with Symbicort and Advair/Serodtide. However, the tide could turn if the product could become the first COPD therapy to gain a mortality claim if the outcome of the SUMMIT trial is positive. In the words of one KOL: "Let's assume that this study is positive. Then the whole field would change dramatically. This would cause an avalanche."

Takeda's Daxas/Daliresp (roflumilast) was the first, and remains the only, oral PDE-IV inhibitor available but sales are hampered by poor tolerability, unpleasant side effects, variable US formulary coverage and restrictions on use in some EU markets. Chiesi's CHF 6001 (Phase II) inhaled PDE-IV inhibitor is showing promising and is "extremely well tolerated in extended safety studies."

A Complete Ongoing Analysis of Current Trends, Future Forecasts and Landscape Modifiers

For instant access to an accurate, unbiased, qualitative review of the latest treatment trends along with a five-year quantitative COPD market forecast look no further than FirstWord's Therapy Trends: COPD. This comprehensive FirstWord research is available in two comprehensive modules:

The KOL Insight: COPD module provides a complete review and is enhanced with exclusive in-depth interviews with leading KOLs from the US and Europe

The Consensus Outlook: COPD data analysis module provides annual historical and forecast product-level sales data from an average of leading equity analysts' projections. Key findings are provided in report which brings together data in charts and tables.

## **KOL Insight**

### **KOL Insight Report**

A qualitative analysis of the current and predicted treatment trends, clinical

products and commercial changes in the global COPD market informed by in-depth expert views of leading clinicians

Compare the market's key players, products, late-stage pipeline drugs, product positioning, in the context of COPD market trends.

### **Event Bulletins**

Benefit from the latest KOL views about significant event driven changes in COPD treatment trends.

### **Consensus Outlook**

#### **Consensus Report**

An in-depth 5-year Consensus Outlook report of predicted quantitative changes in key COPD market forecast parameters drawn from 13 leading analyst and brokerage companies

Chart COPD market size, product sales, market share by company, competitive status and detailed market forecasts

### **Interactive Analytics File**

Use the interactive Excel market analytics module of detailed market and product sales data from 2007 to 2017 to drill down and assess key company, market and product trends

### **KOL Insight Benefits**

Understand and assess future COPD market development

Analyse current and future treatment algorithm

Understand the market dynamics between the LAMA's, LABA's, combination

ICS/LABA's and fixed dose LAMA/LABA's

Assess how prescribing trends will change with launch of new products

Learn about late-stage pipeline products

Track KOL views for the next 12 months

### **Consensus Outlook Benefits**

Evaluate future sales forecasts and predicted market growth

Map your market parameters and chart commercial prospects

Assess market share by company and product

Tailor your strategic and investment focus based on the competition

Set proactive launch and branding strategies

Keep up with event-driven market data updates

### **Informing users in:**

Business development

New product planning

Strategic brand planning

Market research

Competitive Intelligence

Forecasting and market analytics

Medical affairs

Clinical trials

Relationship management

Market Access

Marketing

Sales

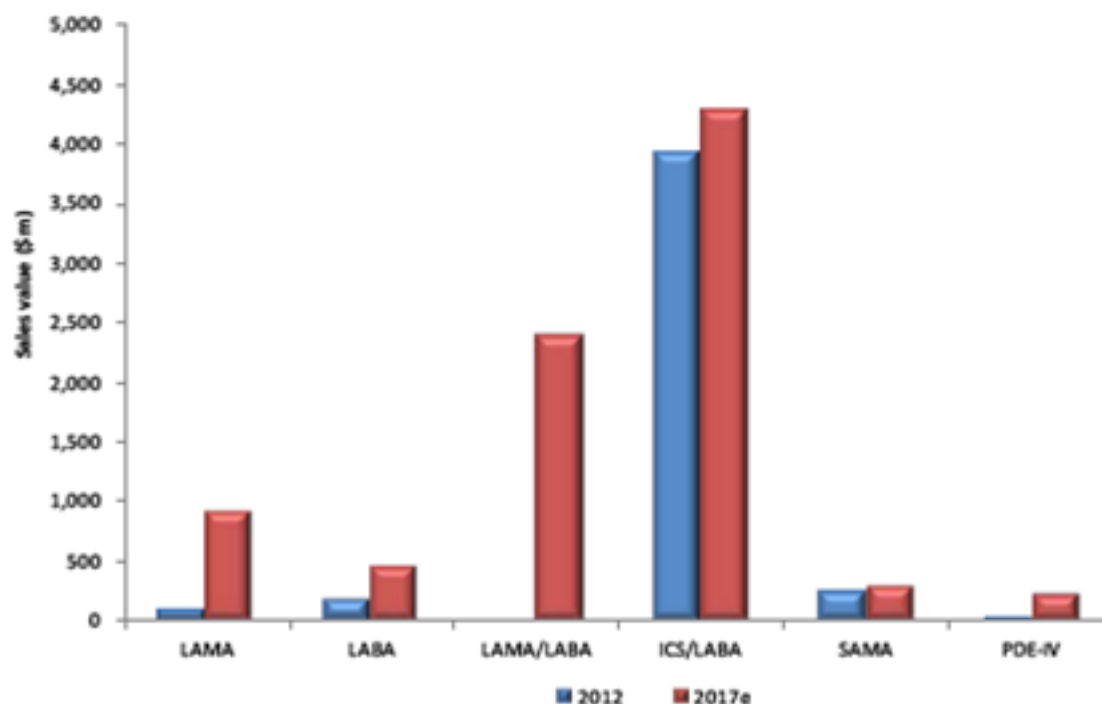
## About

### Chronic Obstructive Pulmonary Disease Class Dynamics

Historically market growth has been driven by Long Acting Muscarinic Antagonists (LAMAs) and inhaled corticosteroid/ Long Acting Beta Agonists (ICS/LABAs). Boehringer Ingelheim and Pfizer's Spiriva (tiotropium) accounted for 98 percent of the worldwide LAMA market in 2012, while GlaxoSmithKline's Seretide/Advair (fluticasone propionate/salmeterol) represented 71 percent of the ICS/LABA market share.

The other main class in COPD was the Short Acting Beta 2 Agonist/Short Acting Anticholinergic (SAMA/SABA), which is comprised of Combivent (salbutamol/ipratropium; Boehringer Ingelheim) and used in conjunction with the long-term maintenance LAMA or ICS/LABAs.

### Chronic Obstructive Pulmonary Disease Class Key Class Worldwide Market Sales Value, 2012 And 2017

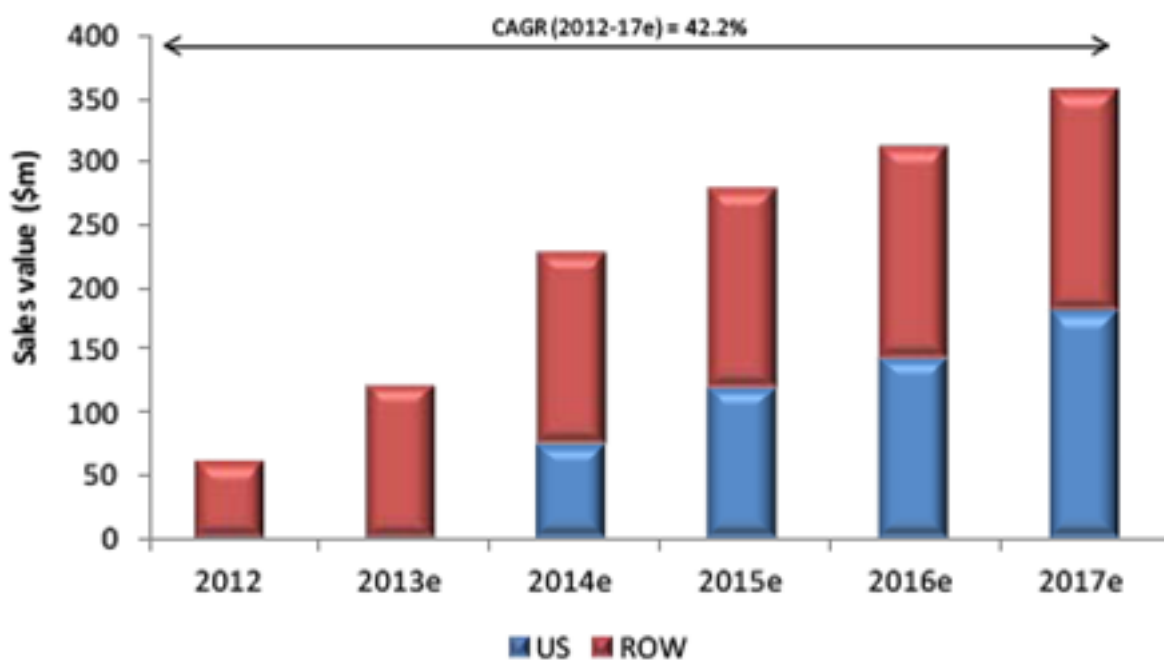


### Seebri (glycopyrronium; Novartis) forecast

Novartis's Seebri (glycopyrronium) is the latest Long Acting Muscarinic Antagonist (LAMA) to be approved in Europe. US approval is expected in 2014. Novartis licensed the formulation of glycopyrronium from Vectura/Sosei. Glycopyrronium is administered

in the Breezhaler DPI, the same device used to deliver Novartis’s Arcapta/Onbrez (indacaterol). Clinical trials have showed Seebri provides rapid bronchodilation following the first dose. In 2012, Seebri generated \$61 million in the European markets where it is approved.

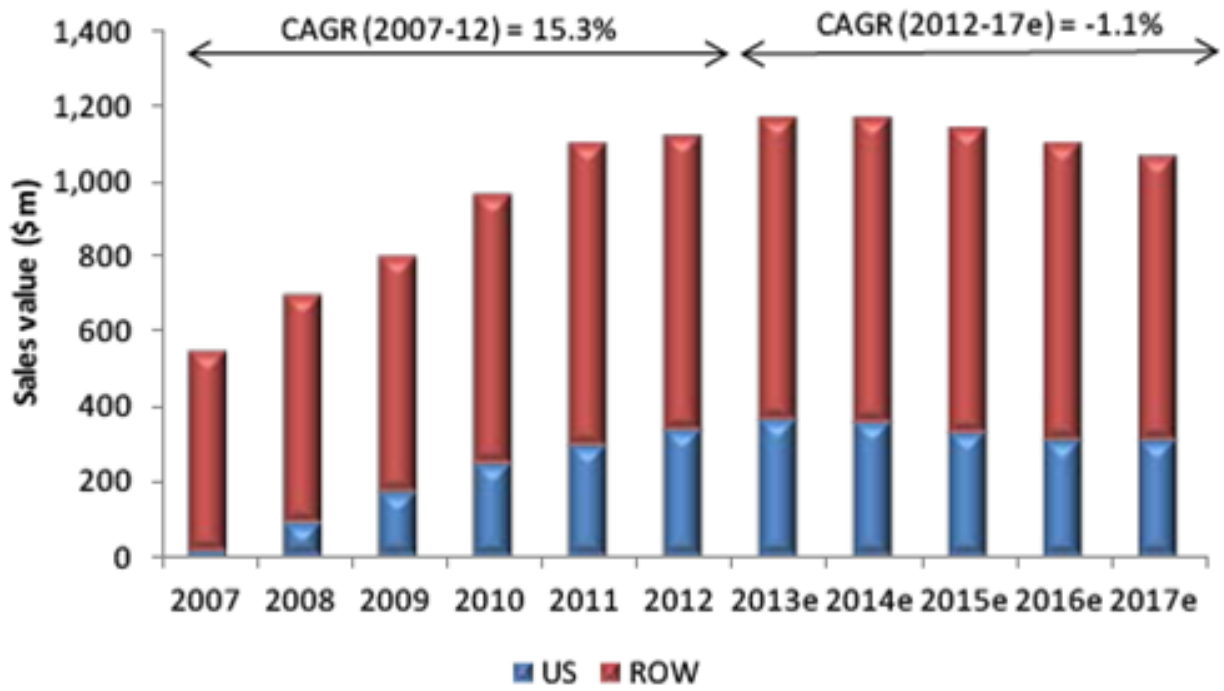
**Sales dynamics of Seebri (glycopyrronium; Novartis), 2012-2017**



**Symbicort (budesonide/formoterol; AstraZeneca) forecast**

Symbicort (budesonide/formoterol; AstraZeneca) became the second inhaled corticosteroid/Long Acting Beta Agonist (ICS/LABA) combination behind Seretide/Advair (fluticasone propionate/salmeterol; GlaxoSmithKline) to be approved in the respiratory markets. An approval in chronic obstructive pulmonary disease (COPD) followed in the EU in 2003 and in the US in February 2009.

**Sales dynamics of Symbicort (budesonide/formoterol; AstraZeneca), 2007-2017**





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