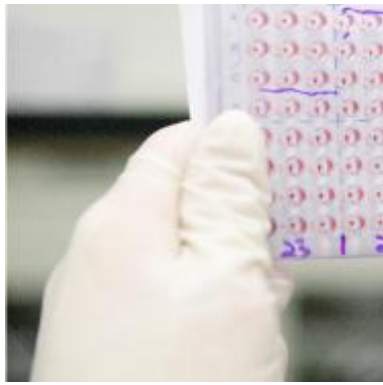
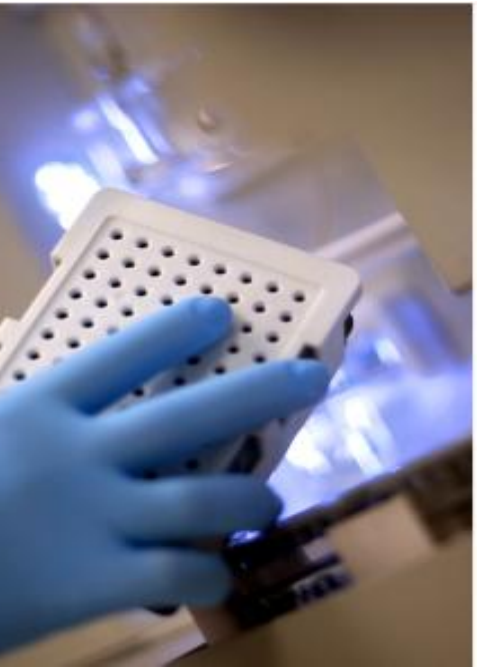


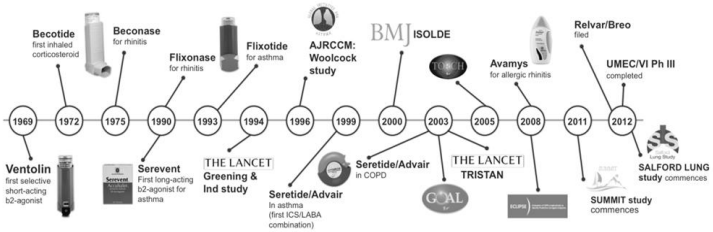



# ATS Analyst and Investor Event

Darrell Baker, SVP & Head, Global Respiratory Franchise

Tuesday 21st May 2013

# We have made significant progress in our respiratory portfolio in 2013; data at ATS demonstrates research breadth




**RELVAR™** *for asthma and COPD*
filed in EU and Japan

**ANORO™** *for COPD*
filed in US

**BREO™** *for COPD*
filed in US

2012

**SALFORD LUNG**
**study** commences

**fluticasone furoate (FF) mono**
*for asthma*
PhIII completed

**mepolizumab**
*for severe refractory asthma*
PhIII commences

**ANORO™** *for COPD*
filed in EU and Japan

2013

**BREO™** *for COPD*
approved in US

**umeclidinium (UMEC) mono**
*for COPD*
filed in US and EU

# Significant milestone achieved: BREO™ ELLIPTA™ gains US approval for the treatment of COPD


In the US, BREO™ ELLIPTA™ is approved as a combination inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/LABA) " (FF/VI 100/25 mcg) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. BREO™ ELLIPTA™ is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

Important Limitations of Use: BREO™ ELLIPTA™ is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

BREO™ ELLIPTA™ will be available in the US during Q3 2013

# Further data at ATS demonstrates depth of FF/VI research

| Filings | Asthma | COPD |
|---|---|---|
| US | Additional PhIII study ongoing | ✓Approved BREO™ |
| EU / Japan | ✓ Filed RELVAR™ | ✓Filed RELVAR™ |

Once a day ICS/LABA (FF/VI)


## Data at ATS:

Phase IIIb RELVAR™/BREO™ versus SERETIDE™/ADVAIR™ in COPD – pooled analysis

Once-Daily (OD) Fluticasone Furoate/Vilanterol (FF/VI: 100/25mcg) compared with twice-daily (BD) Fluticasone Propionate/Salmeterol (FSC: 250/50mcg) in patients with COPD

Ph III real-world study (protocol only) RELVAR™/BREO™ versus existing COPD maintenance therapy

# Fluticasone furoate mono on track to file in 2013, commencing with US and Japan; ATS data aids understanding of response in asthma

Once a day ICS mono (FF mono)


Data at ATS:

PhIIIa study of FF 50mcg monotherapy versus placebo in asthma

Studies at 100 & 200mcg doses contained within FF/VI package previously published / presented
Further FF mono data will be presented at future meetings

# ANORO™ ELLIPTA™ filings in 2013

Once a day LAMA/LABA (UMEC/VI)


| Filings | COPD |
|---|---|
| US | ✓ Filed Dec 2012 |
| EU | ✓ Filed Jan 2013 |
| Japan | ✓ Filed Apr 2013 |

## Data at ATS:

Three pivotal efficacy PhIIIa studies

ANORO™ ELLIPTA™ is the proposed brand name for UMEC/VI and is not yet approved.

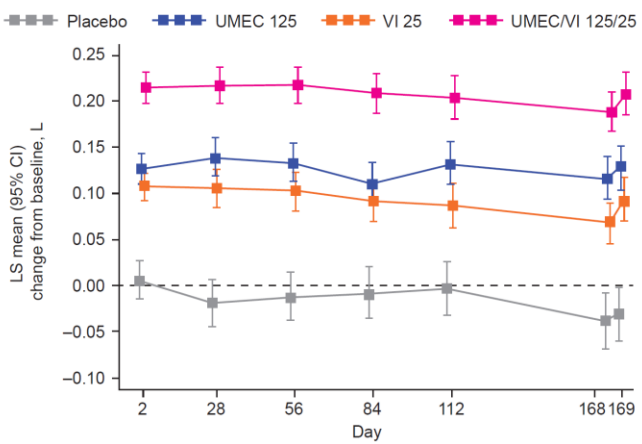
# PhIII data presented at ATS supports the filings of ANORO™ ELLIPTA™ and umeclidinium mono

Efficacy based on trough FEV1 at end of treatment

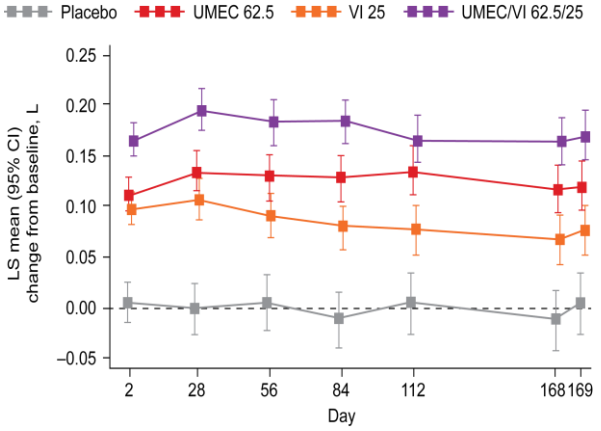
PhIIIa study of ANORO™ (**125/25mcg**) versus individual components

PhIIIa study of ANORO™ (**62.5/25mcg**) versus individual components

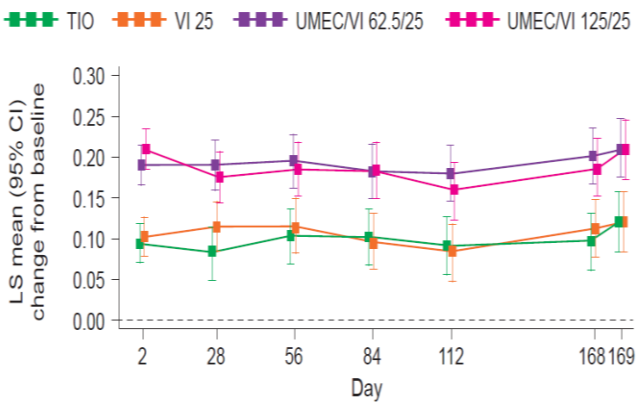
Phase IIIa study of ANORO™ versus **TIO** and VI in COPD




*Study #: DB2113361 on CSR*




*Study #: DB2113373 on CSR*




*Study #: DB2113360 on CSR*

Full efficacy and safety findings from each study are presented at ATS and posted to the GSK Clinical Study Register. In July 2012 we communicated the results of 4 pivotal efficacy studies, of which 3 are presented at ATS 2013. In these four studies the most common adverse events across all treatment arms, including placebo, were headache, nasopharyngitis, upper respiratory tract infection, cough, oropharyngeal pain and back pain. Additionally, the incidence of cardiovascular adverse events across all treatment groups was similar (5-9% of placebo group, 7-11% of VI group, 10% of UMEC 62.5mcg group, 7-9% UMEC 125mcg group, 6-11% UMEC/VI 62.5/25mcg group, 6-7% of UMEC/VI 125/25mcg group and 4-8% tiotropium). The incidence of serious adverse events across all treatment groups was similar (3-6% of placebo group, 5-7% of VI group, 6% of UMEC 62.5mcg group, 5-7% UMEC 125mcg group, 5-10% UMEC/VI 62.5/25mcg group, 2-7% of UMEC/VI 125/25mcg group and 4-6% tiotropium).

# Umeclidinium mono filings supported by data from the ANORO™ ELLIPTA™ registration package

Once a day LAMA mono (UMEC mono)


| Filings | COPD |
|---|---|
| US | ✓ Filed April 2013 |
| EU | ✓ Filed April 2013 |
| ROW | Planned during the course of 2013 |

## Data at ATS:

Ph IIIa UMEC mono versus placebo in COPD

# We continue to progress our Respiratory portfolio across varied mechanisms of action

| | SABA | ICS | LABA | ICS/ LABA | LAMA | LAMA/ LABA | MABA | ICS/ LAMA | Anti-IL 5 | p38 | FLAP |
|---|---|---|---|---|---|---|---|---|---|---|---|
| GlaxoSmithKline | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Company 1 | | | ✓ | ✓ | ✓ | ✓ | | | | | |
| Company 2 | | | ✓ | | ✓ | ✓ | | | | | |
| Company 3 | | | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| Company 4 | | | ✓ | ✓ | ✓ | ✓ | | | | | |
| Company 5 | | ✓ | ✓ | ✓ | | | ✓ | | ✓ | ✓ | |
| Company 6 | | | | | | | | | | ✓ | |

| Market size* | | |
|---|---|---|
| | **£2.3bn:** rescue | **£4.8bn:** maintenance bronchodilator |
| | **£8.1bn:** ICS/LABA | **£0.6bn:** biological severe asthma |
| | **£2.8bn:** steroid | **£2.4bn:** oral asthma |

**Source: GSK R3 Model based on IMS Health MAT Dec 2012.*

*Includes marketed and development products for GSK and other companies*