Vectura Group plc

Launch of Utibron™ Neohaler® in the US

Chippenham, UK – 3 April 2017: Vectura Group plc (LSE: VEC) (“Vectura”, “the Group”), an industry-leading device and formulation business for inhaled airways products, confirms that Sunovion Pharmaceuticals Inc. (“Sunovion”), the US licensee of the Group’s partner Novartis AG (“Novartis”) has launched Utibron™ Neohaler® (indacaterol/glycopyrrolate) (“Utibron™”) in the US.

Sunovion entered into an exclusive license agreement with Novartis for the US commercialisation rights to three of Novartis’ COPD treatments, including Utibron™ and Seebri™ Neohaler® (“Seebri™”), on 21 December 2016.

Sunovion has confirmed that they also expect to launch Seebri™ in the US during the next twelve months.

Vectura is eligible to receive royalties on net sales of the product as well as certain milestones based on global calendar year combined net sales of Utibron™ Neohaler®, Seebri™ Neohaler®, Ultibro® Breezhaler® and Seebri® Breezhaler®. The royalties earned upon net sales of Utibron™ Neohaler® are the same as those for Ultibro® Breezhaler®.

James Ward-Lilley, Chief Executive Officer of Vectura:

“We are pleased with the confirmation of launch of Utibron in the US market by Sunovion. Utibron is an important dual-bronchodilator handheld inhaler that is well aligned to the recently updated GOLD guidelines and it represents the latest combination therapy now available for the millions of patients living with COPD in the US. We look forward to Sunovion progressing the launch of Seebri later this year. We are confident Sunovion will be highly effective in the commercialisation of Utibron and Seebri given its strong established US respiratory commercialisation expertise and track record in COPD.

“Royalties earned from sales of Utibron in the US will make a further contribution to the substantial recurring and growing royalty stream we already receive from Novartis for sales of Ultibro Breezhaler and Seebri Breezhaler in Europe and the Rest of the World.”

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About Vectura

Vectura, a FTSE250 company listed on the London Stock Exchange (LSE: VEC), is an industry-leading device and formulation business for inhaled airways products offering a uniquely integrated inhaled drug delivery
platform. With our extensive range of device and formulation technologies, integrated capabilities and collaborations, we are a leader in the development of inhalation products, increasing our ability to help patients suffering from respiratory diseases.

Vectura has seven inhaled, four non-inhaled and ten oral products marketed by partners with growing global royalty streams, and a portfolio of drugs in clinical development, a number of which have licence agreements with several global pharmaceutical and biotechnology companies including Hikma, Novartis, Sandoz, Mundipharma, Kyorin, Baxter, GSK, UCB, Ablynx, Grifols, Bayer, Chiesi, Almirall, Janssen, and Tianjin KingYork.

For further information, please visit Vectura’s website at www.vectura.com.

About Utibron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder
Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder is a twice-daily combination long-acting beta agonist and long-acting muscarinic antagonist (LABA/LAMA) approved in the US for the long-term maintenance treatment of airflow obstruction in people with COPD, including chronic bronchitis and/or emphysema. Phase III clinical trials demonstrated that Utibron™ Neohaler® has the additive benefits of the LABA indacaterol and the LAMA glycopyrrolate compared to each component alone. Utibron™ Neohaler® also improved overall quality of life as measured by the St. George’s Respiratory Questionnaire (SGRQ) total score, reduced COPD rescue medication use and improved breathlessness as measured by the Transitional Dyspnea Index (TDI) total score in patients as compared to placebo.

The most common adverse reactions (≥1% and more common than placebo) reported in two 12-week clinical trials with Utibron™ Neohaler® (and placebo) were: nasopharyngitis, 4.1% (1.8%); hypertension, 2.0% (1.4%); back pain, 1.8% (0.6%); oropharyngeal pain, 1.6% (1.2%).

About LAMAs and LABAs
Long-acting bronchodilators currently are the first-line standard of care maintenance therapy for symptomatic patients with COPD.1 Within that class there are long-acting muscarinic antagonists (LAMAs) and long-acting beta agonists (LABAs), both of which are widely used and important therapeutic approaches. LAMA and LABA medicines dilate, or open, the airways in the lungs to reduce symptoms such as wheezing, cough, chest tightness and shortness of breath. Combining a LAMA and a LABA may offer additive benefits, including increased efficacy, compared with the LAMA or LABA alone. As a result, patients with increasing severity are often treated with both a LAMA and LABA.

About COPD
Chronic obstructive pulmonary disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases. The main risk factor for COPD is tobacco smoking, but other environmental exposures may contribute.1 Approximately 15.7 million adults in the US report that they have been diagnosed with COPD.2 It is estimated that several million more adults have undiagnosed COPD.3 COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the US.3 COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to perform routine activities.2 Symptoms of COPD include coughing, wheezing, shortness of breath, excess production of mucus in the lungs, the inability to breathe deeply and the feeling of being unable to breathe.3 The symptoms of COPD can be most severe during the night and early morning.4 Morning symptoms can be associated with limitation of activities during the day, impaired health status and increased

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risk of exacerbation.⁵ Night-time symptoms disturb sleep, reduce sleep quality and, in the long term, may be associated with development or worsening of cardiovascular diseases, cognition, depression and increased mortality.⁶

About Seebri™ Neohaler®
Seebri™ Neohaler® (glycopyrrolate) 15.6 mcg is a twice-daily LAMA bronchodilator. In the US, Seebri™ Neohaler® is a prescription medicine approved as a long-term maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema.⁷ It is not approved for the treatment of asthma.

Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Vectura and Sosei.

About Sunovion Pharmaceuticals Inc. ("Sunovion")
Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion’s vision is to lead the way to a healthier world. The company’s spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions. Sunovion’s track record of discovery, development and commercialization of important therapies has included Ultibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, BROVANA® (arformoterol tartrate), LATUDA® (lurasidone HCl) and APTIOM® (eslicarbazepine acetate).


Ultibro®, Seebri®, Breezhaler®, Neohaler®, are registered trademarks of Novartis AG. Seebri™ and Ultibron™ are trademarks of Novartis AG.

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