Novartis out-licenses three COPD products in the US

Dec 21, 2016

- Sunovion assumes US commercialization rights for Utibron™ Neohaler®, Seebri™ Neohaler® and Arcapta® Neohaler
- Novartis will continue to manufacture these important medicines for Sunovion
- In line with its global commitment to respiratory patients, Novartis will continue to bring Ultibro® Breezhaler®, Seebri® Breezhaler® and Onbrez® Breezhaler® to patients with COPD outside of the US

East Hanover, N.J., December 21, 2016 – Novartis announced today that it has signed a licensing agreement with Sunovion Pharmaceuticals Inc. (Sunovion) for the US commercial rights to its three treatments for chronic obstructive pulmonary disease (COPD), Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Seebri™ Neohaler® (glycopyrrolate) inhalation powder, and Arcapta® Neohaler® (indacaterol) inhalation powder.

This deal is specific to the US only and has no implications outside this market. Novartis will continue to manufacture these medicines for Sunovion. Novartis will also continue to bring Ultibro® Breezhaler® (indacaterol/glycopyrronium), Seebri® Breezhaler® (glycopyrronium) and Onbrez® Breezhaler® (indacaterol) to patients living with COPD outside of the US.

“Given the evolving market dynamics, we believe these products will have the greatest impact in the US when commercialized by a company with an established presence in the COPD field,” said Fabrice Chouraqui, President of Novartis Pharmaceuticals Corporation. “Novartis will continue to focus on areas in the US where we have strong capabilities and leadership, and can bring the greatest value to physicians and patients.”

Outside the US, Novartis’ indacaterol/glycopyrronium formulation Ultibro Breezhaler 110/50 mcg administered once-daily is the leading therapy in sales in its class. In all markets other than the US, Novartis has a full respiratory presence and portfolio and is committed to building category leadership and meeting the evolving needs of patients living with respiratory diseases including asthma and COPD. The COPD portfolio remains a global priority for Novartis.

In the US, Novartis remains committed to improving care across respiratory diseases including asthma and cystic fibrosis and, through its pipeline, anticipates expanding its respiratory portfolio.

About Utibron Neohaler

Utibron Neohaler (indacaterol/glycopyrrolate) 27.5/15.6 mcg is a twice-daily fixed dose combination of long-acting beta2-adrenergic agonist (LABA) and long-acting muscarinic antagonist (LAMA). In the US, Utibron 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[1]. It is not approved for the relief of acute bronchospasm or the treatment of asthma.

Utibron Neohaler was approved in October 2015 in the US with a dose of indacaterol/glycopyrrolate 27.5/15.6 mcg administered twice-daily, which is different from the product marketed outside the US. Recent new data from two head-to-head studies showed Utibron Neohaler provided clinically meaningful and comparable bronchodilation to GSK’s Anoro™ Ellipta® in US patients with COPD. However, the primary endpoint in terms of 24-hour lung function improvement (FEV_1

AUC_{0-24h}) was not met statistically. A full evaluation of this new data is ongoing and will be communicated in due course. The primary objectives of the two head-to-head studies were to demonstrate that Utibron Neohaler was non-inferior to Anoro Ellipta in terms of improving lung function over a 24-hour period (FEV_1 AUC_{0-24h}), after 12 weeks of treatment. More information on the trial design can be found at: Clinicaltrials.gov[2,3].

Outside the US, Utibron Neohaler is not available. Outside the US, the dose and regimen of indacaterol/glycopyrronium is different than in the US. It is available as a once-daily formulation, marketed as Ultibro® Breezhaler®, and is available as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD[4]. Once-daily Ultibro Breezhaler is currently approved for use in over 90 countries worldwide, including countries within the EU and Latin America, Japan, Canada, Switzerland and Australia.

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[5]. It is not approved for the treatment of asthma.

Outside the US, Seebri Neohaler is not available. Outside the US, the dose and regimen of glycopyrronium is different than the dose and regimen in the US. It is available as a once-daily formulation of glycopyrronium, marketed as Seebri® Breezhaler® 50 mcg, and is available as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD[6]. Once-daily Seebri Breezhaler is approved for use in over 90 countries, including countries within the EU and Latin America, Japan, Canada, Switzerland and Australia.

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

About Arcapta® Neohaler®

Arcapta Neohaler (indacaterol) 75 mcg, is a once-daily LABA **bronchodilator. It is a prescription medicine approved in the US as 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. Outside the US, it is marketed as Onbrez® Breezhaler® (indacaterol) 150 mcg and 300 mcg[8].**

INDICATION

UTIBRON NEOHALER, SEEBRI NEOHALER, and ARCAPTA NEOHALER are prescription medicines used to treat chronic obstructive pulmonary disease (COPD) in adults. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. UTIBRON and SEEBRI are used long-term, inhaled twice a day; ARCAPTA is used long-term, inhaled once daily, to improve symptoms of COPD for better breathing.

UTIBRON contains the long-acting beta2-adrenergic agonist (LABA) indacaterol, and the anticholinergic glycopyrrolate. SEEBRI contains the anticholinergic glycopyrrolate. ARCAPTA contains the LABA indacaterol. These medicines work by

helping the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath.

UTIBRON, SEEBRI, and ARCAPTA are not used to treat sudden symptoms of COPD, won't replace a rescue inhaler, and are not for the treatment of asthma.

IMPORTANT SAFETY INFORMATION

People with asthma who take long-acting beta$_2$-adrenergic agonist (LABA) medicines, such as indacaterol (the medicine in ARCAPTA NEOHALER and one of the medicines in UTIBRON NEOHALER), have an increased risk of death from asthma problems. It is not known if LABA medicines increase the risk of death in people with COPD. UTIBRON NEOHALER and ARCAPTA NEOHALER are not for the treatment of asthma.

Call your doctor or get emergency medical care if your breathing problems worsen quickly, if you need to use your rescue inhaler more often than usual, or if you use your rescue inhaler medicine but it does not relieve your breathing problems. Call your doctor if breathing problems worsen over time while using UTIBRON, SEEBRI, or ARCAPTA.

Do not use UTIBRON NEOHALER if you are allergic to indacaterol, glycopyrrolate, or any of the ingredients in UTIBRON. Do not use SEEBRI NEOHALER if you are allergic to glycopyrrolate or any of the ingredients in SEEBRI. Do not use ARCAPTA NEOHALER if you are allergic to indacaterol or any of the ingredients in ARCAPTA. Ask your doctor if you are not sure.

Do not swallow UTIBRON, SEEBRI, or ARCAPTA capsules. Only use UTIBRON, SEEBRI, or ARCAPTA capsules with the NEOHALER inhaler. Never place a capsule in the mouthpiece of the NEOHALER inhaler.

Do not use UTIBRON or ARCAPTA more often or at higher doses than prescribed.

Tell your doctor about all of your medical conditions including heart problems, high blood pressure, seizures, thyroid problems, diabetes, or liver problems before using UTIBRON or ARCAPTA; tell your doctor about kidney problems, eye problems such as glaucoma, prostate problems, bladder problems, problems passing urine, or other medical conditions. Tell your doctor if you are pregnant, planning to become pregnant or breastfeeding, before using UTIBRON, SEEBRI, or ARCAPTA.

Tell your doctor if you are allergic to UTIBRON or SEEBRI or any of their ingredients, any other medicines, or food products. UTIBRON, SEEBRI, and ARCAPTA contain lactose (milk sugar) and small amounts of milk proteins. It is possible that allergic reactions may happen in people who have a severe milk protein allergy.

Tell your doctor about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Using UTIBRON or SEEBRI with other medicines may cause serious side effects. Tell your doctor if you take anticholinergics (including umeclidinium, tiotropium, ipratropium, aclidinium, glycopyrrolate), because taking them together with UTIBRON or SEEBRI can increase side effects. Tell your doctor if you take LABA medicines (including

formoterol, salmeterol, vilanterol, indacaterol, olodaterol) because taking them together with UTIBRON or ARCAPTA can increase side effects. Do not take UTIBRON and SEEBRI, or UTIBRON and ARCAPTA, together.

UTIBRON, SEEBRI, and ARCAPTA may cause serious side effects, including life-threatening sudden shortness of breath immediately after use and serious allergic reactions including rash; hives; swelling of the tongue, lips, and face; difficulty breathing or swallowing. If you have any of these symptoms, stop taking UTIBRON, SEEBRI, or ARCAPTA and get immediate medical help.

UTIBRON and ARCAPTA may cause serious side effects, including effects on your heart (including fast and/or irregular heartbeat, increased blood pressure, or chest pain) and changes in laboratory values (including high levels of blood sugar and low levels of potassium, which may cause symptoms of muscle spasm, muscle weakness, or abnormal heart rhythm). If you have any of these symptoms, stop taking UTIBRON or ARCAPTA and get immediate medical help.

UTIBRON and SEEBRI can cause new or worsened eye problems, including acute narrow-angle glaucoma, which can cause permanent loss of vision if not treated. Symptoms may include: eye pain or discomfort, nausea or vomiting, blurred vision, seeing halos or bright colors around lights, or red eyes. If you have any of these symptoms, stop taking UTIBRON or SEEBRI and call your doctor right away.

UTIBRON and SEEBRI can cause new or worsened urinary retention. Symptoms of urinary retention may include: difficulty urinating, painful urination, urinating frequently, or urination in a **weak stream or drips. If you have these symptoms, stop taking UTIBRON or SEEBRI and call** your health care provider right away.

Common side effects of UTIBRON include sore throat, runny nose, high blood pressure, and back pain. Common side effects of SEEBRI include upper respiratory tract infection, sore throat, and runny nose. Common side effects of ARCAPTA include runny nose, cough, sore throat, headache, and nausea.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information, including Medication Guide at:
www.pharma.us.novartis.com/product/pi/pdf/utibron.pdf for Utibron Neohaler;

www.pharma.us.novartis.com/product/pi/pdf/seebri.pdf for Seebri Neohaler; and
www.pharma.us.novartis.com/product/pi/pdf/arcapta.pdf for Arcapta Neohaler.

Read the **step-by-step instructions** for using UTIBRON NEOHALER, SEEBRI NEOHALER, and ARCAPTA NEOHALER at the end of the **Prescribing Information.**

About the Novartis US COPD portfolio

The Novartis US COPD portfolio includes Utibron Neohaler, Seebri Neohaler and Arcapta Neohaler, which are all indicated as maintenance treatments for COPD patients and use transparent capsules to help with dose confirmation.

About COPD

Chronic obstructive pulmonary disease (COPD) affects an estimated 27 million people in America[9], claiming the lives of 143,489 Americans in 2012[10]. It is progressive (usually gets worse over time), and can be a life-threatening disease[11,12]. COPD makes it difficult to breathe, with symptoms that can have an impact on health-related quality of life[11,12].

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “will,” “commitment,” “believe,” “can,” “ongoing,” “in due course,” “committed,” “evolving,” “building,” “priority,” “pipeline,” “anticipates,” or similar terms, or by express or implied discussions regarding potential benefits, synergies or opportunities as a result of the sale of US commercialization rights for Utibron Neohaler, Seebri Neohaler and Arcapta Neohaler to Sunovian, potential new indications or labeling in markets outside the US for Ultibro Breezhaler, Seebri Breezhaler and Onbrez Breezhaler, potential marketing approvals for the product candidates in the Novartis respiratory portfolio, or regarding potential future revenues from such products and product candidates. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that Novartis will be able to realize any or all of the potential benefits, synergies or opportunities as a result of the sale of US commercialization rights for Utibron Neohaler, Seebri Neohaler and Arcapta Neohaler to Sunovian. Neither can there be any guarantee that Ultibro Breezhaler, Seebri Breezhaler and Onbrez Breezhaler will be submitted or approved for any additional indications or labeling in any market outside the US, or at any particular time. Nor can there be any guarantee that the product candidates in the Novartis respiratory portfolio will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Ultibro Breezhaler, Seebri Breezhaler, Onbrez Breezhaler and the product candidates in the Novartis respiratory portfolio will be commercially successful in the future. In particular, management’s expectations regarding the sale of US commercialization rights for Utibron Neohaler, Seebri Neohaler and Arcapta Neohaler to Sunovian, and the products and product candidates in the Novartis respiratory portfolio could be affected by, among other things, the possibility that the potential benefits, synergies or opportunities expected from the sale may not be realized or may take longer to realize than expected; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety, quality or manufacturing issues, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis Pharmaceuticals Corporation offers a broad range of medicines for cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions.

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion

excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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