Novartis receives FDA approval for Arcapta™ Neohaler™, a novel once-daily bronchodilator for chronic obstructive pulmonary disease

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- Arcapta is the only once-daily long-acting beta2-agonist (LABA) approved in US for maintenance treatment of airflow obstruction in patients with COPD
- Clinical studies with Arcapta showed sustained improvement in lung function; improvements were seen at 5-minutes after first dose[1]
- Arcapta is approved with data demonstrating improvements in health-related quality of life
- COPD is a progressive and life-threatening lung disease that affects more than 12 million Americans[2] and is a major cause of long-term disability[3]

East Hanover, NJ, July 1, 2011 – Novartis announced today that the US Food and Drug Administration (FDA) has approved once-daily Arcapta™ Neohaler™ (indacaterol inhalation powder) 75 mcg for the long-term maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Arcapta is not indicated for acute deteriorations of COPD or to treat asthma.

The decision makes Arcapta, formerly known as QAB149, the first once-daily therapy in the long-acting beta2-agonist (LABA) class to be approved in the US for maintenance treatment of airflow obstruction in COPD patients.

“With millions of Americans known to be affected by COPD, the approval of Arcapta is good news for patients,” said John W. Walsh, president and co-founder of the US-based COPD Foundation. “A new once-daily medicine is a welcome addition to the treatment options for people suffering with this serious and debilitating disease.”

Arcapta 75 mcg was studied in a total of 641 COPD patients in two key Phase III trials lasting 12 weeks. Results at week 12 showed that Arcapta significantly improved lung function at 24 hours compared to placebo. Lung function improvements were seen five minutes after the first dose and consistently maintained over 12 weeks. Arcapta also significantly reduced the need for patients to use daily rescue medication. Additionally, Arcapta improved health-related quality of life compared to placebo, as measured with the St George’s Respiratory Questionnaire (SGRQ). The SGRQ is widely used in clinical trials to measure symptoms, activities, and impact of COPD on daily life as reported by patients.

The clinical trial program supporting US submission evaluated safety in 2,516 patients who received Arcapta for at least 12 weeks at doses of 75 mcg or more, with results supporting the safety and tolerability profile of Arcapta. The most common adverse reactions in 449 patients taking Arcapta 75 mcg (i.e. those reported in more than 2% of patients and with higher incidence than placebo) were cough, nasopharyngitis, headache, nausea, and oropharyngeal pain.

“Novartis is focused on bringing innovative, safe and effective COPD medicines to patients and physicians,” said Trevor Mundel, MD, Global Head of Development in the Pharmaceuticals Division of Novartis AG.

“Indacaterol is the cornerstone of our respiratory portfolio and this US approval represents a significant clinical and regulatory milestone.”

Indacaterol was first approved in November 2009 in the European Union under the brand-name Onbrez® Breezhaler®. It is now approved in more than 60 countries for the treatment of COPD, and is available in more than 30 countries with additional launches planned during 2011. The Arcapta US launch is planned for the first quarter of 2012.

COPD is a progressive and life-threatening lung disease that makes it difficult to breathe. More than 12 million people in the US are affected, while another estimated 12 million people are believed to have the disease but remain undiagnosed. COPD ranks as the third leading cause of death in the US and is a major cause of serious long-term disability.

Important Safety Information

WARNING: ASTHMA-RELATED DEATH

Long-acting beta2-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta2-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including indacaterol, the active ingredient in Arcapta Neohaler. The safety and efficacy of Arcapta Neohaler in patients with asthma have not been established. Arcapta Neohaler is not indicated for the treatment of asthma.

All LABA are contraindicated in patients with asthma without use of a long-term asthma control medication.

Arcapta should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition, or used as rescue therapy for acute episodes of bronchospasm.

Arcapta should not be used more often, at higher doses than recommended, or in conjunction with other medications containing long-acting beta2-agonists, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

Arcapta may produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, Arcapta should be discontinued immediately and alternative therapy instituted.

Arcapta can produce a clinically significant cardiovascular effect in some patients and should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Arcapta should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

The most commonly reported adverse reactions in patients taking Arcapta Neohaler (>2% and higher than placebo) were cough (6.5%), nasopharyngitis (5.3%), headache (5.1%), nausea (2.4%), and orpharyngeal pain (2.2%).

Arcapta should be used with extreme caution in patients treated with monoamine oxidase inhibitors, tricyclic antidepressants, or other drugs known to prolong the QTc interval because the action of adrenergic agonists on the cardiovascular system may be potentiated.

Arcapta should be used with caution in patients treated with additional adrenergic drugs, non¬potassium-

sparing diuretics, and beta-blockers.

Arcapta capsules must not be swallowed as the intended effects on the lungs will not be obtained. Arcapta capsules are only for oral inhalation and should only be used with the Neohaler device. The Neohaler device should not be used with any other capsules.

Please see full prescribing information about Arcapta Neohaler, including BOXED WARNING at http://www.pharma.us.novartis.com/info/products or contact Christine Cascio at 862-778-8026 or christine.cascio@novartis.com.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “milestone,” “planned,” or similar expressions, or by express or implied discussions regarding the development and marketing of potential future respiratory product, regarding future launches of indacaterol, or regarding potential future revenues from indacaterol. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis will successfully develop or bring to market any additional respiratory products. Nor can there be any guarantee that indacaterol will be launched in any particular countries, or at any particular time. Neither can there be any guarantee that indacaterol will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding indacaterol could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including unexpected reimbursement difficulties or delays; competition in general; government, industry and general public pricing pressures; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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 researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group’s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit

http://www.novartis.com.

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Novartis Media Relations

Christine Cascio
Novartis Pharmaceuticals Corporation
+1 862 778 8026 (direct)
+1 862 926 7992 (mobile)
christine.cascio@novartis.com

e-mail: media.relations@novartis.com
Anna Frable
Novartis Pharmaceuticals Corporation
+1 862 778 5388 (direct)
+1 732 673 5262 (mobile)
anna.frable@novartis.com

Novartis Investor Relations

Central phone: +41 61 324 7944
Susanne Schaffert +41 61 324 3769
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188
e-mail: investor.relations@novartis.com

North America:
Richard Jarvis +1 212 830 2433
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456
e-mail: investor.relations@novartis.com

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7. mailto:media.relations@novartis.com
8. mailto:anna.frable@novartis.com
9. mailto:investor.relations@novartis.com
10. mailto:investor.relations@novartis.com