FDA advisory committee recommends US approval of Novartis once-daily bronchodilator QAB149 for COPD

Mar 08, 2011

- Phase III program demonstrated significant improvement in lung function lasting for 24 hours and supported safety and tolerability profile of QAB149[1]
- 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, March 8, 2011 – An advisory committee recommended today that the Food and Drug Administration (FDA) approve QAB149 (indacaterol) 75 mcg in the US as a once-daily long-term maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

The committee voted 13 to four in favor of recommending approval of the 75 mcg dose. The advisory committee also voted 12 to five against recommending approval of the 150 mcg dose. The 75 mcg dose was seen as effective as the 150 mcg dose and the committee endorsed the safety of both doses.

The recommendation by the Pulmonary-Allergy Drug Advisory Committee (PADAC) followed a request from the FDA to further explore the efficacy and safety of lower doses of QAB149, an investigational medicine in the long-acting beta2-agonist (LABA) class.

The FDA has the option of seeking the advice of its advisory committees when it is reviewing a new drug for approval, although it is not obliged to follow the committee's recommendations.

"Novartis is committed to addressing the needs of patients with COPD and we are encouraged by the advisory committee's recommendation for approval of QAB149," said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. "The company is focused on bringing innovative, safe and effective treatment options to patients and physicians, and we will work closely with the FDA as it completes its review of QAB149."

The advisory committee reviewed an extensive program of clinical trials in which the efficacy of QAB149 at 75 and 150 mcg was studied in a total of 1,282 COPD patients in five key Phase III trials lasting 12-26 weeks. Results showed that both doses of QAB149 significantly improved lung function compared to placebo. These improvements were seen five minutes after the first dose and lasted for 24 hours.

The clinical trial program supporting US submission evaluated safety in 4,764 patients who received QAB149 for at least 12 weeks at doses of 75 mcg and greater, with results supporting the safety and tolerability profile of QAB149. The most commonly reported adverse events with both the 75 and 150 mcg doses were worsening of COPD, nasopharyngitis, cough, and headache.
"We must intensify our efforts to increase awareness, prevention and detection, and to develop new treatments to help reduce the enormous burden COPD places on patients,

their families and our healthcare system," said John W. Walsh, president and co-founder of the US-based COPD Foundation. "Deaths from COPD are increasing much faster than previously projected, which should be a wake-up to all of us."

QAB149 is approved at 150 and 300 mcg once-daily doses in more than 50 countries worldwide under the brand-name Onbrez® Breezhaler®. Altogether, the clinical trial program for QAB149 involved more than 15,000 people of whom 9,243 were given QAB149 at varying doses and assessed for safety.

In the US, Novartis is seeking approval for the use of QAB149 as a once-daily long-term maintenance bronchodilator treatment for airflow obstruction in patients with COPD, including bronchitis and/or emphysema. Novartis is not seeking an indication for asthma. If approved in the US, the proposed brand name will be Arcapta™ Neohaler™.
COPD, a progressive and life-threatening lung disease making it difficult to breathe, affects more than 12 million people in the US, while another 12 million people are estimated to have the disease but are undiagnosed. COPD ranks as the third leading cause of death in the US and is a major cause of serious long-term disability.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "recommends," "recommended," "recommending," "recommendation," "recommendations," "committed," "focused," "will," "projected," "seeking," or similar expressions, or by express or implied discussions regarding potential marketing approvals for QAB149 or regarding potential future revenues from QAB149. 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 QAB149 will be approved for sale in the US or in any additional market, or regarding the timing of any such approvals. Nor can there be any guarantee that QAB149 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding QAB149 could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. 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 (including 16,700 Alcon associates) and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

###

Novartis Media Relations

Christine Cascio Anna Frable
Novartis Pharmaceuticals Corporation Novartis Pharmaceuticals Corporation +1 862 778 8026 (direct) +1 862 778 5388 (direct) +1 862 926 7992 (mobile) +1 732 673 5262 (mobile) christine.cascio@novartis.com anna.frable@novartis.com
e-mail: media.relations@novartis.com

Novartis Investor Relations
Central phone: +41 61 324 7944 Susanne Schaffert +41 61 324 3769 North America: Pierre-Michel Bringer +41 61 324 1065 Richard Jarvis +1 212 830 2433 Thomas Hungerbuehler +41 61 324 8425 Jill Pozarek +1 212 830 2445 Isabella Zinck +41 61 324 7188 Edwin Valeriano +1 212 830 2456
e-mail: investor.relations@novartis.com e-mail: investor.relations@novartis.com

---

Source URL: *https://prod1.novartis.com/us-en/news/media-releases/fda-advisory-committee-recommends-us-approval-novartis-once-daily-bronchodilator-qab149-copd*

List of links present in page

1. https://prod1.novartis.com/us-en/us-en/news/media-releases/fda-advisory-committee-recommends-us-approval-novartis-once-daily-bronchodilator-qab149-copd
2. http://www.novartis.com
3. mailto:christine.cascio@novartis.com
4. mailto:anna.frable@novartis.com
5. mailto:media.relations@novartis.com
6. mailto:investor.relations@novartis.com
7. mailto:investor.relations@novartis.com