

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Novartis investigational bronchodilator QAB149 improves lung function and reduces breathlessness compared to tiotropium in patients with COPD**

- *New data show a higher proportion of patients treated with QAB149 achieved clinically relevant improvements in symptoms of breathlessness compared to tiotropium<sup>1</sup>*
- *Patients taking QAB149 experienced 20 percent more days free of 'relief' medication, used to treat acute episodes of severe breathlessness, compared to tiotropium<sup>2</sup>*
- *The Phase III data reinforce that once-daily QAB149 combines relevant 24-hour bronchodilation<sup>3,4</sup> with an onset of action within five minutes<sup>5</sup>*

**Basel, September 15, 2009** — Novartis announced today results from Phase III trials showing QAB149 (indacaterol), an investigational once-daily bronchodilator for chronic obstructive pulmonary disease (COPD), significantly improves lung function<sup>3</sup> and provides a significant reduction in breathlessness<sup>1</sup> compared to tiotropium, a current treatment option. The data were presented this week at the European Respiratory Society (ERS) 2009 Annual Congress in Vienna, and build on those presented at the American Thoracic Society (ATS) Annual Meeting earlier this year.

"QAB149 has the potential to be recognized as the best bronchodilator for COPD by providing patients with significantly greater lung function improvement and reductions in breathlessness compared to other bronchodilators," said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. "We also plan for QAB149 to form the foundation of a new portfolio of products, designed to improve patients' respiratory health."

At 12 weeks of treatment, QAB149 150 µg and 300 µg improved trough FEV<sub>1</sub><sup>§</sup>, a key measure of lung function, by 50 ml and 40 ml respectively over tiotropium 18 µg ( $p \leq 0.01$ )<sup>3</sup>. New data show at week 26, that patients on QAB149 300 µg continued to show greater improvement in trough FEV<sub>1</sub> than tiotropium ( $p < 0.05$ )<sup>3</sup>.

Further new data shows that a higher proportion of patients treated with QAB149 achieved a significant clinically relevant improvement in their symptoms of breathlessness compared to tiotropium<sup>1</sup>. Patients on QAB149 also had a highly significant greater than 20 percent increase in days during which no 'relief' medication, therapies used to treat acute episodes of severe breathlessness, was required compared to patients treated with tiotropium<sup>2</sup>.

If approved, QAB149 would become the first once-daily bronchodilator to combine clinically relevant 24-hour bronchodilation<sup>3,4</sup> with onset of action within five minutes<sup>5</sup>. QAB149 is currently undergoing regulatory review in the European Union, the United States and other countries around the world for the treatment of COPD.

"As most COPD patients want to remain active, we need new therapy options that alleviate some of the lifestyle compromises patients are forced to make due to their COPD," said Professor Ronald Dahl, University Hospital of Aarhus, Denmark. "These indacaterol data in

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<sup>§</sup> Forced expiratory volume in the first second

effect mean that the improvements in lung function are accompanied by important quality-of-life improvements that our patients need.”

Data presented on all evaluated doses of QAB149 highlights a good overall safety and tolerability profile<sup>6,7</sup>. The most common adverse drug reactions were nasopharyngitis, cough, upper respiratory tract infection, and headache. These were mild or moderate in the vast majority of cases and became less frequent if treatment was continued.

COPD is a progressive, life-threatening respiratory disease<sup>8</sup> that affects 210 million people worldwide<sup>9</sup>. Commonly caused by cigarette smoke and other harmful fumes, COPD is characterized by a persistent obstruction of airflow in the lungs, resulting in breathlessness<sup>8</sup>. According to the World Health Organization, COPD is currently projected to become the third leading cause of death worldwide by 2030<sup>10</sup>. Bronchodilators are a group of drugs that widen the airways in the lungs. While incurable, COPD is manageable and improving airflow with the use of long-acting bronchodilators is central to symptomatic relief<sup>11</sup>.

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## Novartis Media Relations

**Central media line :** +41 61 324 2200

**Eric Althoff**

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

[eric.althoff@novartis.com](mailto:eric.althoff@novartis.com)

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

**Rebecca Fisher-Pollard**

Novartis Pharma Communications

+41 61 324 91 66

+41 79 426 46 84

[rebecca.fisher-pollard@novartis.com](mailto:rebecca.fisher-pollard@novartis.com)

## Novartis Investor Relations

**Central phone:** +41 61 324 7944

Ruth Metzler-Arnold +41 61 324 9980

Pierre-Michel Bringer +41 61 324 1065

John Gilardi +41 61 324 3018

Thomas Hungerbuehler +41 61 324 8425

Isabella Zinck +41 61 324 7188

**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](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)