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New study shows potential benefits of innovative Xolair® anti-IgE therapy in treating children suffering from moderate-to-severe allergic asthma

- *Results demonstrate that Xolair significantly reduces asthma attacks in children aged six to 11 years¹*
- *Xolair could offer innovative approach to treating asthmatic children by targeting IgE, a root cause of the symptoms of allergic asthma*
- *Asthma is the most common chronic disease of childhood affecting up to 20% of children in some countries²; around 78% of cases associated with high IgE³*
- *Xolair currently approved for adults and adolescents – worldwide submissions to treat children aged six to 11 years are planned*

Basel, October 6, 2008 — A new clinical study shows that Xolair® (omalizumab), an innovative treatment for allergic asthma in adolescents and adults, significantly reduced asthma attacks (or ‘exacerbations’) in children aged six to 11 years with uncontrolled moderate-to-severe persistent allergic asthma¹.

Asthma is the most common chronic disease of childhood, affecting as many as 10-20% of children in the US, Europe and Australia². Up to 78% of these cases are associated with high levels of the immunoglobulin E (IgE) antibody³, a root cause of allergic asthma.

Xolair is a unique treatment which blocks the action of IgE. By targeting the underlying mechanism of the disease, Xolair can prevent the onset of debilitating symptoms, such as wheezing and shortness of breath, in severely affected patients.

Results of a Phase III study in children were presented today at the annual meeting of the European Respiratory Society (ERS) in Berlin.

The study showed that after 24 weeks, children treated with Xolair suffered 31% fewer clinically significant exacerbations than those receiving placebo or dummy drug ($p=0.007$)¹. The study therefore met its primary endpoint. Over the entire one-year study, children treated with Xolair suffered 43% fewer exacerbations than those on placebo ($p<0.001$)¹. Xolair was generally safe and well-tolerated in the clinical trial with no differences in adverse events compared with placebo¹.

“These data represent an important new approach to treating allergic asthma in children who remain uncontrolled despite their treatment,” said Professor Bobby Lanier of the University of North Texas Health Science Center, USA. “These children are particularly vulnerable and their lives can be severely affected or even cut short by this disease.”

Xolair is approved for adults and adolescents (aged 12 years or above) with moderate to severe persistent asthma in the US, and with severe allergic asthma in the EU. Patients must

have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and their symptoms must be inadequately controlled with inhaled corticosteroids. Xolair was approved in the US in 2003 and the EU in 2005, and is now available in 56 countries. Worldwide submissions to treat children aged six to 11 years are planned.

The double-blind, placebo-controlled study presented at ERS assessed the efficacy and safety of Xolair in children aged six to 11 years (n=628) with moderate-to-severe persistent allergic (IgE-mediated) asthma¹. The study comprised a 24-week fixed-dose steroid phase, followed by a 28-week phase in which steroid dose could be reduced and a 16-week safety follow-up period.

“Xolair continues to improve the lives of asthma patients across the world, and Novartis is excited about the future opportunity to extend the use of this breakthrough treatment to help younger patients and their families,” said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG.

Asthma causes children to lose many school-days and may limit their academic achievements and harm social relationships⁴. Despite treatment, nearly 497,000 children were hospitalized for asthma in the US alone in 2004⁵.

Previous Xolair studies have included 479 children aged six to 12 years. In one Phase III double-blind, placebo-controlled study evaluating Xolair as add-on therapy in children with moderate-to-severe allergic asthma treated with inhaled corticosteroids, Xolair reduced the number of exacerbations, and decreased the use of oral corticosteroids⁶.

The results of the studies in children are consistent with earlier clinical trials in adults and adolescents, which showed an average 38% reduction in exacerbations vs. placebo (p<0.001) with halving of severe exacerbations and hospitalizations⁷.

Xolair, a humanized monoclonal antibody, is administered by a healthcare provider through subcutaneous (under the skin) injection once every two or four weeks. The efficacy of Xolair has already been recognized in international treatment guidelines such as those issued by the Global Initiative for Asthma (GINA), which recommends anti-IgE therapy as add-on treatment for patients with severe allergic asthma that is inadequately controlled by standard clinical options⁸.

In clinical studies, the most common side effects in patients receiving Xolair included injection site reactions, viral infections, upper respiratory tract infection, sinus infection, headache, and sore throat. The most serious adverse events reported with Xolair have been anaphylaxis and malignancies. Anaphylaxis, a potentially-life-threatening allergic reaction, has occurred in some patients after they received Xolair. Xolair should always be injected in a doctor’s office and patients should be instructed to seek emergency medical treatment immediately if symptoms occur.

Xolair is manufactured by Novartis Pharma AG. In the US, it is co-promoted by Novartis Pharmaceuticals Corporation and Genentech, Inc.

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implied by such statements. There can be no guarantee that Xolair will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Xolair will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Xolair 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; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; 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.

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