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FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

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THE SECURITIES EXCHANGE ACT OF 1934

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(Commission File No. 1-15024)

Novartis AG

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- Investor Relations Release -

One-year Phase III study confirms Ilaris® offers long-term remission in patients with CAPS, a severe lifelong auto-inflammatory disease

- *New Ilaris data in The New England Journal of Medicine show rapid sustained efficacy in patients with cryopyrin-associated periodic syndrome (CAPS)(1)*

- *CAPS is a debilitating genetic disorder with potentially fatal complications and limited treatments available(1),(2),(3)*

- *Ilaris selectively blocks interleukin-1ß (IL-1ß), a key driver in inflammation and tissue destruction therapy being investigated for other inflammatory diseases(1),(3),(4)*

- *Regulatory submissions completed in major countries with priority review granted in US, Switzerland and Australia*

Basel, June 3, 2009 New results from a one-year Phase III study have confirmed that the investigational biological therapy Ilaris® (canakinumab, formerly ACZ885)(1) produced rapid and sustained remission of symptoms in the majority of children and adults with a rare and potentially life-threatening auto-inflammatory disease called cryopyrin-associated periodic syndrome (CAPS)(1),(2),(3).

The study showed that more than 90% of CAPS patients treated with Ilaris (28 out of 31) remained in remission at the end of the final four-month phase of the study(1). This finding supported interim data from earlier phases showing efficacy in 97-100% of patients(1),(5). The full results have now been published in *The New England Journal of Medicine*(1).

This study represents an important step forward for the rare disease community, as canakinumab treats the underlying causes of CAPS rather than just the symptoms, said Helen J. Lachmann, MD of the UK National Amyloidosis Centre at the Royal Free and University College Medical School in London, UK. In the study, patients experienced a benefit within hours after receiving a single dose of canakinumab and only needed further treatment every two months to control their symptoms. This may give canakinumab a significant advantage over current therapies in an area of unmet medical need.

CAPS includes a number of lifelong diseases associated with a gene mutation and characterized by the overproduction of interleukin 1-β (IL-1β), a protein (or cytokine) that has a pivotal role in driving inflammation and tissue destruction(1),(2),(6),(7). The clinical benefits of Ilaris, a fully human monoclonal antibody, are due to its selective and long-lasting blockade of IL-1β(1),(6). By neutralizing IL-1β for a sustained period, Ilaris switches off all symptoms of inflammation in CAPS, as demonstrated in new research published in *The Journal of Experimental Medicine(1),(4),(6)*.

(1) Tradename Ilaris (spelt: I-L-A-R-I-S) is subject to regulatory approval.

The success in treating CAPS led Ilaris to be investigated also in other rare diseases such as systemic juvenile idiopathic arthritis (SJIA), or more common ones such as some forms of gout, chronic obstructive pulmonary disorder (COPD), rheumatoid arthritis and type 2 diabetes(4),(6),(8),(9).

The Novartis research and development strategy for Ilaris involves using proof-of-concept studies which are small-scale Phase I clinical trials in genetically well-defined diseases to determine how genes interact in molecular or signaling pathways(10). The resulting clinical and biomarker data are then subjected to state-of-the-art modeling and simulation to yield new insights into the regulation of IL-1ß in patients(10).

Ilaris is the outcome of our highly innovative approach to research and development that is designed to bring more and better targeted medicines to patients in the shortest possible time, said Trevor Mundel, MD, Head of Global Development at Novartis Pharma AG. We are extremely excited about the efficacy shown by Ilaris in patients with CAPS, and we hope to be able to extend these benefits to many more patients with other inflammatory diseases which are more widespread, and often equally debilitating.

CAPS comprises three syndromes of increasing severity: familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS) and neonatal-onset multisystem inflammatory disease (NOMID)(1),(2). Patients with CAPS experience debilitating fatigue, fever and chronic anemia from infancy(1),(2),(11). Inflammation can affect the skin, eyes and bones causing rashes, conjunctivitis and destructive arthritis(1),(2),(11). Other severe complications of CAPS include progressive hearing loss, visual and intellectual impairment, and amyloidosis, a condition in which the build-up of proteins can cause vital organs to fail(1),(2),(3),(11). About 25% of CAPS patients develop systemic amyloidosis resulting in renal failure, and usually in death within five to 10 years(3).

The Phase III clinical trial in CAPS was a multinational, randomized, double-blind and placebo-controlled study designed to assess the efficacy, safety and tolerability of Ilaris(1). The 48-week study involved 35 patients aged nine to 74 years old and was divided into three parts(1). First interim results were presented at the American Rheumatology College meeting in October 2008(5), while full one-year results are now published for the first time in *The New England Journal of Medicine*(1).

In the first part of the study lasting eight weeks, 35 patients received a single dose of Ilaris (150 mg by subcutaneous injection). All but one patient (97%) showed a rapid and complete response(1). After this, 31 patients who maintained their response proceeded to part two, a randomized 24-week, double-blind placebo-controlled phase. Patients were treated every eight weeks with either Ilaris or placebo and if a relapse occurred, they entered part three.

Part two of the study included the primary endpoint, a comparison between the number of patients treated every eight weeks with Ilaris who experienced disease relapse or flares vs. those on placebo. Results showed that no patients in the Ilaris group experienced a disease flare compared to 13 out 16 patients in the placebo group (0% vs. 81%, $p<0.001$)(1).

Following either completion of part two or occurrence of a disease flare, patients proceeded to part three which involved at least two further doses of Ilaris for a minimum of 16 weeks. Out of 31 patients who entered part three, 28 completed this phase of the study without suffering a relapse (90%)(1). One patient suffered a relapse on the last day of the study, i.e. 62 days after receiving their last dose of Ilaris(1). In addition, one patient discontinued the study due to a perceived lack of therapeutic response, and one discontinued because of a urinary tract infection(1).

Ilaris was generally well tolerated, with no consistent pattern of adverse events beyond an increase in all suspected infections(1). Two patients experienced serious adverse events but there were no deaths or life-threatening adverse events during the study(1).

Ilaris has orphan drug status in the EU, US, Switzerland and Australia for the treatment of CAPS and is currently under priority review by the regulatory authorities in US, Switzerland and Australia. Regulatory review is also underway in the EU. Orphan drugs are those designed to treat serious or life-threatening diseases affecting fewer than 200,000 people (in the US)(12) or fewer than five out of 10,000 people (in the EU)(13). Ilaris has also been granted orphan drug status for SJIA in the EU, Switzerland and in the US.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potentially, being investigated, priority review, may, designed to, hope to, or similar expressions, or by express or implied discussions regarding potential future regulatory filings or marketing approvals for Ilaris or regarding potential future revenues from Ilaris. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Ilaris to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Ilaris will be approved for sale in any market, or for any particular indication. Nor can there be any guarantee that Ilaris will achieve any levels of revenue in the future. In particular, management s expectations regarding Ilaris 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 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 AG 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 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB et al. A Randomized Trial of Canakinumab in Cryopyrin-Associated Periodic Syndrome. NEJM. 2009.

(2) K. L.W Durrant, R. Goldbach-Mansky, H. Hoffman, K.Leslie, B. Rubin. CAPS Cryopyrin-Associated Periodic Syndromes 2008. Available at: http://www.nomidalliance.net/Download1.html, last accessed 19.04.09.

(3) National Horizon Scanning Centre. Canakinumab for cryopyrin associated periodic syndrome. November 2008. Available at: http://www.pcpoh.bham.ac.uk/publichealth/horizon/outputs/documents/2008/sept-dec/Canakinumab.pdf Accessed: 21.04.09

(4) Alten R, Gram H, Joosten LA, *et al.* The human anti-interleukin-1ß (IL-1ß) monoclonal antibody ACZ885 is effective in joint inflammation models in mice and in a proof of concept study in rheumatoid arthritis patients. Arthritis Res Ther 2008;10:R67.

(5) Lachmann HJ, Kone-Paut I, Kümmerle-Deschner J *et al*. Efficacy and safety of canakinumab (ACZ885), a fully human anti-interleukin-1β antibody, in cryopyrin associated periodic fever syndrome: Results of a multicenter, randomized, double-blind, phase III study. Poster presented at the American College of Rheumatology 2008. 24-29 October. San Francisco, USA.

(6) Lachmann HJ, Lowe P, Felix SD *et al*. In vivo regulation of interleukin 1 in patients with cryopyrin-associated periodic syndromes. J. Exp. Med. 2009. Published online April 13 2009. Available at: www.jem.org/cgi/doi/10.1084/jem.20082481

(7) Joost PH, Drenth MD, Jos W.M. van der Meer. The Inflammasome - A Linebacker of Innate Defense. NEJM 2006. Vol 355:730-732. Number 7

(8) Church LD, Cook GP, McDermott MF. Primer: inflammasomes and interleukin 1ß in inflammatory disorders. Nat Clin Pract Rheumatol 2008;4:34-42.

(9) Dinarello C.A. Blocking IL-1 in systemic inflammation. JEM Vol. 201, No. 9, May 2, 2005 1355 1359

(10) Novartis data on file

(11) Kastner DL. Hereditary Periodic Fever Syndromes. Hematology 2005 American Society of Hematology Education Program. 2005: 74-81.Available at: http://asheducationbook.hematologylibrary.org/cgi/reprint/2005/1/74

(12) Orphan Drug Act. US Food and Drug Administration. Section 526 (2), Line 2.

(13) The orphan drug strategy. Europa: Gateway to the European Union. Paragraph 1, Line 1.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: June 3, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting