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ACZ885, a new biological drug in development, shows potential in treating serious life-long autoinflammatory diseases

- *Patients with inherited autoinflammatory conditions achieved long-lasting remission after treatment with ACZ885^{1,2}*
- *Human monoclonal antibody ACZ885 blocks interleukin 1 β , a key chemical messenger that causes inflammation and tissue destruction*
- *Autoinflammatory diseases produce symptoms such as fever, joint pain and skin rash and can lead to severe complications*
- *ACZ885 also being investigated for rheumatoid arthritis using innovative personalized approach to treatment*

Basel, April 8, 2008 – New data demonstrate that ACZ885, a human monoclonal antibody in Phase III development, achieves long-lasting clinical remission in patients with genetic autoinflammatory diseases^{1,2}.

The results indicate that ACZ885 could develop into a major therapeutic advance in the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), a group of rare but serious life-long diseases including Muckle Wells Syndrome³.

In the Phase II study, CAPS patients treated with ACZ885 showed an improvement in symptoms within one day and all achieved complete clinical remission within seven days¹. Clinical remission lasted 115 days on average¹. The results were presented today at the Fifth International Congress on Familial Mediterranean Fevers and Systemic Autoinflammatory Diseases in Rome.

“The latest findings are a promising step forward for patients with rare autoinflammatory diseases,” said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. “We are optimistic that ACZ885 could become an innovative treatment option for patients affected by inflammatory diseases involving IL-1 β . ACZ885 reflects our commitment to developing innovative treatments that address unmet medical needs, in patients with serious but rare conditions.”

ACZ885 is also being investigated in more common inflammatory diseases such as rheumatoid arthritis (RA), which affects up to 1% of the world’s population⁴. A study in RA currently under way uses an innovative tailored approach with biomarkers to predict response to treatment. If successful, this will give suitable patients a personalized approach to treating their disease.

Unlike other agents, ACZ885 blocks solely interleukin 1 β (IL-1 β), one form of interleukin-1 protein that causes the body to ‘attack’ itself in autoinflammatory diseases such as CAPS. Patients affected by CAPS have symptoms such as fever, fatigue, skin rash, painful joints and muscles, and severe headache. They can also suffer from more severe complications

like hearing loss and amyloidosis, a group of diseases in which some organs accumulate high deposits of proteins causing kidney failure and leading to dialysis or transplantation³.

The study results presented in Rome involved 20 patients with CAPS aged between six and 50 years, who received an injection of ACZ885 every two months dosed at 150 mg for adults or two mg per kilo body-weight for children^{1,2}. ACZ885 was well-tolerated in the study, with only mild skin reactions at the injection site. The most common adverse events were upper respiratory tract infections².

“Traditional drugs for autoinflammatory diseases, which work by suppressing the immune system as a whole, are not always effective, while newer therapies control the disease better but are short-acting,” said Professor Philip Hawkins of the National Amyloidosis Centre at the Royal Free and University College Medical School, London. “The data for ACZ885 are exciting for the medical community as symptoms disappeared within a few days of treatment and the response was sustained, so patients may only need to be treated every second month.”

The potential of ACZ885 is reflected in its broad development program. In addition to the Phase III study program in CAPS and the Phase II study in rheumatoid arthritis, a Phase II study is also ongoing in another condition called Systemic Onset Juvenile Idiopathic Arthritis (SJIA).

Orphan drug status has already been granted to ACZ885 in the European Union and US for treating CAPS, and in the EU for SJIA. Orphan drugs are those designed to treat serious or life-threatening diseases affecting less than 200,000 people (in the US)⁵ or less than five out of 10,000 people (in the EU)⁶.

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The foregoing release contains forward-looking statements that can be identified by terminology such as “in development”, “potential”, “can”, “being investigated”, “could”, “promising”, “optimistic”, “commitment”, “will”, “may”, or similar expressions, or by express or implied discussions regarding potential marketing approvals for ACZ885 or regarding potential future revenues from ACZ885. 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 ACZ885 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that ACZ885 will be approved for sale in any market. Nor can there be any guarantee that ACZ885 will achieve any levels of revenue in the future. In particular, management’s expectations regarding ACZ885 could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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, 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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