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Emselex® Receives Positive CHMP Opinion for the Treatment Of Overactive Bladder

Basel, 30 July 2004 – Novartis Pharma AG announced today that the Committee for Medicinal Products for Human Use (CHMP), adopted a positive opinion recommending that the European Commission (EC) grant a Marketing Authorisation for Emselex® (darifenacin hydrobromide), 7.5mg and 15mg, for the treatment of overactive bladder (OAB) in all 25 European Union (EU) countries as well as Norway and Iceland. Upon receipt of the EC approval, Novartis will be able to market Emselex throughout these countries.

“We are delighted by the CHMP’s positive opinion for Emselex, to provide overactive bladder sufferers with a new safe and effective treatment option”, said Jörg Reinhardt, Global Head of Development Novartis Pharma AG. “Due to its M₃ selectivity, Emselex provides effective overactive bladder symptom relief while decreasing the potential risk of safety issues such as cognitive impairment or effects on cardiac function.”

OAB affects almost one in six adults in Europe¹. Symptoms of overactive bladder are urinary urgency (a sudden compelling desire to pass urine, which is difficult to defer) with or without urge incontinence (involuntary leakage accompanied by urgency), urinary frequency (voiding the bladder too often), and nocturia (waking at night one or more times to void the bladder).

The CHMP based its positive opinion on Emselex’s comprehensive data package for OAB. The safety and efficacy of Emselex has been extensively studied in over 90 pre-clinical studies and clinical trials, involving more than 5,000 patients. Pivotal studies explored key endpoints including the reduction in the number of incontinence episodes per week, the reduction in the number of voluntary urination episodes (micturition) per day, the reduction in the episodes and severity of urgency and an increase in the average volume of urine passed per micturition.

The phase III clinical trials demonstrated the efficacy, safety and tolerability of Emselex. A pooled analysis of three multicentre, double-blind, placebo-controlled studies included a population of 1,049 adults with OAB symptoms for more than 6 months. Results demonstrated that Emselex reduces the number of weekly incontinence episodes by up to 77%¹. Emselex was well tolerated and discontinuation rates due to dry mouth or constipation were very low with each dose of Emselex compared to placebo². Also, central nervous system (CNS) and cardiovascular safety of Emselex were comparable to placebo at both doses¹. Another study showed Emselex does not impair cognitive function such as memory, choice reaction time and word recognition, compared to placebo³.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 80 000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

Disclaimer

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as “upon receipt of ... approval”, “will be able to market”, “potential”, “may be” or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of Emselex. 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 the actual results with Emselex to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Emselex will be approved for sale in any new market or that it will reach any particular sales levels. Any such commercialisation can be affected by, amongst other things, uncertainties relating to clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, government, industry, and general public pricing pressures, as well as factors discussed in the Company's Form 20F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as 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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