

Novartis Receives European Marketing Authorization for Emselex(R)

Basel, Switzerland (ots/PRNewswire) -

- New M3 selective receptor antagonist treatment for overactive bladder

Novartis Pharma AG announced today that Emselex(R) (darifenacin hydrobromide), 7.5 mg and 15 mg, has been granted Marketing Authorization by the European Commission for the treatment of overactive bladder (OAB) in all 25 European member states as well as Norway and Iceland.

"The approval of Emselex will provide many people in Europe who experience OAB symptoms a safe and effective new treatment option," said Jorg Reinhardt, Global Head of Development, Novartis Pharma AG. "Emselex has an excellent efficacy as well as central nervous system and cardiovascular safety profile, offering physicians a new choice for treating people with overactive bladder."

Emselex is a once-daily M3 selective receptive antagonist (M3 SRA) oral treatment that works by selectively inhibiting the detrusor muscle that controls bladder contraction while sparing the M1 and M2 receptors believed to be involved in central nervous system (CNS) and cardiovascular (CV) function, respectively.(1) Emselex has been shown to reduce the number of weekly incontinence episodes by up to 77%(2) versus placebo. Additional clinical trials have shown that Emselex works without impairing cognitive function(3) and without cardiovascular safety concerns(2).

To date, 97 clinical trials with Emselex have been carried out involving more than 10,500 subjects and patients, of whom 7,146 were treated with darifenacin. Across a range of pivotal endpoints, Emselex has been shown to significantly improve all other key symptoms of OAB, including the number of times patients had to visit the bathroom each day, bladder capacity, frequency of urgency, severity of urgency and number of incontinence episodes leading to a change in clothing or pads.(1)

About OAB

Symptoms of overactive bladder include urinary urgency (a sudden and 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).

Disclaimer

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "will provide", or similar expressions, or by express or implied discussions regarding potential additional 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 receive any additional marketing approvals in any other countries, or that it will reach any particular sales levels. Any such results can be affected by, among 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, competition in general, government, industry, and general public pricing pressures, as well as factors discussed in the Company's Form 20-F filed 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 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.

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>.

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References

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2. Chapple C. Darifenacin is effective in improving the major symptoms of overactive bladder: A pooled analysis of phase III studies. *Eur Urol Suppl* 2004;3(2):A512
3. Wesnes K, Lipton R, Kolodner K, Edgar C. Darifenacin, an M3 selective receptor antagonist for the treatment of overactive bladder, does not affect cognitive function in elderly volunteers. *Eur Urol Suppl* 2004;3(2):A513

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