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Novartis Receives Recommendation for Approval of Patch Formulation of Exelon®, Only Skin Patch for the Treatment of Alzheimer's Disease in EU

Novartis AG (Basel, Switzerland) announced on July 19, 2007 (local time, Switzerland) that a patch formulation of Exelon®, only skin patch therapy for the treatment of Alzheimer's disease which the company had filed new drug applications for approval in the EU, was recommended for approval in the European Union. For your information, the attached is the announcement text that the company released.

In Japan, the drug has been jointly developed by Novartis Pharma K.K. and Ono Pharmaceutical Co., Ltd. based on the License Agreement entered in December 2005, and the phase III clinical study is now underway by both companies.

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Exelon® skin patch recommended for European approval, the first use of this new technology to treat patients with Alzheimer's disease

- *Once-daily patch offers novel approach to treating Alzheimer's disease, providing smooth and continuous delivery of drug over 24 hours[1]*
- *Similar efficacy to highest doses of Exelon capsules with significant improvement in memory and ability to perform everyday activities compared to placebo[1]*
- *Designed with compliance in mind and preferred by caregivers, helping them manage patient care and giving visual reassurance of treatment[2]*
- *Minimizes gastrointestinal side effects seen with oral form of drug[1]*

Basel, July 19, 2007 – A patch that delivers Exelon®, an effective Alzheimer's disease medication, through the patient's skin has been recommended for approval in the European Union – the first time this technology has been applied to treat the disease in the EU.

Exelon (rivastigmine transdermal patch) received a positive opinion for treating mild to moderately severe forms of Alzheimer's disease from the Committee for Medicinal Products for Human Use (CHMP), the body that reviews drug applications for all 27 EU member states as well as Iceland and Norway.

This announcement comes on the same day that the CHMP recommended approval for two other Novartis medicines, Galvus® (vildagliptin) for type 2 diabetes and Aclasta® (zoledronic acid 5 mg) for postmenopausal osteoporosis. So far this year Novartis has received a total of seven product approvals and four positive opinions from the US and European regulatory authorities, providing innovative treatments to patients and creating a strong new growth platform.

The European Commission generally follows the recommendation of the CHMP and is expected to issue a decision on Exelon patch within three months. The announcement comes a few weeks after this medicine was approved in the US.

"Exelon patch offers unique therapeutic benefits because it maintains steady drug levels in the bloodstream, improves tolerability and allows a higher proportion of patients to receive therapeutic doses of medication," said Alexander Kurz, MD, Professor of Psychiatry and Head of the Centre for Cognitive Disorders at the Department of Psychiatry and Psychotherapy of Technische Universität München, Munich, Germany.

"Coupled with the clear benefits for caregivers in terms of ease of administration, it represents a significant advance in the treatment of Alzheimer's disease. We look forward to the time when this important new therapy will be available throughout the EU," Dr. Kurz said.

Alzheimer's disease is a progressive disorder that alters the brain, causing impaired memory, thinking and behavior, and is estimated to affect 18 million people worldwide[3]. The patch is applied to the back, chest or upper arm, and provides smooth and continuous delivery of medication through the skin over 24 hours with the potential for improved efficacy[1].

A key attribute of Exelon patch is a sharp reduction in gastrointestinal side effects commonly seen with the oral forms of this class of drugs called cholinesterase inhibitors. In a clinical trial these side effects were greatly reduced, with three times fewer reports of nausea and vomiting than with the capsule form of the drug[1].

Designed with compliance in mind, Exelon patch was preferred to capsules by more than 70% of caregivers in a clinical study as a method of drug delivery because it helped them follow the treatment schedule, interfered less with their daily life, and was easier to use overall than an oral medication[2].

"The positive recommendation in Europe, coming so soon after the US approval, highlights the tremendous importance of Exelon patch as an innovative way of delivering a proven medicine," said James Shannon, MD, Global Head of Development at Novartis Pharma AG. "The patch offers visual reassurance that the medication has been given, and helps caregivers cope with the daily challenges of looking after someone with this devastating disease."

The EU positive opinion was based on results from the international IDEAL (Investigation of Transdermal Exelon in ALzheimer's disease) trial, which showed that patients receiving the Exelon patch demonstrated improved memory, overall functioning, and ability to perform everyday activities than those taking placebo[1].

Since 1997, Exelon (rivastigmine) has been used to treat mild to moderate Alzheimer's disease in more than 70 countries. Exelon is the only cholinesterase inhibitor to be approved for both mild to moderate Alzheimer's disease and Parkinson's disease dementia in both Europe and the US. The US Food and Drug Administration approved Exelon®Patch (rivastigmine transdermal system) on July 6 for the treatment of both mild to moderate Alzheimer's disease and Parkinson's disease dementia.

Alzheimer's disease affects one in 10 people over the age of 65, making it the most common form of dementia and the third leading cause of death in this age group behind cardiovascular disease and cancer[3]. The global direct costs of dementia were estimated at USD156 billion in 2003[4].

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Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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