

ExelonPatch, the First and Only Skin Patch for the Treatment of Alzheimer's disease, Receives First Worldwide Approval in US

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Once-daily skin patch offers novel approach to treating mild to moderate Alzheimer's disease, providing smooth and continuous delivery of drug over 24 hours

Similar efficacy to highest doses of Exelon capsules with significant improvement in memory and ability to perform everyday activities compared to placebo

Exelon Patch preferred by caregivers in a study because it helps manage patient care and gives visual reassurance that medication has been administered

Exelon Patch minimizes gastrointestinal side effects seen with oral form of drug

Basel, July 9, 2007 - ExelonPatch (rivastigmine transdermal system) has received its first worldwide approval in the United States as an innovative way to deliver an effective medicine for mild to moderate Alzheimer's disease patients through a skin patch instead of an oral capsule.

This new therapy is the first and only transdermal treatment for this degenerative condition affecting millions of people in the US. Exelon Patch offers effective treatment based on placebo-controlled clinical trial results showing significant benefits to patients in terms of their memory and ability to perform everyday tasks as well as helping their overall functioning.

Exelon Patch maintains steady drug levels in the bloodstream, improving tolerability and allowing a higher proportion of patients to receive therapeutic doses of medication, with potential improvements in efficacy. It is applied to the back, chest or upper arm, and provides smooth and continuous delivery of medication through the skin over 24 hours.

Gastrointestinal side effects are commonly seen with this class of drugs called cholinesterase inhibitors. The target dose of Exelon Patch greatly reduces these side effects, with three times fewer reports of nausea and vomiting than with the capsule form of the drug.

"Exelon Patch represents a significant advance in the treatment of this debilitating disease," said George Grossberg, MD, at St. Louis University in St. Louis, Missouri. "The unique delivery system helps both the patient and the caregiver by providing a much easier way to manage their therapy. The patch provides a visual reassurance for the caregiver that the patient is receiving their medication and helps the patient stay engaged in the activities of daily living."

Exelon Patch is expected to be available in US pharmacies soon. The medication was submitted for review in the European Union in late 2006.

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

The approval of Exelon Patch is based on results from the international IDEAL (Investigation of Transdermal Exelon in Alzheimer's disease) clinical trial, involving nearly 1,200 patients with mild to moderate Alzheimer's disease. Exelon Patch showed similar efficacy to the highest doses of Exelon capsules¹ and the target dose (9.5 mg/24 hours) was well tolerated by patients.

"Innovation isn't just about developing new compounds, but also about meeting therapeutic needs by taking existing knowledge and applying it in new ways," said James Shannon, MD, Global Head of Development at Novartis Pharma AG. "Exelon Patch addresses an important medical need by delivering a proven drug in an entirely new form that meets the needs of patients and their caregivers."

Alzheimer's disease is a progressive, degenerative disease that alters the brain, causing impaired memory, thinking and behavior.

Approximately 18 million people worldwide have Alzheimer's disease.

In the US, more than five million people suffer from Alzheimer's disease and almost 10 million people provide care for someone living with dementia, most of which is related to Alzheimer's disease. By 2030, the number of people in the US who are age 65 and over with Alzheimer's disease is estimated to reach 7.7 million, more than 50% more than current levels.

The FDA also approved the use of Exelon Patch in treating patients with mild to moderate Parkinson's disease dementia. Parkinson's disease is a chronic and progressive neurological condition that affects approximately 1.5 million people in the US. Parkinson's disease dementia is a distinct and common disorder, one characterized by impairments in executive function, memory retrieval, and attention, in patients with an established diagnosis of Parkinson's disease. Two of five people with Parkinson's disease are estimated to have Parkinson's disease dementia.