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Exelon® patch receives European Union approval, the first skin patch therapy to treat Alzheimer's disease

- *Once-daily patch provides smooth and continuous delivery of drug through skin, helps to achieve optimal dosing and offers potential for improved efficacy¹*
- *Shows similar efficacy to highest Exelon capsule doses; significant improvement in memory and ability to perform everyday activities compared to placebo¹*
- *Minimizes gastrointestinal side effects seen with oral form of drug, a common issue for this class of medicines¹*
- *Designed with compliance in mind, skin patch delivery preferred by caregivers because it helps manage patients and gives visual reassurance of treatment²*

Basel, September 24, 2007 – The European Commission has approved Exelon® patch (rivastigmine transdermal patch), an innovative way to deliver this effective medicine to patients suffering from mild to moderately severe Alzheimer's disease.

Exelon patch is the first and only transdermal treatment for Alzheimer's disease, a degenerative brain disorder affecting 18 million people worldwide and the third leading cause of death behind cardiovascular disease and cancer³. The skin patch is applied once-daily to the back, chest or upper arm of patients.

"Exelon patch represents a therapeutic innovation that is designed specifically to meet the needs of patients, caregivers and physicians involved with this devastating disease," said James Shannon, MD, Global Head of Development at Novartis Pharma AG.

"The patch has been shown to increase compliance, reduce side effects, and allow medication to be delivered through the skin into the bloodstream smoothly and continuously over 24 hours, helping to achieve optimal dosing. All these benefits offer the potential for improved outcomes in patients," Shannon said.

The European Union approval, coming soon after the US approval in July 2007, was based on results from the international IDEAL (Investigation of Transdermal Exelon in Alzheimer's disease) study, which involved nearly 1,200 patients with mild to moderate Alzheimer's disease¹.

The patch showed similar efficacy to the highest doses of Exelon capsules, as well as significant improvement in memory and the ability to perform everyday activities compared to placebo¹. In addition, the IDEAL study demonstrated three times fewer reports of gastrointestinal side-effects (nausea and vomiting) with the patch than the oral form of the medication¹.

“The patch is an important new addition to existing oral treatment options since it provides visual reassurance that patients have ‘taken’ their medicine,” said Bruno Dubois, Professor of Neurology at the Hôpital Pitié Salpêtrière, Centre de Neuropsychologie, Paris, France. “Just having to apply a patch can help reduce the burden of daily life for people with Alzheimer’s disease and their families.”

Designed with compliance in mind, the patch was preferred by more than 70% of caregivers as a method of drug delivery because it helped them follow treatment schedules and was easier to use than an oral medicine².

“People with Alzheimer’s disease and their caregivers welcome every new therapy for the disease,” said Mark Wortmann, Executive Director of Alzheimer’s Disease International – an umbrella organization of Alzheimer Associations around the world which offer support and advice to people with the disease and their carers. “I am pleased that the patch offers a new approach to treatment.”

Exelon (rivastigmine) in capsule form has been approved since 1997 to treat patients with mild to moderate Alzheimer’s disease in more than 70 countries.

Since 2006, Exelon in capsule form or oral solution has been the only member of the cholinesterase inhibitor class of medicines that is approved in both Europe and the US for treating mild to moderate Alzheimer’s disease as well as Parkinson’s disease dementia. On July 6, 2007, the US Food and Drug Administration (FDA) approved Exelon[®] Patch (rivastigmine transdermal system) for the treatment of mild to moderate Alzheimer’s disease and Parkinson’s disease dementia.

Alzheimer’s disease affects one in 10 people over age 65, making it the most common form of dementia³. The global direct costs of dementia in 2003, for example, were estimated at USD 156 billion⁴.

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