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Higher dose of Novartis drug Exelon® Patch showed statistically significantly less decline in function in Alzheimer's vs. lower dose

Apr 26, 2012

- • In the trial, patients on Exelon Patch 13.3 mg/24 h showed less functional decline vs. 9.5 mg/24 h patch in mild to moderate Alzheimer's disease
- • Numerical trend toward cognitive efficacy was seen with the higher dose of Exelon Patch compared to the lower dose
- • Consistent safety profile with fewer adverse event-related discontinuations with higher vs. lower dose
- • Data are basis of supplemental New Drug Application (sNDA) to expand label to include 13.3 mg/24 h dose for the treatment of mild to moderate Alzheimer's

East Hanover, NJ, April 25, 2012 — Data from a pivotal Phase III trial show that declining patients with mild to moderate Alzheimer's disease receiving Exelon® Patch (rivastigmine transdermal system) 13.3 mg/24 h experienced a statistically significant ($p<0.05$) lesser decline in function compared with Exelon® Patch 9.5 mg/24 h at 48 weeks, a primary endpoint. Declining patients on the higher dose patch also showed less cognitive decline at all time points, but did not achieve a statistically significant change at 48 weeks of treatment, also a primary endpoint. The study findings were presented today at the 64th Annual Meeting of the American Academy of Neurology (AAN) in New Orleans.

"Progressive symptomatic decline in Alzheimer's disease is inevitable and can trigger a long and difficult journey for both patients and caregivers," said Jeffrey Cummings, MD, a study investigator and Director of the Cleveland Clinic Lou Ruvo Center for Brain Health. "It is our profound hope to find new therapies that can ease the burden on patients. Any development that gives families more hope is an exciting one."

Novartis filed a supplemental new drug application (sNDA) based on these data with the US Food and Drug Administration (FDA) on October 31, 2011, seeking to expand the label for Exelon Patch to include the 13.3 mg/24 h dose in the treatment of mild to moderate Alzheimer's disease patients.

"There remains a significant gap between the therapeutic needs of patients and current therapies, which is why Novartis continues to study Exelon Patch in Alzheimer's disease," said Usman Azam, MD, head of US Medical & Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation. "These data are exciting because they suggest that, if approved, a higher dose may help fill this unmet need and become an important treatment option for patients."

During the 48-week dose-comparison phase of OPTIMA (OPtimizing Transdermal Exelon In Mild to Moderate Alzheimer's Disease), no unexpected adverse events (AEs) leading to discontinuation were reported, and the safety profile of the higher dose was consistent with that of the established profile of currently approved doses of Exelon Patch. Overall, the percentage of patients with AEs leading to discontinuation was lower in the Exelon Patch 13.3 mg/24 h group compared to the Exelon Patch 9.5 mg/24 h group (9.6% vs. 12.7%, respectively).

Study Details

The OPTIMA trial was a double-blind, randomized, active-comparator study designed to compare the efficacy of the Exelon Patch 9.5 mg/24 h vs. Exelon Patch 13.3 mg/24 h in mild to moderate Alzheimer's disease patients. The trial was conducted globally with 140 centers enrolled in seven countries.

The initial open-label phase was 24 to 48 weeks. Patients who demonstrated functional and cognitive decline during this time were randomly assigned to receive treatment with the Exelon Patch 9.5 mg/24 h or 13.3 mg/24 h during a 48-week double-blind treatment phase.

The primary endpoints of the study were the change from baseline to week 48 of the double-blinded phase in function and cognition as assessed by the ADCS-Instrumental ADL (ADCS-IADL) scale and the ADAS-Cog scale, respectively.

One of two primary endpoints was met. Patients receiving Exelon Patch 13.3 mg/ 24 h experienced a statistically significant ($p<0.05$) lesser decline in function from week 16 to week 48 as compared with the 9.5 mg/24 h dose, meeting the primary endpoint criteria for functionality. The 13.3 mg/24 h patch was numerically better on decline in cognition as compared with the 9.5 mg/24 h patch, but the difference was not statistically significant at week 48, the primary endpoint. However, statistical significance between the groups was reached at week 24 ($p=0.027$). OPTIMA is the longest double-blind trial in decliners to date to study the efficacy of Exelon Patch in the treatment of mild to moderate Alzheimer's disease.

About Alzheimer's Disease
Alzheimer's disease is a gradually progressing and fatal degeneration of the brain characterized by cognitive and memory determination, progressive impairment of activities of daily living, and behavioral disturbances.1 It is the most common cause of dementia among people age 65 and older.2 Approximately 70% of Alzheimer's disease patients receive care at home.1

About Exelon Patch
Exelon Patch is a prescription medicine used to treat people with mild to moderate Alzheimer's dementia.

Exelon Patch is also used to treat people with mild to moderate Parkinson's disease dementia (PDD). Persons who have been diagnosed with Parkinson's disease for at least two years and in whom other causes of dementia have been ruled out may have PDD if they experience trouble with the following: executive function (i.e. remembering things, solving problems, and planning), memory retrieval, and attention.

Important Safety Information
Exelon Patch should not be used if the patient is allergic to rivastigmine or any of the other ingredients of Exelon Patch, or has had an allergic reaction to a similar type of medicine. Speak to the doctor before using Exelon Patch.

Mistakes in using Exelon Patch have resulted in serious side effects; some cases have required hospitalization, and rarely, led to death. Most mistakes have involved not removing the old patch when putting on a new one and the use of multiple patches at one time. Only one Exelon Patch should be worn at a time. If you accidentally apply more Exelon Patches than you should, remove all Exelon Patches and inform the doctor immediately.

At higher than recommended doses, Exelon Patch is associated with significant stomach related side effects such as: nausea, vomiting, diarrhea, decreased appetite, and weight loss. For this reason, people should always start at the low dose. Your doctor may change the dose as needed. If you have not taken Exelon Patch for more than three days, do not start taking it again until you have talked to a doctor.

In a study, the most common side effects with Exelon Patch were nausea, vomiting, and diarrhea.

Weight should be checked while the person is using Exelon Patch. Weight loss/loss of appetite may occur. People below 50 kg, or 110 lbs, may experience more side effects and may have to stop using Exelon Patch due to these side effects.

People at risk for stomach ulcers or who take certain medicine should tell their doctor before starting Exelon Patch, because serious stomach problems such as bleeding may occur. Exelon Patch may cause fainting or slow heart rate; people with certain heart conditions should tell their doctor before starting therapy. People with serious lung conditions and difficulty breathing, bladder problems, or seizures should consult their doctor before using Exelon Patch. Extrapyramidal symptoms (e.g. uncontrollable facial or body movements, including tremor, restlessness) could occur or get worse. Parkinsonian symptoms, particularly tremor, have worsened in Parkinson's disease dementia patients treated with Exelon capsules. People on Exelon Patch who feel dizzy or drowsy should not drive or use machines.

Tell the doctor about all other prescription or nonprescription medicines the patient is taking. Exelon Patch should not be taken at the same time with other medicines that have a similar effect on the body and the brain (cholinomimetic agents) or with anticholinergic medicines. Inform the doctor if the patient needs surgery requiring anesthesia while using Exelon Patch.

Please see Exelon Patch Full Prescribing Information, and Exelon Patch Patient Product Information

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Novartis is proud to offer Patient Assistance Now, an easy-to-use, comprehensive resource that allows you to access programs that may help you pay for your Novartis medicines.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "hope," "seeking to expand," "suggest," "may," or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Exelon Patch, or regarding potential future revenues from Exelon Patch. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Exelon Patch to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Exelon Patch will be approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Exelon Patch will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Exelon Patch could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file 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 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 Pharmaceuticals Corporation researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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