Novartis Exelon® Patch now FDA approved to treat patients across all stages of Alzheimer's disease

Jun 28, 2013

- - Latest FDA approval based on high dose Exelon Patch 13.3 mg/24h for severe Alzheimer's; 24-week study showed statistically significant improvement in overall cognition and function compared to 4.6 mg/24h dose
- - Exelon Patch first and only transdermal therapy approved to treat all stages of Alzheimer's
- - More than five million Americans are living with Alzheimer's, a progressive disease with limited treatment options (1,2)
- - Exelon Patch already approved for treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease

/* Style Definitions */ span.prnews_span { font-size:8pt; font-family:"Arial"; color:black; } a.prnews_a { color:blue; } li.prnews_li { font-size:8pt; font-family:"Arial"; color:black; } p.prnews_p { font-size:0.62em; font-family:"Arial"; color:black; margin:"0in"; } .prngen2{ BORDER-BOTTOM:1pt; BORDER-LEFT:1pt; PADDING-LEFT:0.50em; PADDING-RIGHT:0.50em; VERTICAL-ALIGN: BOTTOM; BORDER-TOP:1pt; BORDER-RIGHT:1pt } .prntblns{ BORDER-BOTTOM: 1pt; BORDER-LEFT: 1pt; BORDER-COLLAPSE: collapse; BORDER-TOP: 1pt; BORDER-RIGHT: 1pt } .prnsbb1{ BORDER-BOTTOM:1pt } .prnsbr1{ BORDER-RIGHT:1pt } .prnpl6{ PADDING-LEFT:0.50em } .prnsbt1{ BORDER-TOP:1pt } .prnvat{ VERTICAL-ALIGN: TOP } .prnpr6{ PADDING-RIGHT:0.50em } .prnsbl1{ BORDER-LEFT:1pt }

EAST HANOVER, N.J., June 27, 2013 /PRNewswire/ -- The US Food and Drug Administration (FDA) has expanded the approved indication for Exelon® Patch (rivastigmine transdermal system) to include the treatment of people with severe Alzheimer's disease (AD) with Exelon Patch 13.3mg/24h. Exelon Patch is now the first and only transdermal therapy approved to treat patients with mild, moderate and severe AD.

"Millions of patients currently suffer from Alzheimer's, a debilitating and heartbreaking disease marked by a decline in overall cognition and function," said John Schall, CEO, Caregiver Action Network. "While there is currently no cure, there is help for patients along the journey, and new treatment options play an important role."

The approval of Exelon Patch for severe AD was based on the pivotal ACTION (ACTivities of Daily Living and CognitION in Patients with Severe Dementia of the Alzheimer's Type) study. In this randomized, double-blind study, Exelon Patch 13.3 mg/24h demonstrated statistically significant improvement in overall cognition and function in severe AD patients versus the 4.6 mg/24h dose at week 24, as assessed by measures of cognition and daily function (SIB and ADCS-ADL-SIV*), respectively. These data support the efficacy of Exelon Patch 13.3 mg/24h in this advanced population of patients suffering from AD.

The most commonly observed adverse reactions included application site erythema (redness or rash), fall, insomnia, vomiting, diarrhea, weight loss and nausea. These reactions were observed in a higher percentage of patients in the Exelon Patch 13.3 mg/24h dose than in the Exelon Patch 4.6 mg/24h dose.

"This approval is a significant milestone in the treatment of Alzheimer's disease. It exemplifies Novartis' continuing commitment to the Alzheimer's community," said Andre Wyss, President of Novartis

Pharmaceuticals Corporation. "With this expanded indication, Exelon Patch can now address a wider range of Alzheimer's patients, including the large population of people in the severe stage of the disease."

Alzheimer's is an irreversible degeneration of the brain that causes disruptions in memory, cognition, personality, and other functions and is the most common form of dementia among people age 65 and older.(2) This disease affects not only patients but the millions of family members who have become caregivers for their loved ones.(1)

* Severe Impairment Battery (SIB), Alzheimer's Disease Cooperative Study (ADCS), Activities of Daily Living (ADL) and Severe Impairment Version (SIV)

Indications
EXELON® PATCH (rivastigmine transdermal system) is a prescription medicine used to treat mild, moderate and severe memory problems (dementia) associated with Alzheimer's disease.

EXELON PATCH is also used to treat people with mild to moderate memory problems (dementia) associated with Parkinson's disease.

Important Safety Information
EXELON PATCH should not be used if the patient is allergic to any component in EXELON PATCH including the active ingredient rivastigmine. EXELON PATCH should also not be used if the patient has had a skin reaction that spread beyond the patch size, had blisters, increased skin redness, or swelling, or did not get better within 48 hours after removal of the 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 than one EXELON PATCH, remove all of them and inform the doctor immediately.

EXELON PATCH can also cause serious stomach side effects, including nausea, vomiting, diarrhea, dehydration, decreased appetite, weight loss, and bleeding in your stomach (ulcers). Dehydration may result from prolonged vomiting or diarrhea and can be associated with serious outcomes. Some people have had a serious skin reaction called allergic contact dermatitis (ACD) when using EXELON PATCH. Stop using EXELON PATCH and call your healthcare provider right away if you experience reactions that spread beyond the patch size, are intense in nature and do not improve within 48 hours after the patch is removed. Symptoms of ACD may be intense and include itching, redness, swelling, warmth or tenderness of the skin, or peeling or blistering of the skin that may ooze, drain or crust over. The incidence and severity of these reactions are dose related. For this reason, treatment should be initiated with EXELON PATCH at a dose of 4.6 mg/24 hours and titrated to a dose of 9.5 mg/24 hours, and then 13.3mg/24 hours, if appropriate. If you have not taken EXELON PATCH for more than 3 days, do not start taking it again until you have talked to a doctor.

The most common side effects of EXELON PATCH include depression, headache, anxiety, dizziness, stomach pain, urinary tract infections, muscle weakness, tiredness, and trouble sleeping.

Weight should be checked while the person is using EXELON PATCH. Weight loss/loss of appetite may occur. People below 50 kg (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 medicines 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 (rivastigmine tartrate) capsules. People should also tell their doctor about any medical condition they have before using EXELON PATCH, including if they have had a loss of appetite or are losing weight, or if they have had a skin reaction to rivastigmine (the medicine in EXELON PATCH) in the past. 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 "continuing," "commitment," "can," 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. Nor can there be any guarantee that Exelon Patch will achieve any particular levels of revenue in the future. In particular, management's expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures, and unexpected reimbursement decisions; unexpected regulatory actions or delays or government regulation generally; unexpected manufacturing issues; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

(1) Alzheimer's Association. 2013 Facts and Figures. Available at: http://www.alz.org/downloads/facts_figures_2013.pdf. Accessed on June 27, 2013.

(2) National Institute of Neurological Disorders and Stroke. NINDS Alzheimer's Disease Information Page. Available at: http://www.ninds.nih.gov/disorders/alzheimersdisease/alzheimersdisease.htm. Accessed on June 27, 2013.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

Novartis Media Relations

Julie Masow	Mary Halliwell
Novartis Media Relations	Novartis US Pharma Communications
+1 212 830 2465 (direct)	+1 862 778 5076 (direct)
+1 862 579 8456 (mobile)	+1 973 781 5066 (mobile)
julie.masow@novartis.com	mary.halliwell@novartis.com

e-mail: us.media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

SOURCE Novartis

---

1. https://qa1.novartis.us/us-en/us-en/news/media-releases/novartis-exelon-patch-now-fda-approved-treat-patients-across-all-stages-alzheimers-disease
2. http://www.pharma.us.novartis.com/cs/groups/public/@nph_us_it/documents/digitalmedia/n_int_055114.pdf
3. http://www.pharma.us.novartis.com/cs/groups/public/@nph_us_it/documents/digitalmedia/n_int_055115.pdf
4. http://www.fda.gov/Safety/MedWatch/default.htm
5. http://www.patientassistancenow.com/index.jsp
6. http://www.novartis.com/
7. http://twitter.com/novartis
8. http://www.alz.org/downloads/facts_figures_2013.pdf
9. http://www.ninds.nih.gov/disorders/alzheimersdisease/alzheimersdisease.htm
10. http://twitter.com/novartis
11. mailto:julie.masow@novartis.com
12. mailto:mary.halliwell@novartis.com
13. mailto:us.media.relations@novartis.com
14. http://www.thenewsmarket.com/Novartis
15. mailto:journalisthelp@thenewsmarket.com