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FDA News

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FDA Approves New Treatment for Parkinson's Disease

The Food and Drug Administration today approved Azilect (rasagiline), a new molecular entity, for the treatment of Parkinson's disease. The drug is a monoamine oxidase type-B (MAO-B) inhibitor that blocks the breakdown of dopamine, a chemical that sends information to the parts of the brain that control movement and coordination.

"This is a welcome development for the more than 50,000 Americans who are each year diagnosed with Parkinson's disease," said Dr. Steven Galson, Director of the Center for Drug Evaluation and Research. "Parkinson's is a relentless disease with limited treatment options, and each new therapy is an important addition to the physicians' treatment options."

Parkinson's disease is a chronic, progressive neurodegenerative condition caused by the destruction of the brain cells that produce dopamine. As the level of this chemical declines, messages from the brain telling the body how and when to move are delivered more slowly, leaving a person incapable of initiating and controlling movements in a normal way.

Azilect was approved for use as an initial single drug therapy in early Parkinson's disease, and as an addition to levodopa in more advanced patients. Levodopa is a standard treatment for Parkinson's disease. The safety and effectiveness of Azilect was demonstrated in three 18- to 26-week controlled clinical trials.

One of the studies compared the effects of Azilect with the effects of placebo in 404 patients with early Parkinson's. Compared with patients on placebo, the condition of patients on Azilect showed significantly less worsening on a rating scale that measures the ability to perform mental and motor tasks as well as daily living activities.

The other two studies compared the effects of Azilect with placebo when taken together with levodopa by over 1100 patients with more advanced Parkinson's. In these studies, patients using Azilect together with levodopa had significantly less time per day with relatively poor function and mobility as compared with patients on levodopa and placebo.

Azilect may be associated with hypertensive crisis if patients also consume tyramine-rich foods, beverages (such as cheese and red wine) or dietary supplements or amines contained in many cough/cold medications. Therefore, patients will need to avoid these sources of tyramine and amines when taking Azilect. As with most other medications for Parkinson's, Azilect has the potential to cause involuntary movements (dyskinesias), hallucinations and lowered blood pressure. These side effects are described in the product labeling.

During development, melanoma was diagnosed in a small number of patients treated with Azilect. Although the FDA has concluded that the available data do not establish that Azilect is associated with an increased risk for melanoma, it appears that compared to the general population, patients with Parkinson's disease have an increased risk for this form of skin cancer. In order to address the question of whether or not Azilect itself increases such risk, the drug's manufacturer will perform a Phase 4 (postmarket) study. The product labeling will recommend that patients undergo

periodic dermatologic examinations.

Azilect is manufactured by Teva Pharmaceutical Industries in Tel Aviv, Israel.

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