



FDA Approves AVONEX® PEN™ and Dose Titration Regimen

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Dosing Enhancements May Improve Treatment Experience for Patients Receiving AVONEX® (interferon beta-1a) for Multiple Sclerosis

WESTON, Mass.--([BUSINESS WIRE](#))--Today [Biogen Idec](#) (NASDAQ: BIIB) announced that the U.S. Food and Drug Administration (FDA) has approved two separate dosing innovations designed to improve the treatment experience for patients receiving once-a-week AVONEX for relapsing forms of multiple sclerosis (MS).

- AVONEX PEN, the first intramuscular (IM) autoinjector approved for MS, incorporates a smaller needle and easier administration to help patients reduce anxiety about AVONEX self-injection.
- A new dose titration regimen, which gradually escalates the dose of AVONEX at treatment initiation, reduces the incidence and severity of flu-like symptoms that can occur at the beginning of therapy.

"AVONEX has been an effective treatment for MS for more than 15 years, and data have shown it to have the highest adherence rate among currently marketed injectable therapies," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "However, anxiety around administration and the potential for flu-like symptoms can be a barrier for some patients. AVONEX PEN and the new titration regimen reflect our commitment to enhancing the Biogen Idec products that people with MS rely on today."

AVONEX PEN (AVONEX 30mcg/0.5mL solution for injection) is an automated injection device designed to be easier to use than the currently available AVONEX Prefilled Syringe. AVONEX PEN also incorporates a substantially smaller needle, which may reduce injection anxiety and pain. AVONEX PEN was approved based on data from a Phase 3b study in which approximately nine out of 10 patients used the device successfully. Ninety-four percent of patients in the study also expressed a preference for AVONEX PEN over the AVONEX Prefilled Syringe. AVONEX PEN was approved in the European Union and Canada in 2011.

The updated prescribing information also provides physicians and patients with a regimen to titrate therapy at treatment initiation to reduce the incidence and severity of flu-like symptoms. This optional titration schedule, which can be facilitated by the new AVOSTARTGRIP™ devices, is based on data from an eight-week, randomized, healthy-volunteer study that showed a three-week titration period at treatment initiation reduced the severity of flu-like symptoms by 76 percent, as well as significantly reduced the flu-like symptom incidence, versus no titration four to six hours post-injection. After the titration period, patients may continue treatment with AVONEX PEN or other administration options.

"Enhancements to improve the administration of AVONEX have helped thousands of patients around the world, and we will make AVONEX PEN and the AVOSTARTGRIP kit available to patients in the United States as soon as possible," continued Dr. Williams.

About AVONEX PEN

AVONEX PEN is the first single-use, once-a-week, fully integrated IM autoinjector for MS. It is designed for use with AVONEX treatment in patients with relapsing forms of MS. AVONEX PEN integrates the currently approved AVONEX Prefilled Syringe and incorporates a smaller needle (25 gauge, 5/8 inch), which is thinner and 50 percent shorter than the standard AVONEX Prefilled Syringe needle.

Additional features of AVONEX PEN include: a protective injector shield that conceals the needle prior to injection; automated needle insertion and medication delivery; and a diameter and length designed to stabilize AVONEX PEN during the injection procedure. In addition, AVONEX PEN incorporates a safety lock, which helps prevent injection error and a display window that confirms complete delivery of the medication.

The efficacy and safety of AVONEX PEN was evaluated in an open-label, multicenter, Phase 3b study (n=70). Efficacy was assessed through objective and subjective assessments of key aspects of patients' use of AVONEX PEN.

About Titration

The AVONEX label provides physicians and patients with a clinically-supported schedule for gradually escalating the dose of AVONEX at the start of therapy, which has been shown to reduce the incidence and severity of flu-like symptoms that can occur with AVONEX treatment. In an eight-week, healthy-volunteer, randomized, Phase 1 study (n=234), a three-week titration period at the initiation of AVONEX treatment reduced the incidence (Odds Ratio: 0.18) of flu-like symptoms versus no titration four to six hours post-injection. It also reduced the severity of flu-like symptoms by 76 percent versus no titration four to six hours post-injection.

Titration with AVONEX can be facilitated by the AVOSTARTGRIP kit, a set of three devices that work with the AVONEX Prefilled Syringe to administer three titrated doses of AVONEX over a three-week period: 7.5mcg, 15mcg and 22.5mcg. The full dose should be administered at week four.

A titration regimen should only be considered for patients initiating AVONEX therapy. Once patients have completed the titration regimen, treatment can be continued with AVONEX PEN or other administration options.

About AVONEX

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide and has been approved for use in the United States for more than 15 years. AVONEX is indicated for the treatment of patients with relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with MS.

AVONEX should be used with caution in patients with depression or other mood disorders and in patients with seizure disorders. AVONEX should not

be used by pregnant women. Patients should also be monitored for signs of hepatic injury. Rare cases of anaphylaxis have been reported. Patients with cardiac disease should be closely monitored. Routine periodic blood chemistry and hematology tests are recommended during treatment with AVONEX.

The most common side effects associated with AVONEX treatment are flu-like symptoms, including chills, fever, myalgia, and asthenia.

For the complete United States prescribing information, please visit <http://www.AVONEX.com>.

About Biogen Idec

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than \$5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

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