PLEGRIDY™ (peginterferon beta-1a)
Key Milestone Timeline

May 2007
First patient enrolled in Phase 1 study evaluating the safety of PLEGRIDY in humans

June 2009
First patient enrolled in Phase 3 ADVANCE clinical trial evaluating PLEGRIDY in patients with relapsing-remitting multiple sclerosis (RRMS)

January 2013
Biogen Idec announces positive top-line results from ADVANCE, reporting that PLEGRIDY reduced annualized relapse rate (primary endpoint) and met all secondary endpoints at year one

March 2013
Detailed positive results from year one of ADVANCE are presented at the American Academy of Neurology's (AAN) 65th annual meeting

July 2013
Biogen Idec announces that the FDA has accepted its Biologics License Application (BLA) for marketing review of PLEGRIDY in the United States and the European Commission (EC) has validated the company's Marketing Authorisation Approval (MAA) for review of PLEGRIDY in the European Union

October 2013
Additional results from year one of ADVANCE showing significant clinical and MRI improvements with PLEGRIDY are presented at the 29th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)

March 2014
FDA extends the review period of the BLA for the marketing approval of PLEGRIDY by the standard extension period of three months

April 2014
New data from year two of ADVANCE are presented at the AAN's 66th annual meeting; Additional analyses of year one results show high rates of freedom from measured disease activity and recovery from relapses

May 2014
The Lancet Neurology publishes results from year one of ADVANCE

May 2014
The Committee for Medicinal Products for Human Use (CHMP) in the European Union issues a positive opinion recommending the approval of PLEGRIDY for adults with relapsing-remitting multiple sclerosis (RRMS)

July 2014
The EC grants marketing authorisation for PLEGRIDY in adults with RRMS

August 2014
The FDA approves PLEGRIDY for adults with RMS

plegridy™
(peginterferon beta-1a)
SUBCUTANEOUS INJECTION

Indication

PLEGRIDY™ (peginterferon beta-1a) is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Important Safety Information

- PLEGRIDY is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta or peginterferon, or any other component of the formulation.
- Severe hepatic injury, including hepatitis, autoimmune hepatitis, and rare cases of severe hepatic failure, have been reported with interferon beta. Asymptomatic elevation of hepatic transaminases has also been reported, and in some patients has recurred upon rechallenge with interferon beta. Elevations in hepatic enzymes and hepatic injury have been observed with the use of PLEGRIDY in clinical studies. Monitor patients for signs and symptoms of hepatic injury.
- Depression, suicidal ideation, and suicide occur more frequently in patients receiving interferon beta than in patients receiving placebo. Advise patients to report immediately any symptom of depression or suicidal ideation to their healthcare provider. If a patient develops depression or other severe psychiatric symptoms, consider stopping treatment with PLEGRIDY.
- Seizures are associated with the use of interferon beta. Exercise caution when administering PLEGRIDY to patients with a seizure disorder.
- Anaphylaxis and other serious allergic reactions are rare complications of treatment with interferon beta. Discontinue PLEGRIDY if a serious allergic reaction occurs.
- Injection site reactions, including injection site necrosis, can occur with the use of subcutaneous interferon beta. Decisions to discontinue therapy following necrosis at a single injection site should be based on the extent of the necrosis. For patients who continue therapy with PLEGRIDY after injection site necrosis has occurred, avoid administration of PLEGRIDY near the affected area until it is fully healed. If multiple lesions occur, discontinue PLEGRIDY until healing occurs.
- Congestive heart failure, cardiomyopathy, and cardiomyopathy with congestive heart failure occur in patients receiving interferon beta. Monitor patients with significant cardiac disease for worsening of their cardiac condition during initiation and continuation of treatment with PLEGRIDY.
- Interferon beta can cause decreased peripheral blood counts in all cell lines, including rare instances of pancytopenia and severe thrombocytopenia. Monitor patients for infections, bleeding, and symptoms of anemia. Monitor complete blood cell counts, differential white blood cell counts, and platelet counts during treatment with PLEGRIDY. Patients with myelosuppression may require more intensive monitoring of blood cell counts.
- Autoimmune disorders of multiple target organs including idiopathic thrombocytopenia, hyper and hypothyroidism, and autoimmune hepatitis have been reported with interferon beta. If patients develop a new autoimmune disorder, consider stopping PLEGRIDY.
- The most common adverse reactions associated with PLEGRIDY treatment are injection site erythema, influenza-like illness, pyrexia, headache, myalgia, chills, injection site pain, asthenia, injection site pruritus, and arthralgia.
- Advise patients that PLEGRIDY should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

Please see PLEGRIDY.com for full Prescribing Information for additional important safety information.