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News Release

Intended for U.S. Media

Bayer Receives FDA Approval of myBETAapp™ and BETACONNECT Navigator™

Now-approved combination of medicine, device, mobile and cloud-based health technology

WHIPPANY, N.J., May 30, 2017 – Bayer today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) for myBETAapp™ and the BETACONNECT Navigator™.

With this software in relapsing-remitting multiple sclerosis, people using the electronic BETACONNECT autoinjector to administer BETASERON® (interferon beta-1b) can use Bluetooth technology to connect their current autoinjector to the new myBETAapp on their mobile device or computer.¹ Patients have the opportunity to share their injection data with their BETA Nurse and healthcare team. Viewing this data through the BETACONNECT Navigator may be a useful tool for the health care team to gain insights into patients' injection history and provide support to those taking BETASERON.²

“Since introducing the first FDA approved treatment option for relapsing remitting multiple sclerosis patients more than two decades ago, we’ve listened closely to the community to understand their needs and how we can support them,” said Mark Rametta, D.O., FACOI, FACP, Bayer’s medical director for Neurology.³ “The myBETAapp and BETACONNECT Navigator add to the services that we’ve developed based on patient feedback, including 24/7 access to nurse support and the first and only electronic autoinjector for patients taking BETASERON.”

Patients should not take BETASERON (interferon beta-1b) if they are allergic to interferon beta-1b, to another interferon beta, to human albumin, or mannitol.³ BETASERON can cause serious side effects, such as liver problems including liver failure. Symptoms of liver problems may include yellowing of your eyes, itchy skin, feeling very tired, flu-like symptoms, nausea or

vomiting, bruising easily or bleeding problems. A healthcare provider will do blood tests to check for these problems while the patient is taking BETASERON.³

Patients using other injection methods to take their BETASERON can also manually enter injection information into the myBETAapp and participate in the sharing of data with their BETA Nurse and healthcare team.¹

“The myBETAapp and BETACONNECT Navigator work cohesively together to support communication and connection between people living with relapsing remitting multiple sclerosis and their BETA Nurse and health care team,” said Daniel Kantor, M.D., FAAN and President Emeritus, Florida Society of Neurology.

The myBETAapp will be available for free download at the Apple app store, Google Play or Betaseron.com in mid-July. Patients enrolled in BETAPLUS®, Bayer's comprehensive patient support program, can speak directly to a BETA Nurse, who is specially trained in MS.

The BETACONNECT autoinjector, myBETAapp and the BETACONNECT Navigator were designed and developed by Medicom Innovation Partner, headquartered in Struer, Denmark.

Multiple sclerosis is a chronically inflammatory, incurable and usually intermittent disease of the central nervous system. The most common form of multiple sclerosis is relapsing-remitting MS (RRMS), where symptoms flare up and then improve, making it critical for doctors to track the severity of the disease on a regular basis. Out of the 400,000 people living with MS in the United States, approximately 320,000 people are initially diagnosed with RRMS. Injectable beta-interferons are a prescribed class of immunomodulatory drugs for RRMS.

About Betaseron

Indications

BETASERON® (interferon beta-1b) is a prescription medicine used to reduce the number of relapses in people with relapsing forms of multiple sclerosis (MS). This includes people who have had their first symptoms of multiple sclerosis and have an MRI consistent with multiple sclerosis. BETASERON will not cure MS but may decrease the number of flare-ups of the disease.³

Important Safety Information for BETASERON (interferon beta-1b)

Do not take BETASERON (interferon beta-1b) if you are allergic to interferon beta-1b, to another interferon beta, to human albumin, or mannitol.³

BETASERON can cause serious side effects, including:

Liver Problems Including Liver Failure. Symptoms of liver problems may include yellowing of your eyes, itchy skin, feeling very tired, flu-like symptoms, nausea or vomiting, bruising easily or bleeding problems. Your healthcare provider will do blood tests to check for these problems while you take BETASERON.³

Serious Allergic Reactions. Serious allergic reactions can happen quickly and may happen after your first dose of BETASERON or after you have taken BETASERON many times. Symptoms may include difficulty breathing or swallowing, swelling of the mouth or tongue, rash, itching, or skin bumps.³

Depression or Suicidal Thoughts. Call your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse or worry you: thoughts about suicide or dying, new or worse depression (sinking feeling or sadness), new or worse anxiety (feeling uneasy, nervous or fearful for no reason), trouble sleeping (insomnia), acting aggressive, being angry, or violent, acting on dangerous impulses, hallucinations, other unusual changes in behavior or mood.³

Other possible serious side effects with BETASERON include:

Heart Problems. BETASERON may worsen heart problems including congestive heart failure. Symptoms of heart problems may include swollen ankles, shortness of breath, decreased ability to exercise, fast heartbeat, tightness in chest, increased need to urinate at night, not being able to lay flat in bed.³

Injection Site Problems. Serious skin reactions can happen in some people including areas of severe damage to skin and the tissue below the skin (necrosis). These reactions can happen anywhere you inject BETASERON. Symptoms of injection site problems may include swelling, redness, or pain at the injection site, fluid drainage from the injection site, breaks in your skin or blue-black skin discoloration. Change your injection site each time you inject BETASERON as it will lessen the chance of you having a serious skin reaction. Avoid injecting BETASERON into an area of the skin that is sore, reddened, infected or has other problems.³

Flu-like Symptoms. BETASERON can cause flu-like symptoms including fever, chills, tiredness, sweating, muscle aches when you first start to use it. These symptoms may decrease over time. Taking medicines for fever and pain relief on the days you are using BETASERON may help decrease these symptoms.³

Seizures. Some people have had seizures while taking BETASERON, including people who have never had seizures before. It is not known if the seizures were related to MS, to BETASERON, or to a combination of both. If you have a seizure after taking BETASERON call your healthcare provider right away.³

Blood Problems. You may have a drop in the levels of infection-fighting white blood cells, red blood cells, or cells that help you form blood clots. If drops in levels are severe, they can lessen your ability to fight infections, make you feel tired or sluggish or cause you to bruise or bleed easily.³

Risk to Pregnancy:

BETASERON can harm your unborn baby. BETASERON may cause you to lose your baby (miscarry). If you become pregnant while taking BETASERON call your healthcare provider right away. You and your healthcare provider should decide if you should continue to take BETASERON.³

Most Common Side Effects:

The most common side effects of BETASERON include low white blood cell count, increases in your liver enzymes, headache, increase in your muscle tension, pain, rash, problems sleeping, stomach pain, weakness. These are not all the possible side effects of BETASERON.³

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Tell your healthcare provider about all the medicines you take and your medical conditions.

For full prescribing information visit:

http://labeling.bayerhealthcare.com/html/products/pi/Betaseron_PI.pdf

For BETACONNECT Instructions for Use please visit:

http://labeling.bayerhealthcare.com/html/products/Betaconnect_IFU.pdf

For myBETAapp Instructions for Use please visit:

http://labeling.bayerhealthcare.com/html/products/mybetaapp_IFU.pdf

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an

independent company named Covestro on October 6, 2015. For more information, go to www.bayer.us.

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Forward-Looking Statement

This news release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

¹ myBETAapp Instructions for Use

² BETACONNECT Instructions for Use. Important Information about Your Autoinjector

³ BETASERON® (interferon beta 1-b) [Prescribing Information], Whippany, N.J.: Bayer HealthCare Pharmaceuticals, May 2017