



PHILLIPS-MEDISIZE ANNOUNCES FDA APPROVAL OF myBETAapp and BETACONNECT Navigator

Combination of medicine, device, mobile and cloud-based health technology

Hudson, WI – October 17, 2017 – Phillips-Medisize, LLC (Phillips-Medisize) is honored to announce Bayer's recent approval from the U.S. Food and Drug Administration (FDA) for the myBETAapp™ and BETACONNECT™ Navigator. Phillips-Medisize designed and developed the BETACONNECT autoinjector, myBETAapp and the BETACONNECT Navigator via its Medicom device strategy and design services group.

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.ⁱ 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 healthcare team to gain insights into patients' injection history and provide support to those taking BETASERON.ⁱⁱ

"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.ⁱⁱⁱ "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."

"Connected health is more than a buzz word at Phillips-Medisize. It is a strategy that includes the offering of device strategy and design services (via Medicom) to medical and pharmaceutical companies helping them deliver to their patients a connected health device solution. We are proud of the BETACONNECT, myBETAapp and BETACONNECT Navigator Phillips-Medisize developed (via Medicom) for Bayer. Our broad capabilities and technologies enable Phillips-Medisize to provide a turn-key connected health solution, which few companies can match," comments Matt Jennings, Chairman and Chief Executive Officer, Phillips-Medisize.

"The FDA's approval of myBETAapp and BETACONNECT Navigator work cohesively with the already approved BETACONNECT autoinjector and Bayer's BETASERON® drug. This endorses our view that drug delivery devices, combined with mobile apps, provide support for patients and customers," comments Bill Welch, Chief Technology Officer, Phillips-Medisize.

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

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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



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.

Text: 2917 characters (incl. spaces), 402 words

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About Phillips-Medisize, LLC

Phillips-Medisize, LLC (Phillips-Medisize) is a leading global outsource provider of design and manufacturing services to the drug delivery, consumable diagnostics and medical device, and specialty commercial markets. 85% of the company's revenue comes from drug delivery, medical device, primary pharmaceutical packaging and diagnostic products such as: disposable insulin pens, glucose meters, specialty inhalation drug delivery devices, single use surgical devices and consumable diagnostic components.

Phillips-Medisize features a list of blue chip medical device, pharmaceutical and commercial customers. The company partners with its customers to provide design and development services which accelerate speed to market of innovative products and then works with its customers to deploy advanced automated assembly and quality control technologies which reduce manufacturing cost while improving quality. The company's core advantage is the knowledge of its people to integrate design, molding, and automation to drive low cost and high quality manufacturing solutions.

Phillips-Medisize is headquartered in Hudson, WI, and employs over 5,400 people in 17 locations throughout the United States, Europe, Mexico and China. The company operates a global network of design centers with hubs in Hudson, WI (USA) and Struer, DK.

ⁱ myBETAapp Instructions for Use

ⁱⁱ BETACONNECT Instructions for Use. Important Information about Your Autoinjector

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