



New Clinical Trial to Study the Use of MYOBLOC® Injections into the Salivary Glands to Treat Sialorrhea (drooling)

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LOUISVILLE, Ky.--(BUSINESS WIRE)--US WorldMeds, LLC, today announced the launch of a final Phase 3 clinical trial to investigate the use of MYOBLOC® (rimabotulinumtoxinB) Injection to obtain FDA approval of an indication for sialorrhea, commonly known as “drooling.” This “drooling” is common in patients who may have difficulty swallowing due to neurological disorders such as Parkinson’s disease, Lou Gehrig’s disease, stroke, brain injury, and cerebral palsy. Drooling can also be caused by oral cancers or as a side effect to certain medications, such as drugs used to treat Schizophrenia. This disorder can be socially debilitating, but evidence suggests that the swallowing difficulty and untreated ‘drooling’ may potentially contribute to other more serious medical complications, such as skin breakdown and respiratory infections. Currently, there is no approved pharmacological treatment for ‘drooling’ in adults.

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“As a neurologist, I see the consequences that sialorrhea has on my patients’ quality of life,” stated Fernando Pagan MD, Associate Professor of Neurology, and Director of the Movement Disorders Program at Georgetown University Hospital in Washington, D.C. “I’m thrilled with the possibility of gaining an indication for this condition through this MYOBLOC trial, and I’ve already seen my patients benefit from treatment with MYOBLOC.” Dr. Pagan continued, “This potential new indication will make sialorrhea treatment uniformly available to patients in the United States in need of relief.”

This MYOBLOC trial is a nationwide, multicenter, double-blinded, placebo-controlled study that will enroll patients who have been diagnosed with sialorrhea due to multiple causes. MYOBLOC will be injected directly into the salivary glands, and the efficacy and safety will be analyzed over the course of 1 year. When MYOBLOC is injected directly into the salivary glands, it inhibits the release of the neurotransmitter acetylcholine, resulting in decreased saliva production, thereby decreasing drooling.

MYOBLOC is the only type B botulinum toxin, and is a ready-to-use injectable medication currently indicated for the treatment of cervical dystonia in adults, a condition of abnormal contraction of the muscles of the head and neck, resulting in distorted head positioning and, very commonly, severe pain. MYOBLOC is injected directly into the dystonic muscles of the neck, which inhibits the release of acetylcholine. The result of these injections is decreased abnormal muscle contractions and pain, typically lasting 3-4 months.

MYOBLOC trial sites are located in Albany, NY; Aurora, CO; Baltimore, MD; Bedford, TX; Boca Raton, FL; Cleveland, OH; Escondido, CA; Houston, TX; Kirkland, WA; Los Angeles, CA; New York, NY; Port Charlotte, FL; Port Royal, SC; Salt Lake City, UT; San Antonio, TX; Southfield, MI; St. Louis, MO; Tacoma, WA; Tulsa, OK; and Washington, DC. For more information on the Phase 3 MYOBLOC trial, contact clinicaltrials@usworldmeds.com.

About US WorldMeds

US WorldMeds is a closely-held, Kentucky-based specialty pharmaceutical company. Its mission is to develop, license and commercialize unique and significant specialty pharmaceuticals that address unmet medical needs or overcome limitations of existing products.

US WorldMeds' overriding mission and focus is to identify specialty products for niche patient groups and to increase access to those treatments across the globe. For more information on US WorldMeds or its product portfolio, visit www.usworldmeds.com.

MYOBLOC is a registered trademark of US WorldMeds, LLC.

MYOBLOC is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Important Safety Information for MYOBLOC

MYOBLOC has a boxed warning related to the distant spread of toxin effect: The effects of MYOBLOC and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

The most frequently reported adverse events with MYOBLOC are dry mouth, dysphagia, dyspepsia, and injection site pain. The vast majority of these adverse events were mild to moderate, temporary, self-resolving, and more common with higher doses.

These adverse events may occur within the first week following treatment and may have a duration of several months. In controlled clinical trials, few patients (<1%) stopped treatment due to dry mouth or dysphagia. There is a reduced frequency of dry mouth and dysphagia reported with continued treatment. Dysphagia has commonly been reported by patients treated with all botulinum toxins for cervical dystonia.

Caution should be exercised when administering MYOBLOC to individuals with motor neuron disease (eg, amyotrophic lateral sclerosis), peripheral motor neuropathic diseases (eg, motor neuropathy) or neuromuscular junctional disorders (eg, myasthenia gravis or Lambert-Eaton syndrome). These patients may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of MYOBLOC. In these patients, rare cases of dysphagia severe enough to cause aspiration pneumonia or to warrant the insertion of a gastric feeding tube have also been reported.

Coadministration of MYOBLOC and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare like compounds) should only be performed with caution as the effect of the toxin may be potentiated.

Please review the MYOBLOC full Prescribing Information, Medication Guide and Important Safety Information by visiting www.myobloc.com.

Contacts

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