

## New Data Confirming Effectiveness of Myobloc as a First-line Therapy

a report by

**Solstice Neurosciences, Inc.**

Founded in 2004, Solstice Neurosciences, Inc., is a biopharmaceutical company focused on the development, manufacturing, sales and marketing of specialty products. Solstice's first product, Myobloc® (botulinum toxin type B) Injectable Solution, represents the only botulinum toxin type B currently available to physicians and patients worldwide. Myobloc is sold and distributed in Europe as NeuroBloc®. Myobloc is indicated for the treatment of patients with cervical dystonia (CD) to reduce the severity of abnormal head position and pain associated with CD.

### About CD

CD, also known as 'spasmodic torticollis', is a condition that primarily affects the muscles of the head and neck (the cervical area of the spine). CD is the most common dystonia requiring referral to movement disorder clinics. The neck muscles contract involuntarily causing abnormal movements and positions of both the head and neck. Muscle spasms in the neck often cause great pain, contributing significantly to the disability caused by the disorder.

While the exact cause of CD is unknown, scientists believe the problem originates in the basal ganglia area of the brain which is instrumental in movement. Dystonia has an estimated prevalence of over 300,000 cases in North America. However, it is believed that as few as 5% of these cases have been correctly diagnosed. Treatment is aimed at relaxing contracted muscles and reducing pain. In general, there are three main approaches to the treatment of CD: oral medications, surgery, and toxin therapy.

### About the Randomized, Double-blind Trial Design

One hundred and eleven toxin-naïve (never previously treated with toxin) subjects, participating in centers across nine European countries, were randomized into the ANO72-402 study. Eligible subjects needed to have had CD that involved two or more predefined muscles for at least, and a baseline Toronto Western Spasmodic Torticollis Rating Scales

(TWSTRS—a validated tool to assess the severity of CD) score of at least 20. Subjects were randomly assigned to receive 2cc containing either 150 units of botulinum toxin type A (BOTOX®) or 10,000 units of Myobloc and were evaluated in a blinded fashion at baseline, four, eight and 12 weeks post the initial injection, and every four weeks thereafter until a return to baseline.

### Results

The first and only randomized, double-blind study in toxin-naïve patients with CD compares Myobloc® (botulinum toxin type B) Injectable Solution to BOTOX® Purified Neurotoxin Complex.

Results presented in April 2006 confirm a previously published study in demonstrating that Myobloc and BOTOX have comparable clinical profiles. The results are particularly important because the study enrolled only toxin-naïve patients, whereas earlier studies with Myobloc enrolled patients who had been previously treated with another toxin product.

The duration of effect was 13.6 weeks from injection for Myobloc, while the duration of effect for BOTOX was 13.1 weeks from injection. Patient efficacy outcomes were not different based on a validated rating instrument TWSTRS. The previously published study also utilized the same validated instrument. The study achieved the statistical significance level for the primary efficacy end-point. Both agents were similarly well-tolerated.

These results were presented at the 58th Annual meeting of the American Academy of Neurology (AAN), attended by 10,000 neuroscientists and neurologists seeking the latest developments in cutting-edge scientific research.

Neurologist Dr Eric Pappert, the Medical Director for Solstice Neurosciences, Inc., Assistant Professor of Neurology, and Director of the Parkinson's Disease and Movement Disorders Program at the University of Texas Health Science Center, San Antonio, summarized,

*“This study is important because it reassures physicians that Myobloc can be considered as initial therapy for both toxin-naïve patients, as well as patients previously treated with other botulinum toxin products.”*

This second head-to-head study of Myobloc vs BOTOX validates the usefulness of Myobloc as a treatment for CD in toxin-naïve individuals. Myobloc already has a well-established use in those patients who have become resistant to BOTOX as noted in numerous previous clinical trials. Myobloc also offers

an advantage over BOTOX because it is available in a ready-to-use solution. ■

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