



Evolus Phase III European - Canadian Head-to-Head Trial of prabotulinumtoxinA Compared to Botox® Meets Primary Endpoint

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Results presented today at 2018 Aesthetic and Anti-Aging Medicine World Congress (AMWC)

IRVINE, Calif., April 05, 2018 (GLOBE NEWSWIRE) -- Evolus, Inc. (NASDAQ:EOLS) ("Evolus"), a medical aesthetics company focused on delivering advanced aesthetic procedures and treatments to physicians and consumers, today announced the presentation of data from the European and Canadian Phase III EVB-003 head-to-head comparative trial demonstrating that its investigational prabotulinumtoxinA 900 kilodalton (kDa) neuromodulator met its primary endpoint of non-inferiority at Day 30 in subjects with moderate to severe glabellar lines, also known as "frown lines," compared to onabotulinumtoxinA (Botox®).

The results were presented today in a poster titled "A Multicenter Phase III Study Comparing prabotulinumtoxinA and onabotulinumtoxinA for the Treatment of Glabellar Lines" by Dr. Patricia Ogilvie, M.D., dermatologist and Principal Investigator of the study, at the 2018 Aesthetic & Anti-Aging Medicine World Congress (AMWC), being held April 4-7 in Monte-Carlo, Monaco. The results presented at AMWC expand upon the initial results presented at the American Academy of Dermatology (AAD) annual meeting in February 2018.

"Analysis of this study presented at AMWC shows that prabotulinumtoxinA met its primary endpoint in efficacy as well as its secondary endpoints. In particular, the secondary endpoint of subject satisfaction is important because it represents the opinions of consumers who underwent the treatment," commented Patricia Ogilvie, M.D. "Based on these findings, we believe that prabotulinumtoxinA represents a compelling and innovative option for the aesthetic treatment of glabellar lines."

"The presentation of this expanded data set from the EVB-003 comparative study is another significant milestone in the prabotulinumtoxinA development program," Rui Avelar, M.D., Chief Medical Officer of Evolus. "It further expands and supports the growing body of clinical data suggesting that our product candidate has the potential to be efficacious in the treatment of glabellar lines with a favorable safety profile."

EVB-003 was a 150-day, multicenter, randomized, double-blind, active- and placebo-controlled, single-dose Phase III non-inferiority study evaluating prabotulinumtoxinA and onabotulinumtoxinA, both 900 kDa botulinum toxin type A complexes, in subjects who felt their glabellar lines had an important psychological impact. Adults aged 18 or older with moderate to severe glabellar lines at maximum frown, as assessed by the investigator on the 4-point Glabellar Line Scale (GLS, 0=no lines, 1=mild, 2=moderate, 3=severe), who met these criteria were enrolled. Randomization was 5:5:1 to receive a single treatment of 20 U prabotulinumtoxinA, 20 U onabotulinumtoxinA or placebo (0.9% saline). The primary efficacy endpoint was measured on Day 30 and a responder was defined as a GLS score of 0 or 1 at maximum frown as assessed by the investigator. A total of 540 subjects were enrolled: 245 received prabotulinumtoxinA; 246 received onabotulinumtoxinA; and 49 received placebo. The study met the primary endpoint of non-inferiority at Day 30 with responder rates of 87.2% in the prabotulinumtoxinA group, 82.8% in the onabotulinumtoxinA group, and 4.2% in the placebo group. The absolute differences between prabotulinumtoxinA and placebo groups, and between onabotulinumtoxinA and placebo groups were 83.1% and 78.6%, respectively (both $p < 0.001$). The absolute difference between the prabotulinumtoxinA and onabotulinumtoxinA groups was 4.4%; 95% confidence interval or CI (-1.9, 10.8). The lower bound of the 95% CI for the difference was greater than -10.0% therefore non-inferiority of prabotulinumtoxinA versus onabotulinumtoxinA was achieved. The study concluded that a single dose of 20 U prabotulinumtoxinA was non-inferior to 20 U onabotulinumtoxinA for the treatment of moderate to severe glabellar lines. The percentages of subjects experiencing adverse events assessed as study-drug related were 15.5%, 14.6% and 4.1% in the prabotulinumtoxinA, onabotulinumtoxinA and placebo groups, respectively. There were no serious adverse events that were assessed as study-drug related.

About PrabotulinumtoxinA

PrabotulinumtoxinA is a 900 kDa purified botulinum toxin type A complex. The product candidate's Biologics License Application (BLA) is currently under review by the U.S. Food and Drug Administration (FDA). The product candidate's Marketing Authorization Application (MAA) is currently also under review by the European Medicines Agency (EMA). The FDA application is for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults. The EMA application is for temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines), when the severity has an important psychological impact in adult patients.

About Evolus, Inc.

Evolus is a medical aesthetics company dedicated to bringing advanced aesthetic procedures and treatments to physicians and consumers. Evolus focuses on the self-pay aesthetic market and its lead product candidate DWP-450 (prabotulinumtoxinA neuromodulator), an injectable 900 kDa purified botulinum toxin type A complex.

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