Evolus Announces Presentation of Phase III European - Canadian Comparative Data

February 17, 2018

IRVINE, Calif., Feb. 17, 2018 /PRNewswire/ -- Evolus, Inc. (NASDAQ: EOLS) today announced the presentation of data from the Phase III comparative clinical trial of its investigational prabotulinumtoxinA 900 kilodalton (kDa) neuromodulator at the American Academy of Dermatology (AAD) meeting.

The European and Canadian Phase III study, EVB-003, was presented by Berthold Rzany, M.D during the AAD meeting on Saturday, February 17, 2018. In the study, prabotulinumtoxinA and onabotulinumtoxinA, both 900 kDa botulinum toxin type A complexes, were studied in subjects with glabellar lines, also known as "frown lines" between the eyebrows. "The EVB-003 data presentation marks a milestone achievement for the prabotulinumtoxinA clinical program", commented Rui Avelar, M.D., Chief Medical Officer of Evolus.

About the Phase III EVB-003 Study
EVB-003 was a 150-day, multicenter, randomized, double-blind, active- and placebo-controlled, single-dose Phase III non-inferiority study. 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), were enrolled provided that they also felt their glabellar lines had an important psychological impact. 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 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 adverse event assessed as study-drug related was 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, Inc. is a medical aesthetics company focused on providing physicians and their patients with expanded choices in aesthetic procedures and treatments. Evolus, Inc. focuses on the self-pay aesthetic market and our lead product candidate is an injectable 900 kDa purified botulinum toxin type A complex.

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