



Evolus Announces Presentations of Phase II and Phase III Data of PrabotulinumtoxinA

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SANTA BARBARA, Calif., Oct. 9, 2017 /PRNewswire/ -- Evolus, Inc. (www.Evolus.com) today announced presentations of the data from the Phase II and III clinical trials of its investigational prabotulinumtoxinA 900 kilodalton (kDa) neuromodulator at The American Society of Plastic Surgeons (ASPS) meeting and The American Society for Dermatologic Surgery (ASDS) meeting.

The Phase II (EV-006) and III (EV-001 and EV-002) studies will be presented by Z. Paul Lorenc, M.D., F.A.C.S. at the ASPS meeting today. The Phase III studies were displayed in a poster authored by Ava Shamban, M.D., on behalf of the EV-001 and EV-002 Study Group, at the ASDS meeting (October 5-8). PrabotulinumtoxinA, a 900 kDa purified botulinum toxin type A complex, was studied in subjects with glabellar lines, also known as "frown lines" between the eyebrows.

Z. Paul Lorenc, M.D., F.A.C.S., ASPS presenter and EV-002 and EV-006 investigator, said, "I am looking forward to sharing the trial results for prabotulinumtoxinA, a new 900 kDa botulinum toxin type A."

These study results will also be presented at the upcoming American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS) and American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) meetings.

About the Phase II EV-006 Study

There were 570 subjects in the Phase II EV-006 open label, multiple dose, long term (1 year) study. Over the course of the one year study, approximately 41.2% of the subjects experienced adverse events, 30.5% were assessed as unrelated to the drug and 10.7% were assessed as related to the drug. Most of the adverse events were assessed as mild in severity, and there were no serious adverse events assessed as study drug related. The only adverse event assessed as drug related that occurred in more than 1% of subjects was headache at 8.2%, the next most frequent event was eyelid ptosis in 0.9% of subjects.

About the Phase III EV-001 and EV-002 Studies

A total of 654 subjects were enrolled in the two identical Phase III randomized, multi-center, placebo-controlled, single dose, double blind trials (EV-001 and EV-002). PrabotulinumtoxinA achieved the studies' primary efficacy endpoint at Day 30. To be a responder, a subject needed to have at least a 2-point composite improvement on the Glabellar Line Scale at maximum frown. A composite score required both the investigator and the subject to independently agree that there had been at least a 2-point improvement 30 days after the treatment when compared to baseline (pre-treatment). The responder rate was 67.5% in the EV-001 study and 70.4% in the EV-002 study and both studies were statistically superior to their respective placebo control groups.

Most adverse events were mild and there were no serious adverse events assessed as study drug related. The adverse event rates were 32.1% and 38.2% for the treatment and placebo groups in EV-001 and 26.9% and 28.5% in the treatment and placebo groups in EV-002. The incidence of adverse events assessed as drug related were 13.1 % and 15.4 % in the placebo and treatment groups in EV-001 and in EV-002, the incidence was 7.7% and 9.8% in the placebo and treatment groups. Overall, adverse events assessed as related to the drug with an incidence of 1% or greater were headache at 9.3% in the treatment groups and 8.6% in the placebo groups and eyelid ptosis at 1% in the treatment groups and 0% in the placebo groups.

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 under review by the European Medicines Agency (EMA). Both applications are for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults.

Additional information about the studies can be found at www.clinicaltrials.gov, using clinical trial identifiers NCT02334423 (EV-001), NCT02334436 (EV-002) and NCT02428608 (EV-006).

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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