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Bonti Announces Topline Results of EB-001 Phase 2A Clinical Study in Glabellar Lines

First Clinical Study with Novel Serotype E Botulinum Toxin Confirmed Favorable Safety and Differentiated Efficacy Profile

NEWPORT BEACH, CA, USA – August 9, 2017 – Bonti, a privately-held, clinical-stage biotechnology company, today announced topline results of the first clinical study of its lead product candidate, EB-001, in glabellar (frown) lines. The study achieved its objectives and confirmed both favorable safety and the expected clinical efficacy profile. EB-001 is a novel serotype E botulinum neurotoxin with a unique efficacy profile, characterized by fast onset of action (about 24 hours) and short duration of effect (about 4 weeks). EB-001 is being developed for aesthetic and therapeutic indications with significant addressable market opportunities.

KEY FINDINGS

Efficacy Results: EB-001 demonstrated dose-dependent clinical activity and efficacy at multiple doses. At the high dose cohorts, a 2-point response (assessed by the investigator) was observed within 24 hours of injection. At the two high doses, a 2-point response was reported in 80% of EB-001 subjects and in 14% of the placebo group. The duration of clinical effect was two to four weeks post-injection in the high dose groups.

Safety Results: A total of 42 subjects were enrolled and received study drug. All doses evaluated in the study were well tolerated and there were no serious adverse events (SAEs), or discontinuations due to adverse events (AEs). The overall incidence of treatment-emergent AEs was 14% of EB-001 subjects, and included headache, sore throat and flu-like symptoms, and was 0% in the placebo group. These were transient and mild or moderate in severity. There were no AEs related to local spread of toxin, e.g., no eyelid drooping (ptosis), reported at any dose.

Dosing Implications: This study confirmed the efficacious dose range of EB-001 in the treatment of glabellar lines. Dosing data from this study will inform dose selection for future studies, including a Phase 2B glabellar lines study and Phase 2 studies supporting Bonti’s therapeutic program in the treatment of focal musculoskeletal pain.
Study Design

GL-201 was a randomized, double-blind, placebo-controlled, ascending dose cohort study conducted at two U.S. sites. A total of 42 subjects were randomized to the seven cohorts, 35 received active drug and seven received placebo. The study enrolled toxin naïve adults with moderate to severe glabellar (frown) lines and each subject received a single treatment cycle comprising five injection sites in the forehead glabellar muscles.

“The conclusion of this landmark first-in-human clinical study along with its positive results are tremendously exciting and pivotal for the Bonti team and for our overall development efforts,” said Fauad Hasan, co-founder and CEO at Bonti. “We are exceptionally grateful to our clinical investigators and to the subjects in the study. As we previously remarked, the results from this study are important in addressing significant unmet needs in facial aesthetics. They also enable us to move forward with our therapeutic development efforts to evaluate EB-001 as a long-acting, non-opioid solution for the treatment of focal musculoskeletal pain which will help address the raging opioid epidemic affecting millions in the U.S. annually.”

“I was excited to study this investigational drug and believe that EB-001’s unique product profile differentiates it from, and ultimately complements, the botulinum neurotoxins currently on the market,” commented Dr. Steve Yoelin, one of the study’s principal investigators. “EB-001 will likely expand the aesthetic market because it appears well suited to treat both neurotoxin-naïve patients looking to sample neurotoxins using a short-duration variant such as EB-001 as well as current neurotoxin patients looking to supplement their treatments. EB-001 has the potential to improve all injectors' ability to obtain the very best outcomes for their respective patients.”

About Dr. Steve Yoelin

Dr. Yoelin is a board-certified physician who currently practices in Newport Beach, CA and has been a thought leader in the clinical and research fields. For the past decade he has developed an unprecedented expertise in facial aesthetics including the use of neurotoxins, dermal fillers and collagen stimulators. Dr. Yoelin is focused on innovation and has served as lead investigator in several pilot studies for novel agents, including one that led to a first-in-class FDA approved aesthetic product. Dr. Yoelin has lectured extensively on the use of facial injectables at numerous educational events in the U.S. and at international conferences.

About EB-001

Bonti’s lead product candidate, EB-001, is an investigational botulinum neurotoxin serotype E (BoNT/E). EB-001 has a mechanism of action similar to the marketed botulinum neurotoxin serotype A (BoNT/A) products though it has a differentiated clinical profile. EB-001 has a fast onset of action (about 24 hours) and short duration of effect (about 4 weeks). Currently marketed BoNT/A products have an onset of action around 3-7 days and a duration of effect around 3-4 months. The unique target clinical profile of EB-001 is well suited for a vast range of aesthetic and therapeutic uses, including for the treatment of post-surgical and non-surgical musculoskeletal pain, with currently unmet needs.
About Bonti

Bonti, based in Newport Beach, California, is a rapidly emerging biotechnology company founded by world class neurotoxin experts with proven success at Allergan, one of the Fortune 500 fastest growing pharma companies. This team, with unsurpassed neurotoxin, aesthetic and pain expertise, is uniquely qualified to develop unprecedented treatment paradigms driven by a novel neurotoxin platform to become an innovative leader in both aesthetic and therapeutic markets. By turning the science of neurotoxins into beneficial patient and healthcare provider solutions, Bonti will improve lives by successfully addressing key unmet needs in markets with significant addressable opportunities.

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