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Investor News

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Aesthetic medicine:

Positive results from two European Phase III trials with ATX-101 demonstrate reduction of submental fat

Leverkusen, Germany, April 25, 2012 – Bayer today announced the successful completion of two pivotal European Phase III clinical trials with ATX-101, an injectable drug for the reduction of unwanted fat under the chin. In a top-line analysis of the study data, ATX-101 demonstrated in the primary endpoint statistically significant efficacy ($p<0.001$) compared to placebo in the reduction of the fat, as assessed by two primary measures: a 5-point Clinician-Reported Submental Fat Rating Scale (CR-SMFRS) and a 7-point Subject Satisfaction Rating Scale (SSRS). In addition, in both pivotal trials, ATX-101 demonstrated statistically significant efficacy ($p<0.001$) compared to placebo as evaluated by secondary Patient-Reported Outcome (PRO) measures. These improvements were also confirmed by reductions in submental fat thickness measured using calipers ($p<0.025$). If approved, ATX-101 will be the first in a new class of aesthetic drugs to reduce fat under the chin without surgery. The clinical development of ATX-101 is a joint effort by Bayer and KYTHERA.

“We are very pleased by the ATX-101 efficacy data and the patient satisfaction that has been demonstrated in both Phase III trials,” said Eugene O’Keefe, MD, Vice President and Head of Global Development Dermatology at Bayer HealthCare. “ATX-101 represents a promising candidate for the growing aesthetic medicine market. We have applied the same rigorous and evidence-based development approach to this drug as we customarily do with our other prescription drugs for the treatment of dermatological diseases and disorders.”

Results from both Phase III trials reflect the positive findings already observed in previous Phase II trials, where ATX-101 was well tolerated and yielded statistically significant reduction of unwanted submental fat compared to placebo, based on the assessments of clinicians, patients and objective measurements.

The European ATX-101 Phase III Studies

The two identical Phase III multi-center, randomized, double-blind, placebo-controlled trials enrolled 723 patients and were conducted in 57 centers across the Belgium, Germany, France, United Kingdom, Italy and Spain. In both trials, patients received one of two dosing regimens (1 mg/cm^2 or 2 mg/cm^2) or placebo, administered monthly into the submental fat area for up to four treatment cycles, and were followed up for 12 weeks post treatment. Efficacy of ATX-101 compared to placebo was assessed by a validated 5-point Clinician-Reported Submental Fat Rating Scale (CR-SMFRS). The Patient-Reported Outcomes (PRO) were evaluated on the basis of a 7-point Subject Satisfaction Rating Scale (SSRS), a validated 5-point Patient-Reported Submental Fat Rating Scale (PR-SMFRS) and a Patient-Reported Submental Fat Impact Scale (PR-SMFIS). Calipers, an objective measure of submental fat thickness, also were used to assess the reduction of submental fat.

Adverse events were primarily mild to moderate and transient. The most common adverse events were pain, swelling, numbness, bruising and induration. These adverse events were limited to the injection site; most were temporally associated with treatment. No systemic treatment-related adverse events were reported. The complete data set analysis will be available in the course of 2012.

About ATX-101

ATX-101 is a potential first-in-class injectable drug candidate under clinical investigation for the reduction of localized fat. ATX-101 is a proprietary formulation of synthetic sodium deoxycholate, a well-characterized endogenous compound that is present in the body to promote the natural breakdown of dietary fat. ATX-101 reduces subcutaneous fat through localized fat cell membrane disruption followed by elimination from the treated area. This mechanism may enable a non-surgical alternative for the reduction of unwanted subcutaneous fat. Clinical studies to date have demonstrated that ATX-101 is well tolerated and may effectively reduce localized fat in the submental (under the chin) area.

In August 2010, Bayer Consumer Care AG signed a licensing and collaboration development agreement with KYTHERA, thereby obtaining commercialization rights to ATX-101 outside of the US and Canada. KYTHERA and Bayer are collaborating on the development of ATX-101 in Europe.

About KYTHERA Biopharmaceuticals, Inc.

KYTHERA Biopharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel prescription products for the aesthetic medicine market. In March 2012, KYTHERA initiated a 1,000 patient pivotal Phase III clinical program for ATX-101 in the United States and Canada, to develop the compound for the North American market. The company also maintains an active research interest in hair and fat biology, pigmentation modulation and facial contouring. Find more information at www.kytherabiopharma.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of more than EUR 17.2 billion (2011), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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