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Investor News

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IMCAS Congress 2013

Positive results of Phase-III trials suggest that ATX-101 is effective as a non-surgical treatment for the reduction of unwanted submental fat

Leverkusen, Germany, February 1, 2013 – At the *International Master Course on Aging Skin* (IMCAS) in Paris, France, Bayer presented at a symposium the results of two pivotal European Phase-III studies with ATX-101, an investigational injectable drug for the reduction of unwanted fat deposits under the chin known as submental fat (SMF). Based on efficacy measures, analysis of the Phase-III data demonstrated that ATX-101 significantly reduced SMF compared to placebo.[1,2] These trials are part of the ATX-101 clinical development program conducted jointly by Bayer and KYTHERA Biopharmaceuticals since 2010.

ATX-101 reduces subcutaneous fat by localized fat-cell-membrane disruption followed by elimination from the treated area, and is the first drug undergoing comprehensive evaluation in a clinical trial setting for the reduction of submental fat. Compared to placebo, ATX-101 led to significant improvements in clinician-reported measurements of SMF, supported by objective caliper measurements of SMF thickness. Moreover, patients reported significant reductions in SMF with ATX-101 compared to placebo, and were significantly more satisfied with their chin appearance and their treatment as a result. These positive Phase-III results confirm earlier findings of two Phase-II studies demonstrating positive results for ATX-101.[3,4] Up to now, the aesthetic correction of fatty deposits under the chin has predominantly been performed using surgical procedures involving possible undesirable side effects for the patient. These results were also presented at the IMCAS as poster.[2]

“Both of the Phase-III studies demonstrated the injectable drug ATX-101 to be well tolerated by patients; they yielded a clinically relevant and statistically significant

reduction in unwanted fat deposits under the chin," said Dr. Benjamin Ascher, Plastic Surgeon, Paris Academy, Director of the Aesthetic Surgery Clinic IENA in Paris and scientific director of the IMCAS, in his presentation at the Paris symposium.

"The positive results of the Phase-II and Phase-III studies for ATX-101 make us confident that we are on the right road with our commitment to enter the aesthetic dermatology market," said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Based on evidence-based experience, ATX-101 represents a promising candidate for the reduction of submental fat."

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 United Kingdom, France, Germany, Belgium, Spain and Italy. 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. The efficacy of ATX-101 compared to placebo was assessed using a validated 5-point Clinician-Reported Submental Fat Rating Scale. The Patient-Reported Outcomes were evaluated on the basis of a 7-point Subject Satisfaction Rating Scale, a validated 5-point Patient-Reported Submental Fat Rating Scale and a Patient-Reported Submental Fat Impact Scale. Calipers, an objective measurement of submental fat thickness, were also used to assess the reduction of submental fat.

Adverse events were primarily limited to the injection site; most were temporally associated with treatment. The most common adverse events were pain, swelling, numbness, bruising and induration. Occurrence was transient and predominantly mild to moderate in intensity. No systemic treatment-related adverse events were reported.

About ATX-101

ATX-101 is a potential first-in-class injectable drug candidate under clinical investigation for the reduction of unwanted submental fat. ATX-101 is a proprietary formulation of synthetic deoxycholic acid, a well-characterized endogenous compound that is present in the body to promote the natural breakdown of dietary fat. ATX-101 reduces subcutaneous fat by 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 region (i.e. under the chin). In August 2010 Bayer Consumer Care AG signed a licensing and development collaboration agreement with KYTHERA, thereby obtaining commercialization rights to ATX-101 outside 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. KYTHERA initiated its pivotal Phase-III clinical program for ATX-101 in March 2012, and completed enrollment of more than 1,000 patients, randomized to ATX-101 or placebo, in 70 centers across the U.S. and Canada in August 2012. 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 health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of 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, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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1. Poster 7588 IMCAS 2013 - ***Reduction of submental fat with ATX-101: first results from a European randomized, placebo-controlled, Phase-III clinical trial***. Berthold Rzany, MD, ScM, Division of Evidence-Based Medicine in Dermatology, Charité-Universitätsmedizin Berlin and RZANY & HUND, Privatpraxis für Dermatologie, Berlin, Germany; et al.

2. Poster 7534 IMCAS 2013 - ***Patient-reported outcomes from a second European Phase-III clinical trial of ATX-101, an injectable agent for the reduction of submental fat***. Benjamin Ascher, MD,Clinic of Aesthetic Surgery IENA, Paris, France; et al.

3. Poster P259 (Abstract PRA 12-1030) EADV 2012 - ***ATX-101, a pharmacological treatment, for the reduction of submental fat: results of two pooled Phase-IIa studies.*** Goodman G., Dermatology Institute of Victoria, South Yarra, VIC, Australia; et al.

4. Poster P258 (Abstract PRA 12-1028) EADV 2012- ***Results from a Phase-IIb study evaluating the efficacy and safety of ATX-101 for reduction of submental fat using magnetic resonance imaging and investigator and subject assessment.*** Dover J., Skincare Physicians, Chestnut Hill, CA, United States; et al.

Forward-Looking Statements

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