Bayer

Investor News

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First Patients enrolled in EU Phase III Clinical Development Progam to evaluate ATX-101 for Reduction of Submental Fat

- Bayer's dermatology unit Intendis one step closer to enter aesthetics segment
- Joint development of first-in-class injectable drug for minimally invasive facial fat reduction

Leverkusen, January 10, 2011 – Bayer HealthCare's dermatology business Intendis and KYTHERA Biopharmaceuticals, Inc. today announced the initiation of two European Phase III studies evaluating ATX-101, a first-in-class injectable adipolytic agent, for the reduction of localized fat under the chin (submental fat). The two multi-center, randomized, double-blind, placebo-controlled Phase III studies will enroll approximately 720 patients total to assess safety, tolerability and efficacy of ATX-101 versus placebo in the reduction of submental fat. The primary efficacy endpoints are the reduction of submental fat using a 5-point Clinician-Reported Submental Fat Rating Scale (CR-SMFRS) and subject satisfaction using a 7-point Subject Self Rating Scale (SSRS). Approximately 64 centers across the United Kingdom, France, Germany, Belgium, Spain and Italy take part in these studies.

"I am delighted to be involved in ATX-101 Phase III clinical development program, which I believe to be an important advancement in the aesthetic medicine," said Prof. Dr. Jean Paul Ortonne, dermatologist and ATX-101 clinical investigator in France. "There is a huge demand for a safe, effective and approved injectable treatment for localized fat reduction. These Phase III studies are positive steps toward providing patients with a well-studied, clinically-proven treatment to reduce localized submental fat without surgery."

"ATX-101 represents a promising product for Intendis to enter the growing aesthetic dermatology market," said Marc Lafeuille, President and CEO of Intendis. "We are pleased to progress to Phase III clinical development of ATX-101 and are hopeful that the product will reduce the localized submental fat as expected."

“We are very pleased with the progress that has been made in Europe with ATX-101,” said Keith Leonard, KYTHERA’s President and CEO. “The initiation of these Phase III studies marks an important milestone in our collaboration with Intendis and further demonstrates the potential of ATX-101 as a first-in-class injectable drug for localized fat reduction.”

In August 2010, Intendis announced the licensing and development agreement with KYTHERA receiving the commercialization rights to ATX-101 outside of the US and Canada. KYTHERA and Intendis are collaborating on the development of ATX-101 in Europe. Intendis currently plans to launch the product in selected markets in Europe, Asia and Latin America starting in 2014.

About ATX-101

ATX-101 is a first-in-class injectable drug being studied for the reduction of small volumes of fat, including submental fat. It is based on a well-studied endogenous molecule with unique features including selectivity for adipocytes and rapid clearance. This minimally invasive procedure, done with little or no anesthetic, has the promise to yield consistent and meaningful clinical results. Clinical studies to date have demonstrated that ATX-101 may effectively reduce localized fat deposits, and is safe and tolerable. Three randomized, double-blind, placebo-controlled Phase II studies with ATX-101 in the reduction of submental fat and two Phase I pharmacokinetic and histology studies have been successfully completed. KYTHERA, in late 2010, completed a Phase IIB trial in the United States and will be releasing data later in 2011.

About Intendis

Intendis GmbH is an integrated pharmaceutical company based in Berlin, Germany. As part of Bayer HealthCare, Intendis is completely dedicated to dermatology and focuses on the development and marketing of high quality, innovative topical therapies, targeted to treat skin disorders. The current product portfolio comprises treatments of eczema disorders including atopic dermatitis, psoriasis, acne, rosacea, hemorrhoids and fungal skin infections (mycoses). Find out more at www.intendis.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 15,988 million (2009), 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 53.400 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

About KYTHERA Biopharmaceuticals, Inc.

KYTHERA Biopharmaceuticals, Inc. is a privately held, clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel prescription products for the aesthetic market. KYTHERA has an innovative pipeline, with its lead program in adipolysis (ATX-101) projected to start Phase III studies this year. The company also has active research programs in hair and fat biology, pigmentation modulation and facial contouring. Find more information at www.kytherabiopharma.com.

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