



Press Release – September 15th, 2011

ActoGeniX Announces Positive Results From a Phase 1B Study of AG013 for the Prevention of Oral Mucositis in Cancer patients

Ghent, Belgium –

ActoGeniX, a clinical stage biopharmaceutical company focused on the development and commercialization of ActoBiotics™, a novel class of orally administered and locally acting biopharmaceuticals, today announces the results of a Phase 1B study evaluating the AG013 oral rinsing solution for the prevention of Oral Mucositis in head and neck cancer patients receiving chemo-induction therapy.

AG013 was proven safe and well tolerated. Analysis of initial efficacy showed a 35% reduction of the percentage of days with ulcerative oral mucositis in the AG013-treated patients versus the placebo-treated patients. Furthermore, close to 30% of patients treated with AG013 were full responders (defined as no or 1 day of ulcerative oral mucositis) while all placebo-treated patients developed ulcerative oral mucositis.

The phase 1B study has been designed to be the initial step in evaluating AG013 in cancer patients who develop oral mucositis as a result of chemotherapy or radiation therapy. Oral mucositis is the painful inflammation, necrosis and ulceration of the oral mucosa, affecting nearly every patient that receives radiotherapy of the head/neck region, and a large proportion of solid tumor patients treated with chemotherapy or radiation therapy. It is a severe and debilitating condition, for which no effective cure is available today. Given the high unmet need and the significant number of oral mucositis patients, an effective new product for this indication has a substantial revenue potential, estimated by experts to be more than USD 500 million annually.

The phase 1B study was a randomized, single blinded, placebo-controlled study evaluating safety and tolerability, as well as initial efficacy of AG013 administered as an oral rinsing solution in 3 dose frequencies (once daily, 3 times/day, and 6 times/day) over a 14 day treatment period. The study was conducted in 6 major US cancer centers. In total 19 patients (14 active, 5 placebo) fulfilled the criteria for a per protocol analysis of efficacy. AG013 was safe and well tolerated. Analysis of initial efficacy showed a 35% reduction of the percentage of days



with ulcerative oral mucositis in the AG013-treated patients versus the placebo-treated patients. Furthermore, close to 30% of patients treated with AG013 were full responders (defined as no or 1 day of ulcerative oral mucositis) while all placebo-treated patients developed ulcerative oral mucositis. Although the phase 1B study was designed and powered to primarily demonstrate safety and tolerability, the initial efficacy data demonstrate that AG013 may be effective in the prevention of oral mucositis in cancer patients.

ActoGeniX is currently preparing to bring AG013 to the next phase of clinical development and intends to start the phase 2 study in the course of 2012.

AG013 is the lead product of the ActoGeniX' pipeline of the proprietary ActoBiotics™ platform. ActoBiotics™ represent a novel concept for oral administration of therapeutic proteins, and are designed to be safer and more effective than injectable biopharmaceuticals in selected GI and inflammatory diseases. Besides AG013, ActoGeniX is developing ActoBiotics™ in other mucosal and immune diseases such as inflammatory bowel disease, celiac disease, and type 1 diabetes.

Commenting on the results of the Phase 1B study, **Dr. Stephen T. Sonis**, Clinical Professor of Oral Medicine at Harvard University, and a senior surgeon at Brigham and Women's Hospital and the Dana Farber Cancer Institute states: "The results of this Phase 1B trial are important in confirming the safety and tolerability of ActoGeniX' novel platform as a means of delivering biologically active molecules to the oral mucosa of patients at risk of mucositis. And, although subject numbers are small, the observed efficacy trend fully supports further exploration of AG013 as an oral mucositis intervention."

Dr. Bernard Coulie, CEO and CMO of ActoGeniX comments: "We are very pleased that these results confirm that AG013 is safe and well-tolerated in patients suffering from oral mucositis. The data provide the first clinical evidence that AG013 may be effective in the prevention of oral mucositis, and that our ActoBiotics™ platform may offer therapeutic solutions in other disease areas with a serious medical need. ActoGeniX is fully committed to further develop AG013."

For further information:

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Notes for the editor:

About Oral mucositis

Oral mucositis is the painful inflammation, necrosis and ulceration of the oral mucosa, affecting nearly every patient that receives radiotherapy of the head/neck region or bone marrow transplant, and a large proportion of solid tumor patients treated with chemotherapy or radiation therapy. Cardinal symptoms include ulcerations, debilitating pain and inability to eat and/or sustain anti-cancer therapy. Every year, approximately 4 million new cases of cancer are diagnosed in the Western World, and almost 50% of those will develop oral mucositis. The economical costs due to oral mucositis are substantial, driven by the required additional medical care and extended hospital stay.

About ActoGeniX

ActoGeniX is a biopharmaceutical company focused on the development and commercialization of ActoBiotics™, a novel class of orally available biopharmaceuticals for the targeted treatment of severe diseases with a high medical need. ActoBiotics™ represent a novel concept for oral administration of therapeutic proteins, and are designed to be safer and more effective than injectable biopharmaceuticals. ActoBiotics™ can deliver a wide range of therapeutic peptides and proteins, including cytokines, enzymes, hormones and monoclonal antibodies.

AG013, ActoGeniX's lead product for the treatment of oral mucositis in cancer patients has been evaluated in a phase 1B clinical trial in the US, confirming safety and tolerability as well as initial efficacy. Moreover, in preclinical models, ActoGeniX has confirmed the broad applicability of ActoBiotics™ and its proprietary technology platform for a wide range of diseases, including gastrointestinal, metabolic, immune diseases and allergies.

ActoGeniX was founded in 2006 as a spin-off from VIB and Ghent University. The Company is headquartered in Ghent (Belgium) and employs approximately 20 employees, half of whom are PhD's, MD's, or PharmD's. ActoGeniX raised 35.5 million Euro (approximately 50 million US\$) in two equity financing rounds from a consortium of leading life sciences investors such as Gimv, Biotech Fund Flanders, Baekeland Fund, Biovest (Belgium), Life Sciences Partners, Aescap Venture (The Netherlands) and Ventech (France).

ActoGeniX has a strong and broad intellectual property position with a patent estate encompassing more than 20 distinct patent families. With broad patent claims already granted in major territories like the US and Europe, ActoGeniX is uniquely positioned to successfully exploit the commercial potential of its promising ActoBiotics™.

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