



Press release – August 20, 2009 –

ActoGeniX receives IWT grant for treatment of oral mucositis and starts clinical trial with AG013

Ghent, August 20th, 2009 – ActoGeniX, a development stage biopharmaceutical company, announces that it has been awarded a EUR 0.9 million grant (USD 1.3 million) from the Flemish government through IWT (Institute for Promotion of Innovation by Science and Technology in Flanders), to support the clinical development of AG013, a novel ActoBiotic™ for the treatment of oral mucositis in cancer patients.

The IWT grant will be used to fund further development of AG013, including a phase 1B clinical study which ActoGeniX has initiated this month. This is the second clinical development program in ActoGeniX's portfolio, next to a phase 2A clinical trial with AG011 in inflammatory bowel disease, for which results are expected in October 2009.

In May of this year, the United States Food and Drug Administration (FDA) approved ActoGeniX's Investigational New Drug (IND) application, allowing the Company to initiate a phase 1B clinical trial with AG013 in cancer patients at risk of developing oral mucositis. Meanwhile, ActoGeniX has started this clinical study in collaboration with six reputed oncology centers in the US. The primary aim of the study is to evaluate safety and tolerability of AG013, but it will also allow collection of initial efficacy data.

Dr. Mark Vaeck, CEO of ActoGeniX, comments: "This IWT grant is a strong endorsement of our AG013 program, and allows ActoGeniX to rapidly move forward to develop this product in the clinic. Oral mucositis is a significant challenge in the treatment of cancer, as close to 50% of all cancer patients undergoing chemotherapy or radiation therapy are developing this condition. With AG013 we look forward to offer new and more effective treatment perspectives for these patients."

Oral mucositis is a painful inflammation of the oral mucosa, affecting cancer patients and making daily activities such as eating, drinking and talking difficult or impossible. 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 (approximately 2 million new cases in the US and Europe every year), an effective new product for this indication has a substantial revenue potential, estimated by experts to be in the range of USD 1 billion annually.



AG013 is based on ActoGeniX's proprietary TopAct™ technology platform, and consists of an oral rinsing solution that delivers a potent healing factor to the damaged mucosa in the oral cavity. In preclinical studies, AG013 has already shown significant efficacy and safety results, suggesting that it holds great promise for the treatment of oral mucositis.

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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 IWT

The agency for Innovation by Science and Technology (abbreviated as IWT) is the government agency founded in 1991 by the Flemish Government to support technological innovation projects in Flanders. In 2008 IWT distributed a total of EUR 311 million in subsidies for innovation projects to companies, organizations, research and educational institutions in Flanders. In addition to financial support, IWT also assists companies by, for instance, helping them find the right information or the right partners at home or abroad and providing assistance with the preparation of projects for European programmes. IWT also has an important coordination mandate aimed at promoting close cooperation among all the actors involved in technological innovation in Flanders. IWT Monitoring&Analysis, M&A for short, monitors innovation and regularly publishes studies. For more information, please visit <http://www.iwt.be> or call +32 2 209 09 00.

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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.

AG011, ActoGeniX's lead product for the treatment of Crohn's disease and ulcerative colitis (UC) is currently being evaluated in a phase 2 clinical trial. The Company has also initiated a phase 1B clinical trial in the US with AG013 for the treatment of oral mucositis in cancer patients. 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 40 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 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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