



Press release – May 14, 2009 – 10.00 AM CET

## **ActoGeniX obtains IND approval**

**Ghent, May 14, 2009 – ActoGeniX, a development stage biopharmaceutical company, announced today that the United States' Food and Drug Administration (FDA) has approved the Company's Investigational New Drug (IND) application for AG013, a novel therapeutic product for the treatment of oral mucositis in cancer patients. This IND application approval allows ActoGeniX to initiate a phase 1B clinical trial with AG013, which will now become the second clinical development program in ActoGeniX's portfolio.**

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 disease for which no effective cure is available today.

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

ActoGeniX's phase 1B clinical study will be conducted in six major oncology centers in the US, and will mainly evaluate safety and tolerability of the new product, but will also allow the collection of efficacy data. 21 Patients will be included in this placebo-controlled, single blinded, dose escalation study, which is expected to be completed during the first half of 2010.

Dr. Mark Vaeck, CEO of ActoGeniX, commented: *"We are extremely pleased with this approval by the FDA, which is a clear endorsement of the quality of our preclinical data package and development plan for AG013. Oral mucositis is a very significant and underserved opportunity in the cancer supportive care market, and a novel therapeutic product in this area has huge commercial potential."*

Dr. Bernard Coulie, Chief Medical Officer of ActoGeniX, added: *"With the advancement into clinical development of AG013, our second lead product, ActoGeniX is well on its way to effectively build a significant clinical-stage product pipeline. Moreover AG013 could become the first approved therapy for oral mucositis in patients undergoing treatment of solid tumors or head/neck cancers."*

**For further information please contact:**

ActoGeniX

Dr Mark Vaeck, CEO - Tel. +32 (0) 9 2610600 - mark.vaeck@actogenix.com

**Press contact:**

Across

Luc Osselaer – Mobile +32 (0) 476 45 15 01 – luc.osselaer@a-cross.com

**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.

ActoGeniX's lead product AG011 for the treatment of Crohn's disease and ulcerative colitis (UC) is currently being evaluated in a phase 2 clinical trial. During the coming months the Company will start a phase 1B clinical trial in the US with AG013 for treatment of oral mucositis in cancer patients. Moreover, in preclinical animal models, ActoGeniX has demonstrated the broad applicability of its ActoBiotics™ 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 19 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™.

For more information on ActoGeniX see [www.actogenix.com](http://www.actogenix.com)