



Press Release – February 1st, 2011 – 9 am CET

ActoGeniX receives IWT grant for treatment of *Clostridium difficile*-associated enteric disease

Ghent, February 1st, 2011 – ActoGeniX, a clinical stage biopharmaceutical company, announces that it has been awarded a EUR 0.53 million grant (USD 0.7 million) from the Flemish government through IWT (Institute for Promotion of Innovation by Science and Technology in Flanders), to support the discovery and development of a novel ActoBiotic™ for the treatment of *Clostridium difficile*-associated enteric disease.

The IWT grant will be used to fund the discovery and development of a novel therapeutic approach for the treatment of *Clostridium difficile*-associated enteric disease. This novel approach is based on passive immunization through the local enteric delivery of toxins-neutralizing antibodies which are expressed and secreted at the intestinal mucosal site by an ActoBiotic™. This revolutionary approach of local neutralization of luminal toxins by antibodies may offer a new treatment option for patients who are not responding to standard therapy or in severe disease.

This project will be conducted in close collaboration with the world-leading research group of Prof. Dr. Paul Rutgeerts at the University of Leuven, Belgium, and PharmAbs, the antibody research center of the University of Leuven lead by Dr. Nick Geukens. It builds further on the solid expertise ActoGeniX has gained in the field of mucosal delivery of antibodies by orally administered ActoBiotics™. At the forefront of the antibody program is AG014, an ActoBiotic™ secreting a monoclonal antiTNFalpha antibody for the therapy of inflammatory bowel disease which is currently progressing through preclinical development.

AG013, ActoGeniX's lead product for the treatment of oral mucositis in cancer patients is currently being evaluated in a phase 1B clinical trial in the US.

Dr. Bernard Coulie, CEO of ActoGeniX, comments: "This IWT grant is a strong endorsement of our Actobiotic™-antibody program. It will allow ActoGeniX to expand its current portfolio of products into new areas of high unmet medical



need. *Clostridium difficile*-associated enteric disease is rapidly becoming a significant health burden in hospitalized patients receiving antibiotics. Our program covers a clear need to develop more selective and effective alternatives to combat *Clostridium difficile*-associated enteric disease.”

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Notes for the editor:

About Clostridium difficile-associated enteric disease

Clostridium difficile (*C. difficile*) is an anaerobic, gram-positive, spore-forming, toxin-producing bacillus transmitted between human beings by the fecal–oral route. The most important risk factor for the development of *C. difficile* infection is antibiotic use. *C. difficile* toxins in the colonic lumen lead to clinical disease. The toxin-mediated enteric disease is characterized by diarrhea, fever, enteric ulceration and a characteristic endoscopic appearance defined as “pseudomembranous colitis”.

C. difficile infection constitutes a significant burden to the health care system, totaling more than \$1 billion/year in the United States alone. Standard treatment of patients with *C. difficile* infection is mainly based on the use of metronidazole or vancomycin. Although both antibiotics are effective at inhibiting *C. difficile* and treating symptoms, the use of these drugs does not allow for the reestablishment of normal bowel flora. As a result, 15 to 30% of the patients will have recurrent *C. difficile* infection after cessation of the treatment. Moreover, *C. difficile* strains with increased virulence or antibiotic resistance have led to treatment failures, more frequent relapses, and increased mortality rates. Failure to develop a specific antibody response has recently been identified as a critical factor in recurrence. With these observations and limitations of today’s antibiotic therapy, there is a clear need to develop more selective and effective alternatives to combat *C. Difficile*-associated enteric disease.

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.

www.iwt.be

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 is currently being evaluated in a phase 1B clinical trial in the US. 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™.