ActoGeniX completes Phase 2A clinical trial of AG011

Ghent, October 9th 2009 - ActoGeniX, a development stage biopharmaceutical company, announces that it has completed the phase 2A clinical trial with its lead product AG011 in patients with moderate ulcerative colitis. Primary endpoints of the study have been successfully met.

The initial analysis of the results from this trial reveals that all three primary endpoints of the study have been met: i) safety and tolerability, ii) environmental containment and iii) assessment of biomarkers associated with AG011. With respect to the secondary endpoint, the clinical results did not reveal a statistically significant difference in mucosal healing versus placebo. Overall the data of this phase 2A trial are partially confirming the pre-clinical data and the results from a previous phase 1 study in Crohn’s Disease patients. ActoGeniX is currently completing the analysis of the database and will be considering the optimization of some aspects of the AG011 product in view of the phase 2A results.

Dr. Mark Vaeck, CEO of ActoGeniX comments: “We are pleased that these results confirm that AG011 is safe and well-tolerated in patients suffering from inflammatory bowel disease, which was a primary objective of this study. The data also confirm environmental containment and indicate that our ActoBiotics™ platform holds promise for therapeutic applications in other disease areas with a serious medical need. Whilst additional analysis of the database is warranted before we make any decisions concerning the future development of AG011, we are fully committed to further develop our second lead product, AG013, which has recently been approved for phase 1B testing in oral mucositis patients.”

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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) has completed 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, Blovest (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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