Study Results of ACT-101 in a Model of Inflammatory Bowel Disease (IBD) Presented at the World Congress of Gastroenterology 2017

- Previous placebo controlled clinical trials demonstrated substantial improvement in IBD patients treated with AFP
- ACT-101 has been shown to have no toxicity through phase 1 and 2 trials in other indications
- ACT 101 was independently tested in an acute model of IBD and demonstrated improvement in inflammatory scores as good as or better than anti-TNFα (Humira/Remicade)
- ACT-101 offers the possibility of novel, safe and effective treatment for patients with IBD
- Follow-up study is planned to investigate the feasibility of using oral formulation of ACT-101 in a chronic model of IBD

Toronto, Canada, October 17, 2017 – Alpha Cancer Technologies Inc. (ACT) a biopharmaceutical company focused on therapies for patients with autoimmune diseases and cancer, today announced the results of a study of ACT-101 (recombinant human alpha fetoprotein or rhAFP) in the treatment of Inflammatory Bowel Disease (IBD) at the World Congress of Gastroenterology 2017, held in partnership with The American College of Gastroenterology in Orlando, Florida. The study was sponsored by ACT to corroborate published clinical trial results using native human AFP.

In a small placebo-controlled clinical trial (78 pts) human AFP (hAFP) was reported to effectively reduce symptoms of IBD. After 30 days of treatment 100% of hAFP patients showed clinical improvement. 47% gained significant amount of weight. 30% of Crohn's and 32% of colitis patients had restoration of normal bowel movement. Endoscopy confirmed reduction in the number of ulcerative lesions. Almost half of hAFP-treated patients were able to reduce or eliminate steroid use while no significant changes were observed in placebo patients. (Alpha-Fetoprotein, Chereshnev V. A. et. al. published by Russian Academy of Sciences 2004 pp. 239-245).

Phase I and II clinical trials of ACT-101 (rhAFP) have already demonstrated an excellent safety profile with no serious adverse events or immune reactions. However, there were no published pre-clinical studies evaluating efficacy of AFP in in animal models of IBD.

This preclinical study aimed to investigate the efficacy and mode of action of ACT-101 in a mouse model of TNBS-induced colitis. This model is considered the standard model for testing potential therapeutic agents for the treatment of IBD.

The study was conducted at Intestinal Biotech Development, Lille Medical School, France, one of the premier research centers specializing in animal models of IBD. The study compared the effect of ACT-101 to placebo and anti-TNFα (similar to Humira/Remicade) the most effective therapy in a model of colitis induced by TNBS.

The study results clearly demonstrated that ACT-101 is a highly effective agent in reducing TNBS-induced colonic inflammation. Histological score of inflammation (Ameho’s score) was reduced by 53% compared to placebo treated animals. Furthermore, animals treated with ACT-101 had a statistically greater reduction in histological score of inflammation compared to animals treated with anti-TNFα (53% vs. 45% reduction in Ameho's score). Consistent with the already established excellent safety profile of ACT-101 in patients this degree of efficacy was achieved without any toxic side effects. The study also demonstrated that treatment with ACT-101 results in significant reduction of myeloperoxidase (MPO) level in the colon. Analysis of gene expression of pro- and anti-inflammatory molecules (cytokines) in the colon confirmed that ACT-101 produces significant reduction in such pro-inflammatory cytokines as TNFα, IL-1β, IFNγ and IL-6 while increasing levels of anti-inflammatory cytokine IL-10.

This study confirms the anti-inflammatory activity of ACT-101 in the TNBS model of colitis with efficacy similar or greater than anti-TNFα. Considering the exceptional safety profile of ACT-101 this molecule offers the possibility of novel safe and effective treatment for patients with IBD. A follow-up study will investigate the feasibility of using oral formulation of ACT-101 in a chronic model of IBD.
Dr. Christel Rousseaux, the lead investigator for the study commented “ACT-101 seems to be a very promising compound. Indeed, ACT-101 showed very high anti-inflammatory activity in the gold standard model of colitis induced by TNBS”.

“These results provide strong evidence of ACT-101 ability to reduce autoimmune inflammation safely and without typical side effects of currently used treatment modalities, such as immunosuppressive drugs or steroids. We are continuing our development efforts to make this novel therapy for autoimmune diseases available to patients as soon as possible” said Dr. Igor Sherman, CEO of ACT.

The poster presentation details are as follows:

Title: Anti-inflammatory properties of recombinant human alpha-fetoprotein (rhAFP) in the model of TNBS-induced colitis

Poster Session: Exhibit Hall WB1, Orange County Convention Centre, Orlando, Florida

Session Date/Time: October 16, 2017 from 10:30 am to 4:00 PM

Authors: Christel Rousseaux PhD, Pierre Desreumaux MD, PhD and Igor Sherman PhD

About Alpha Cancer Technologies Inc.

Alpha Cancer Technologies Inc. (ACT) is a private clinical stage biotechnology company with products under development in auto-immune and oncology disease indications. The company’s drug products use proprietary recombinant human alpha fetoprotein (ACT-101 or AFP) to directly impact auto-immune diseases (myasthenia gravis, Inflammatory Bowel Disease (Crohn’s/Colitis), Hashimoto disease) and uses AFP to carry chemotherapy agents (ACT-901, 902, 903) targeted directly to AFP receptors found on most cancer cells.

ACT-101 has received Orphan Drug Designation for the treatment of myasthenia gravis from the U.S. Food and Drug Administration (FDA).

ACT has exclusive worldwide rights to its proprietary recombinant human AFP with over $100 million spent on the technology. Clinical studies of ACT-101 have demonstrated safety in over 300 patients and established a robust Drug Master file with the FDA including manufacturing, toxicology, and human safety.

Forward-Looking Statements

Certain statements contained in this press release constitute forward-looking information within the meaning of applicable securities legislation (collectively, the “forward-looking statements”). These forward-looking statements relate to, among other things, ACT’s objectives, goals, targets, strategies, intentions, plans, beliefs, estimates and outlook, and can, in some cases, be identified by the use of words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “will,” “may” and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These statements reflect management’s current beliefs and are based on information currently available to management.

Certain material factors or assumptions are applied in making forward-looking statements, and actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things: uncertainties and risks related to, the availability of capital, changes in capital markets, uncertainties related to clinical trials and product development, rapid technological change, uncertainties related to forecasts, competition, potential product liability, unproven markets for technologies in development, the cost and supply of raw materials, management of growth, effects of payers’ willingness to pay for products, risks related to regulatory matters and risks related to intellectual property matters.

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