Corporate Background

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 (AFP). In nature AFP is an immune regulatory protein involved in protecting the fetus from attack by the mother's immune system and is a carrier protein known for diverting and transporting nutrients from the mother to AFP receptors which are found exclusively on rapidly growing fetal cells.

In Immunology the company is ready to enter Phase II clinical trials in Myasthenia Gravis (MG) (Orphan Drug Designation from the FDA) followed by Phase II clinical trials in Inflammatory Bowel Disease (IBD) with extensions to Hashimoto Disease and Multiple Sclerosis (MS). ACT-101 (AFP) has been shown to be as safe as placebo in clinical trials in over 300 patients.

In Oncology AFP can deliver chemotherapy to cancer cells on a targeted basis to provide greater efficacy with significantly reduced toxicity.

Celgene, one of the world's largest biotechnology companies owns a 12% equity stake in ACT.

The company has a significantly mitigated risk profile in every area of development and has an expedited clinical development path.

Compelling Rationale – Game Changer

In Immunology it is well-known that many autoimmune diseases in women typically go into remission during pregnancy and there is a strong correlation between the level of AFP in mother's blood and the decrease in the symptoms of her disease. The company is ready to enter Phase II clinical trials in Myasthenia Gravis (MG) (for which the Company has Orphan Drug Designation from the FDA) followed by clinical trials in Inflammatory Bowel Disease (IBD), Hashimoto and Multiple Sclerosis (MS). ACT-101 (AFP) has been shown to be as safe as placebo in clinical trials in over 300 patients.

In a randomized placebo controlled clinical study conducted by Russian and Israeli clinicians in patients with inflammatory bowel disease (IBD – Crohn's/Colitis) using AFP extracted from human fetal tissue, AFP was highly effective in reducing inflammation and producing remission in patients who were unresponsive to standard therapies. Study summary is below:

- *Randomized placebo-controlled study in patients with IBD (78 patients - 56 with colitis, 22 with Crohn's)*
- *Disease duration of 5-15 years with radiological evidence of disease*
- *Patients were treated* with *AFP 4 microg/kg daily (10 Crohn's-IM and 28 colitis - IV) 40 with placebo for 30 days*
- *After 30 days 100% of AFP-treated patients had definite improvement in their symptoms*
- *Laboratory parameters returned to normal (Hemoglobin, albumin, IGA, IGM, decrease in CD71+ cells, etc.). 47% of patients gained weight of up to 12 kg. 30% of Crohn's and 32% of colitis patients had complete restoration of normal bowel movements and no symptoms of disease. Endoscopy confirmed improvement in the intestinal mucosa with reduction of the number of ulcerative lesions. 30% of Crohn's patients were able to reduce steroid dose to half and 20% went off steroids completely. 32% of colitis patients were able to reduce steroid dose by 2-3 fold and 7% went of steroids completely.*
- *No significant changes were observed in placebo patients.*

Studies using preclinical models of IBD were carried out by the Intestinal Biotech Development CRO at the Lille School of Medicine to corroborate these findings and data will be presented on October 16, 2017. In a study conducted at George Washington University in a model of Myasthenia gravis ACT-101 (AFP) has been shown to greatly reduce symptoms of the disease and reduce accumulation of MG antibodies in the neuromuscular gap junctions.

In Oncology Only trace amounts of AFP are found following the fetal stage but receptors for AFP show up again on almost all solid and liquid cancer cells. The company uses its proprietary recombinant human AFP to deliver a chemotherapy payload to selectively kill cancer cells. Lower toxicity of this targeted approach offers the ability to treat the patient more frequently until the patient is cancer free.

ACT has several lead products that include non-covalently bound chemotherapy (paclitaxel, thapsigargin) and chemically linked chemotherapy such as maytansine. In addition to proven efficacy and known safety profile of generic chemotherapy drugs, AFP itself has been proven as safe as placebo in over 300 patients in Phase I and II clinical studies. ACT's products are being developed as a treatment for multiple cancer indications as almost all cancer cells (solid and liquid) express AFP receptors and healthy cells do not.

Product Pipeline

Therapy	Indication	Partners	Discovery	Pre-clinical	Phase I	Phase II
ACT-101 (AFP)	**Autoimmune** a) Inflammatory Bowel Disease (Crohn's/Colitis) b) Myasthenia Gravis (muscle weakness) c) Hashimoto Disease d) Multiple Sclerosis, others					
ACT-901 (AFP + paclitaxel)	**Targeted Oncology** Solid and liquid tumors	Collaboration University Health Network				
ACT-902 AFP + thapsigargin	**Targeted Oncology** Solid and liquid tumors	Collaboration University Health Network, Princess Margaret Cancer Center				
ACT-903 AFP + Linker + maytansine	**Targeted Oncology** Solid and liquid tumors	Collaboration Polytherics (Abzena) U.K.				

Preclinical Studies

In collaboration with researchers at the University Health Network and the Ontario Cancer Institute/Princess Margaret Cancer Centre in Toronto, ACT has completed preclinical studies examining the activity, safety and efficacy of ACT-901 and ACT-902. In vitro and in vivo results have shown that ACT-901 (AFP+ paclitaxel) and ACT-902 (AFP+thapsigargin) can successfully target and kill cancer cells with little to no toxicity and without the "off-target" damage to healthy cells. ACT-903 (AFP+linker+maytansine) is ongoing similar studies currently.

A targeted delivery platform technology, transporting a well-established chemotherapeutic drug directly to cancer cells, will enable uptake and use of ACT's platform in multiple forms of cancer; starting with ovarian and testicular germ cell cancer, rare disease indications, providing ACT-901 a valuable orphan drug designation in the US and Europe, and early commercial approval and expanding usage to other solid and liquid based cancers. Dr. Daniel Von Hoff, a key oncology opinion leader, is advising the company on the upcoming clinical trials.

Additional Potential Benefits of ACT's Approach

Immuno-oncology is currently one of the most active areas of research with almost every major pharmaceutical company developing such products. However, almost all of the approaches being explored aim at unblocking a specific immune check-point in the very complex universe of immune system interactions and carry risk of serious side-effects and limited efficacy in solid tumors.

Recent data suggest that myeloid-derived suppressor cells (MDSCs) may play a major role in allowing tumors to escape immune surveillance. MDSCs are present in large numbers in the vicinity of most cancers and when activated suppress the activity of T cells and NK cells. Our recent work shows evidence that MDSCs express AFP receptors. We therefore expect that ACT's targeted therapies will not only kill cancer cell by selectively delivering chemotherapy drugs to these cells but also have the potential to release the patient's immune system to attack cancers by killing immuno-suppressive MDSCs thus combining immuno- and chemotherapy actions and delivering a double knockout hit to most cancers.

ACT's delivery technology targets receptors on cancer cells. Watch an animation at www.alpha-cancer.com