SUPPORTING INNOVATION AND TECHNOLOGY TRANSFER IN ONCOLOGY

OREGON	*2014_Pitty*

SCOPE	**OREGON first objective is to bring a "First in Class" drug candidate XCE853 into Phase 1 clinical trial for the treatment of human cancer within 3 years.**
KEYWORDS	**OREGON First in Class Pancreas Ovarian & Renal Cancers Resistance**

CONTEXT & BACKGROUND

OREGON THERAPEUTICS has acquired the patents rights for innovative molecules actives for the treatment of cancers. Personal funding from the founder has secured the first steps in the development of OREGON. A team of key managers with strong oncology backgrounds is working in cooperation with international centers of excellence in the field of oncology. This team includes former pharma and biotech executives with successful track records.
18 Millions € have been invested so far in the project.
OREGON THERAPEUTICS proprietary products comprise several families of compounds that belong to novel a class of anticancer drugs with "First in Class" attributes and $1-3 Bn sales potentials.
This novel class of broad spectrum anticancer agents displays unprecedented activity profile *i.e.* high potency on an unusually large variety of resistant tumor cells, and inhibition of a fundamental mechanism exacerbated in multiple forms of drug resistance.

INNOVATIVE COMPONENT & TECHNOLOGY

The company is focusing on the development of its first Drug Candidate XCE853. It has a new Mechanism of action (MOA) and an innovative profile of activity with potent efficacy against different types of tumor cells. XCE853 is particularly active in killing cells resistant to current chemotherapeutical drugs, thus it has the potential to answer a high medical need
From the preclinical data obtained today, and the medical needs in oncology, the first indications could be Ovarian Cancer, Pancreas Cancer and Renal Cell Carcinoma RCC.

OBJECTIVES

The company's short term aim is to create value by performing the Proof of Concept in human of this new drug to treat cancers resistant to current therapies; After completion of the first in man study, the phase II will allow to demonstrate the clinical benefit of XCE853. At this stage, the company expects to have raised a large interest from the pharmaceutical industry, in order to out license the product, or to perform further clinical development to market the new drug via a partnership or an M&A. In the long term and after a first success with XCE853, the company could envision developing other compounds of its portfolio in other cancer indications.

TARGET POPULATION

The development of XCE853 will address large unmet therapeutic needs in a broad range of cancers. The Anticancer therapeutics market represents around 40 B$ worldwide, the 10 best selling drugs have each a market of $Bn 1-7. The potential market for a new drug first in class monotherapy, and in combination therapy acting on a wide range of tumors hard to treat and non-responding to current therapies, is very high.

TARGET PROFILE

Priority Indications will be Pancreas, Ovarian and Renal Cancers

DEVELOPMENT & MATURATION STAGE

Preclinical studies performed to date indicate that the drug candidate XCE853 has a good product profile for further development and the potential for "First in Class" status.
XCE853 is a powerful In vitro, ex vivo, in vivo antitumor drug candidate

- Its MOA is novel: It is a potent inhibitor of Protein Disulfide Inhibitor (PDI), a validated new target that results in the selective induction of autophagy in cancer cells.

- In vitro activities against a large panel of tumor cell lines at **low nM** concentrations
- Proof of concept has been validated in vivo with pancreas and ovarian cancer xenograft mice treated by oral administration (Orally bioavailable with F value 68%)
- The American National Cancer Institute has confirmed the unique profile of XCE853 activity when compare to the 200 anticancer marketed compounds.
- XCE853 is particularly active against tumor cell lines with anticancer drugs resistant phenotypes (Ovarian, pancreas, renal, prostate, leukemia, lung, breast, H&N), and ex vivo cultures from patient's tumor.
- XCE853 is a druggable small molecule following the Lipinsky rules with no early safety alerts identified

To develop XCE853, OREGON is moving the compound from a Drug Candidate to a drug product, which has an established PK/safety profile in Phase I cancer patients within 3 years. Based on the phase I results, the proof of efficacy in human will be performed with a phase IIa study in the following year.

INTELLECTUAL PROPERTY & PATENT CO-OWNER(S)

OREGON has exclusive access to key intellectual property since it acquired a patent family describing the structural basis of all compounds with proven efficiency on cancer resistant cells with a priority date in 2008. A more focused patent application has been filed with a priority 2011, covering all Lead compounds. XCE853 is fully protected with full freedom to operate.

STRENGHTS & COMPETITIVE ADVANTAGES

- The activity against a large number of drug-resistant tumor cells, and the fact that XCE853 is more potent on drug-resistant tumor cells than on their parental cell lines counterparts.
- The "First in Class" positioning: Unique mechanism of action on a validated new target, with no direct competitors;
- Pressures on drug prices to reduce healthcare costs favor small molecule entities, whose much lower manufacturing costs as compared to biologicals.

INDUSTRIAL APPLICATIONS & PARTNERSHIP OPPORTUNITIES

- From the results obtained today, the first indications could be Pancreas, Ovarian and Renal Cancer, where the medical need is very high. Liver, H&N, Lung and Prostate cancers will also be investigated.
- Oregon is looking for investors and/or Industrial partnerships to accelerate its development.

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