Onselex

www.onselex.com

EXECUTIVE SUMMARY

ONX-1006 | Stage IV Pancreatic Cancer |

Company Overview. We took an effective chemotherapy drug and made it much safer, with no side effects. ONX-1006 is a novel nanoparticle formulation of chemotherapy drug, paclitaxel (PTX), designed to concentrate the drug in tumors while protecting healthy cells. More than 30 preclinical tests and about 4,000 pages of data demonstrate greater tumor reduction than Abraxane at the same weekly PTX dose, the highest cancer cell death, and continued drug exposure in tumors.

FDA IND PACKAGE & SEND COMPLETE | NOV 6, 2026 IND package: 25 nonclinical reports (2,122 pages), Investigator's Brochure and Phase I/IIa protocol. All 199 SEND datasets from 15 studies passed Pinnacle 21, a tool used by the FDA. Filing follows cGMP batch.

Preclinical Differentiation

- **Nanoparticle delivery:** Tumor-focused PTX delivery; designed to protect normal cells.
- **High dose, long term tolerance:** Goal: weekly treatment for one year or longer. Abraxane plus gemcitabine may require dose reductions or discontinuation due to toxicity.
- **Beagle dog GLP:** No Side Effects at human equivalent doses of about 480 mg PTX (4 weeks) and 320 mg PTX (13 weeks) for a 60 kg adult, versus about 200 mg PTX for Abraxane with severe side effects.
- **Efficacy:** 20% greater tumor reduction vs. Abraxane in 49 days at equal weekly PTX dose; goal of ongoing tumor cell death through continuous weekly treatment.

Clinical Opportunity and Development Objectives

- **Planned Phase I/IIa:** South Korea; eight treatment-naïve Stage IV pancreatic cancer patients in Cohort 1. Early human data targeted about one year after trial initiation.
- **U.S./Korea IND path:** Onselex USA will file the FDA IND, allowing clinical trials to begin after 30 days if the FDA raises no objections. Onselex Korea will use the FDA IND application materials with written permission from Onselex USA. The South Korean clinical trial is planned to be included under the U.S. FDA IND, with clinical results submitted to the FDA.
- **Development goals: ≥1 year of continuous treatment without side effects; 90–100% tumor elimination; Stage IV Pancreatic Cancer One-Year Survival goal, 70%.**
- **Unmet need:** Despite RASONQUE and other advances, severe treatment-related toxicities and poor long-term survival remain major obstacles to effective pancreatic cancer treatment

Clinical and Capital Strategy

- **NASDAQ pathway:** Investment bank engagement for underwriting and clinical trial initiation.
- **Listing timeline:** 18–30-month target, subject to financing, clinical progress and listing requirements.
- **Strategic value:** Institutional capital, investor liquidity and broader market visibility following successful human clinical data.

Intellectual Property

- **Granted patents:** Japan, EU, UK, Korea, United States and Canada.
- **Additional protection:** Further patent filings in progress.

INVESTMENT PROPOSAL

Raise	$400K-$2M
Price	$0.40 per share
Shares	30M shares
At $2M	cGMP, effective U.S. IND, Korea Cohort 1 start

Use of Proceeds ($400K): cGMP manufacturing initiation, regulatory preparation, patent management, legal and investment bank engagement.

NEAR TERM MILESTONES

1. CAPITAL FORMATION	2. TRIAL ACTIVATION	3. VALUE INFLECTION
Formal investment bank engagement and readiness work for the NASDAQ pathway.	cGMP → U.S. IND effective → South Korea MFDS trial approval → Korea Cohort 1.	Human safety and efficacy data targeted within about one year of clinical trial initiation.

Important: All efficacy, survival and tumor-elimination figures are company targets or preclinical extrapolations and have not yet been demonstrated in human clinical trials.