

Oncolys BioPharma Inc.

Applying its proprietary telomerase specific oncolytic adenovirus technology to create a comprehensive cancer care practice from diagnostic and therapeutic solutions to recurrence and metastatic detection

www.oncolys.com

Oncolys BioPharma Inc.
4-1-28 Toranomon
Minato-ku
Tokyo 105-0001
JAPAN

Founded in: 2004
Founder & CEO: Yasuo Urata
No. of employees: 25
Type of Ownership: public
Primary stock exchange: 4588

March 2016: Co-founded with Prof. Toshiyoshi Fujiwara¹, the inventor of the telomerase specific oncolytic adenovirus technology, Oncolys BioPharma is committed to make its therapeutic and diagnostic products available for patients with intractable cancers.



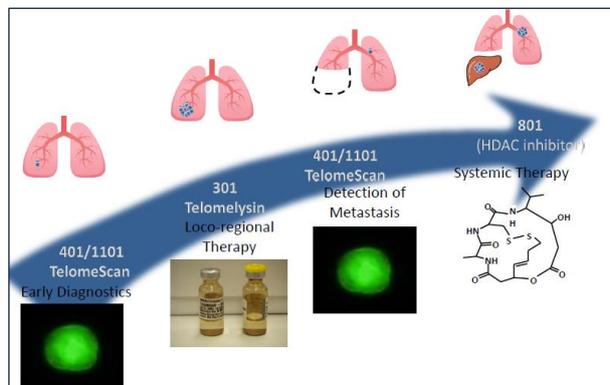
Venture Valuation (VV) interviewed Yasunari Kashihara, Vice President, Business Development, and Kohei Hata, Deputy Director, Corporate Development.

VV: **Oncolys BioPharma has a vision to provide total cancer care from diagnostic and therapeutic solutions to recurrence and metastatic detection.**

Oncolys: We have been primarily developing our clinical-stage products Telomelysin® for therapy and TelomeScan® for diagnosis. They are based on the use of genetically engineered human adenovirus type 5, which is programmed to identify and destroy only telomerase-activated cancer cells while healthy cells are left intact. Telomerase is a well-known cancer detection biomarker for most human cancer cells.

Telomelysin® is monotherapy as well as combination treatment with radiation therapy, immunotherapy, and another anticancer drug.

TelomeScan® is designed to detect a few circulating tumor cells² (CTCs) in blood and so indicate recurrence and metastasis at a very early-



¹ Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences

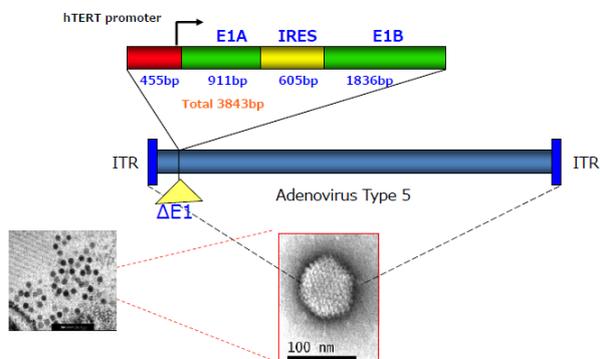
² tumor cells shed from solid tumors and entered the blood circulation

stage. It is constructed by inserting green florescent protein (GFP) gene, a striking molecular marker for imaging in live tissues, into Telomelysin®.

Complementing the above leading products, we have been developing a histone inhibitor, which was licensed from Astellas Pharma Inc., Japan.

VV: **Oncolytic virotherapy has been developed over several decades. Through advancements of genetic engineering, it has made rapid progress. Telomelysin® is one of the promising oncolytic viruses.**

Oncolys: Telomelysin® is based on human adenovirus type 5 which is known to cause the common cold, tonsillitis, and conjunctivitis. It is constructed by replacing the E1 region of the viral genome with a replication cassette of hTERT (human Telomerase Reverse Transcriptase) promotor, E1A viral gene, IRES (Internal Ribosome Entry Site) sequence and E1B viral gene. With this structure, Telomelysin® is able to enhance specificity and its replication rate within cancer cells.



When Telomelysin® is administered by intratumoral injection, endoscopically within a tumor, it infects only telomerase-activated cancer cells, replicates over 100,000-fold, and dissolve them. Replicated Telomelysin® will spread to other cancer cells and continue to break them up.

VV: **What is the development status of Telomelysin®?**

Oncolys: Currently phase I/II studies are ongoing in Taiwan and Korea. They target liver cancer patients who do not respond well to the existing treatments such as sorafenib. These studies apply a monotherapy approach.

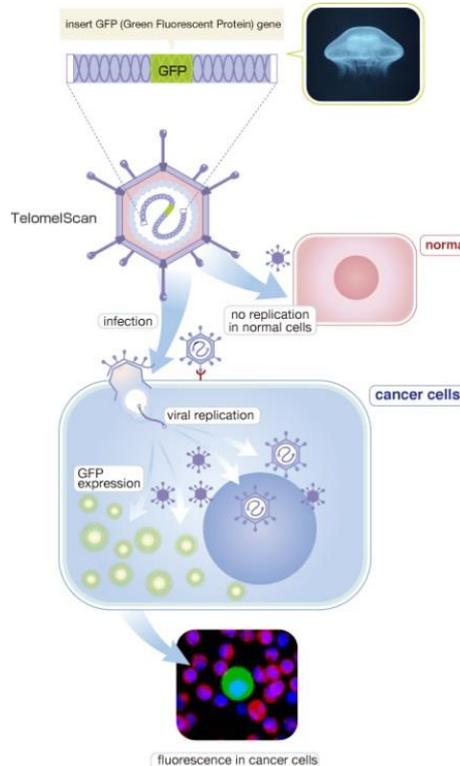
We have already completed a phase I study in the U.S. with patients having various solid cancers. As a next step, a phase II study on melanoma will be planned for a combination therapy with anti-PD-1 antibody, the immune check point inhibitor.

Preceding those clinical studies outside Japan, Prof. Toshiyoshi Fujiwara conducted clinical research with seven esophageal cancer patients from 53 to 92 years old. They were in the condition that neither surgical intervention nor chemotherapy was suitable due to comorbidity. Combining Telomelysin® with radiotherapy successfully demonstrated

synergistic effects, and it was confirmed by an in-vivo imaging system. We have evaluated safety and clinical efficacy. This year another clinical research study will be conducted with up to 24 patients.

VV:
Oncolys:

TelomeScan® is a cancer detection product applying to CTCs.



TelomeScan® is the same structure as Telomelysin®'s but with GFP inserted. When it infects cancer cells, viral replication occurs, and produces green fluorescence. It enables visual detection of live CTCs among millions of peripheral blood³ leukocytes.

A 7.5ml blood sample is enough for testing. This liquid biopsy approach, compared to the biopsy involving surgical intervention to remove tumor samples, provides patients with a less invasive procedure, early diagnosis, and reassurance.

VV:
Oncolys:

What is your strategy to market TelomeScan®?

We will expand our out-licensing partnership throughout the world and develop a variety of test kits and related devices. In the U.S. we are going to apply for FDA 501(k) in the near future.

Our current plan for test kit products consists of two lines: T-CAS (TelomeScan® CTC Analysis System) targeting various solid cancers, cancer stem cells, breast cancer; and T-GEN (TelomeScan® Genotyping System) aiming at prostate cancer, lung cancer, colorectal cancer, and head and neck cancer.

VV Comments after the interview:

The global oncology market is estimated at US\$ 100 billion in annual sales

³ blood circulating throughout the body



and projected to US\$ 147 billion by 2018.⁴ Oncolys BioPharma estimates US \$7.9 billions for the current global CTC diagnostics market. Innovative therapeutics and diagnostics will bring further progress in survival with lower toxicity for cancer patients.

In the growing and competitive market environment, innovative companies like Oncolys BioPharma require a large amount of funds in research and development. In the process of developing and commercializing technology, they need to attract the global attention. Therefore, it is essential for them to improve brand strategy as well as investor relations.

As mentioned in the previous article, Japanese small-sized companies with outstanding technology in particular seem seriously insufficient in disseminating updated information in English. They should more proactively engage in targeted and frequent announcements in English. It would help those companies be better recognized as well as encourage foreign investors to reach out. Especially for publicly listed companies, investors can also be patients, their families and friends, scientists, or medical professionals.

There is a term “galapagos syndrome” or “galapagosization” which was created in Japan several years ago. It meant selling highly advanced products (e.g. 3G mobile phones) in Japan while leaving the rest of the world unaware. The term refers to Galapagos Islands where isolated flora and fauna evolved differently from the rest of the world. Galapagosization must be avoided in the life science industry.

Contact **Mariko Hirano**, m.hirano (at) venturevaluation.com

Venture Valuation specializes in independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, Medtech), ICT, Nanotech, Cleantech and Renewable Energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this “*Let’s Interview Series*” with companies with interesting technologies and services. We select and interview thriving companies and organizations all over the world.

⁴<http://www.forbes.com/sites/matthewherper/2015/05/05/cancer-drug-sales-approach-100-billion-and-could-increase-50-by-2018/#1d9329ce70f4>