ONSSI Corporation

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Who We are …

A biotech venture that strives to bring novel agents developed by Dr. Naka Tetsuji, Director of Center for Intractable Immune Disease, Kochi Medical School, Kochi University, to patients in need of better therapies with a firm determination to contribute to the society.

Mission

To realize a society where patients fighting serious diseases can live through their lives with a smile and dreams for a brighter future.

Business Scheme

For the purpose of providing patients with more treatment options, ONSSI focuses on research and development to acquire POC (Proof Of Concept) of investigational drugs and license them out to pharmaceutical companies in the shortest possible time.

Profiles of Directors

Ohsugi, Yoshiyuki, Ph.D.
Chairman

Joined Chugai Pharmaceutical Co., Ltd. upon graduating Graduate School and School of Pharmaceutical Science, Osaka University in 1969.

A concept of Actemra®, the first innovative antibody drug developed in Japan was inspired by him, and he played a leading role in advancing its research and development accomplishing a launching of the first anti-rheumatic drug in 2008 in Japan.

After holding several essential roles such as Director of Research Laboratories, Managing Director of Research Institute of Molecular Medicine of Chugai, he became a specially appointed professor of Hitotsubashi University, Institute of Innovation Research.

In 2015, he created Ohsugi Biopharma Consulting Services Co., Ltd. with the aim of providing valuable advices on R&D of biopharmaceuticals.

Tanaka, Akio
CEO

Upon graduating from Kobe University majoring in Chemistry, he joined Chugai Pharmaceutical Co., Ltd. in 1976, and led numerous basic scientific research and clinical trials on active vitamin D3 coordinating with KOLs in the field.

After moving to the clinical development department, he conducted the first bridging study of a large overseas trial in Japan on SERM, an agent co-developed with Eli Lilly.

He later was appointed as an executive officer, concurrently a head of oncology unit of Chugai Pharmaceutical.

He serves as an advisor to Ohsugi Biopharma Consulting on the research and development of innovative drugs.

Our Pipeline

I. Novel gene therapy drug using the cytokine signaling inhibitor

Observing the constant activation of Jak-Stat signaling pathway (mainly Stat3) which greatly involves a survival and an increase of cancer cells, SOCS3 that regulates an activation of Stat3 was targeted, and the development of SOCS gene therapy using adenoviral vectors is underway.

Target diseases: **MPM (Malignant Pleural Mesothelioma)**, Head and neck cancer, Esophageal cancer, Hepatic cancer

Status: Investigator-initiated clinical trial on MPM is in preparation

Number of patients

The fatality is estimated to reach a peak of 3,000/year around 2030. The number of deaths exceeded 1,500 in 2015 and has been increasing over the years.

Prognosis

5-year survival rate by the disease stage: 14.6% for Stage-I (n=48), 4.5% for Stage-II (n=22), 8.0% for Stage-III (n=50), and 0.0% for Stage-IV (n=70), respectively, suggesting a poor prognosis at any stage.

Drug formulation

Frozen, Injectable form

Administration method

Intrathoracic injection, Intratumor injection

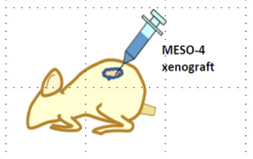
Expected outcomes

Decreasing tumor size and Improved survival times

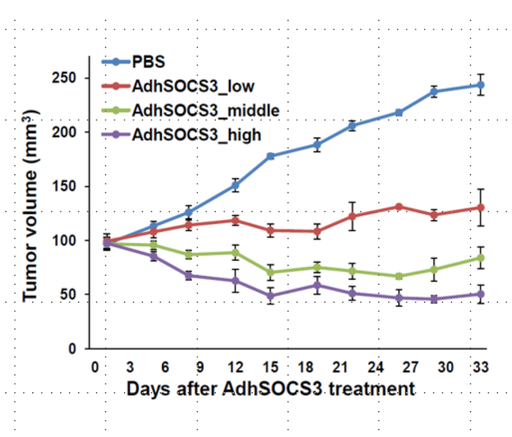
Sales forecast

5 – 15 billion yen at its peak; Product launch is expected in the mid-to-late 2020s; The drug is developed under "SAKIGAKE" strategy package – Japan's regulatory system that facilitates an early practical application of Regenerative Medicines.

Desired drug efficacy is seen at Middle (AdSOCS-3 1x10^8 ifu/body) in mouse models of malignant pleural mesothelioma (MESO-4)



Administered totally 6 times
(2 times/week)
Low: AdSOCS-3 1x10^7 ifu/body
Middle: AdSOCS-3 1x10^8 ifu/body
High: AdSOCS-3 1x10^9 ifu/body



II. ADC (Antibody-drug conjugates) as a novel anti-cancer therapy targeting solid tumors

A comparison of the cell membrane proteins of normal esophagus epithelial cells with those of esophageal cancer cell lines using a quantitative proteomics method was conducted with the purpose of identifying a cell membrane protein overexpressed in intractable cancers for the development of an antibody drug. In the result, Glypican-1 (GPC1) was identified as a cell membrane protein that expresses significantly in esophageal cancer cells, thus the development of anti-GPC1 monoclonal antibody and ADC has been initiated.

Target diseases: **Pancreatic cancer**, Esophageal cancer, Cervical cancer

Status: GLP-TOX and GMP manufacturing are in preparation on pancreatic cancer

Number of patients

40,000 (Male: 20,200, Female: 19,800) in 2018 with a slight increase every year

Prognosis

- 5-year survival rate is 7.7% suggesting a quite low survival.
- Prognosis by stages: Unresectable pancreatic cancer is considered as an intractable cancer with a very poor prognosis. Stage IA (MST 49.0 months), IB (MST 36.3 months), Stage IIA (MST 21.0 months), IIB (MST 16.4 months), Stage III (MST 12.5 months), Stage IV (MST 7.8 months)
- SOC: Postoperative adjuvant chemotherapy after the grossly radical resection as the operation alone shows poor prognosis with the 5-year survival rate only 10%.

Drug formulation

Injectable form (IV); A combined use with other chemotherapies or immune checkpoint inhibitors may be considered

Expected outcomes

Anticancer effects, Improved survival times

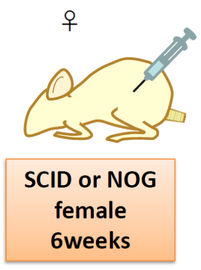
Possibilities of licensing out to overseas companies

Yes (PCT application in the U.S. has been filed)

Sales forecast

40 – 50 billion yen at its peak in Japan; licensing out to a pharmaceutical company at the end of GLP-TOX or Phase I study with a prospect of the product launch in the early 2030s.

Antitumoral activity is observed by mGPC1-ADC in xenograft models of pancreatic cancer



Pancreatic cancer cell line (BxPC3) *(left)*, and Pancreatic cancer tissue (PDX) *(right)* were subcutaneously implanted in the mice.
GPC1 was injected in the tail veins of those mice for 4 times.