Press Release

February 19, 2024

GORYO CHEMICAL

FDA opinion received, indicating
high probability of "De Novo" classification

FDA 513(g) pre-submission consultation completed
for breast cancer navigation drug (GCP-006)

On July 13, 2023, Goryo Chemical Co., Ltd. (head office: Sapporo, Japan; CEO and Representative Director: Ken-ichi Maruyama; hereinafter "Goryo") and Solasia Pharma Co., Ltd. (head office: Tokyo, Japan; President and CEO: Yoshihiro Arai, hereinafter "Solasia") entered into a feasibility study agreement to explore the possibility of jointly commercializing pharmaceuticals based on Goryo's technologies and assets, including the development of candidate drugs for therapeutic as well as in-vitro and in-vivo diagnostic use.

As part of this study, Goryo submitted a "513 (g) application (note 1)" to the US Food and Drug Administration (FDA) for GCP-006, the navigation drug for the breast cancer (note2), which has been returned with an indication that GCP-006 could have a high probability of receiving "De Novo (note3)" classification if submitted to the FDA.

Based on the FDA's indication, we will further advance the joint commercialization study to allow GCP-006 to be marketed and delivered to patients and medical institutions in the US, including the identification of an out-license partner for the US market as well as other regions and countries.

(Note 1) A regulatory scheme that allows you to make a request to the FDA to classify a medical devices targeted for sale in the US, where continuous efforts are being made to incorporate innovative technologies. A 513(g) application scheme can be used to enhance the predictability

of the development process and its efforts, since a device classification can have significant impact on the development cost and speed.

(Note 2) Technology for a diagnostic drug for rapid detection of breast cancer and its remnants during the surgery. An NDA (New Drug Application) was submitted to the regulatory authority in Japan, the PMDA (Pharmaceutical and Medical Devices Agency) on March 28, 2023, and is currently under review.

(Note 3) When a medical device intended for the US market is determined, through the 513(g) scheme, that it does not fit into an existing classification, that no prior device exists, and yet that it is highly unlikely to receive a high-risk classification (Class III), the FDA determines whether the relevant device should be classified as Class I or II, and whether a new product code or regulatory number should be issued for the device. As for classification of new and innovative medical devices, FDA tends to classify them as class III (high-risk classification) device. However, not all of them are necessarily high-risk devices, in which case the FDA could grant "De "Novo status" whereby such device could be marketed without undergoing extensive clinical development.

1. Overview of the companies

Name	Goryo Chemical Co., Ltd.
Head office address	35-100 Kita 8-jo Nishi 18-chome, Chuo-ku, Sapporo, Hokkaido, Japan
Representative	Representative Director and CEO: Ken-ichi Maruyama
Established	July 2010
Business and its scope	Manufacture and sale of functional fluorescent probes, contract synthesis, development of navigational drugs using functional fluorescent probes for cancer surgery

Company Name	Solasia Pharma K.K.
Head office address	Sumitomo Fudosan Shibakoen Tower 4F, 2-11-1 Shibakoen, Minato- ku, Tokyo, Japan
Representative	Representative Director Yoshihiro Arai
Established	January 2006
Business and its scope	Development, sales, import/export, etc. of pharmaceuticals and medical devices

2. (Reference) Goryo Chemical Co., Ltd.

Goryo has developed and manufactured the world's first product that selectively illuminates the cancer tissue only a few minutes after a fluorescent probe is sprayed on a human tissue fragment. Based upon this technology, Goryo has developed reagent businesses for research use and has been expanding its business scope to include developing navigation drugs for both in-vitro and in-vivo diagnostic use to be utilized during surgical procedures, mainly for cancer. The navigation drug, also known as "Fluorescent Image-Guided Surgery" (surgical support using fluorescent imaging (Note 4)), is a new and emerging mode of technology that is increasingly attracting attention for research and clinical use.

Goryo's focus thus far has mainly been on the development of navigation drugs that can be applied in surgery and/or medical checkups for various types of cancers, in order to allow early detection and treatment, prevent recurrence and promote early recovery post-surgery. In addition to developing navigation drugs for cancer, Goryo's unique fluorescent technology can also be applied to the early detection and treatment of non-cancerous diseases. The fluorescent probe to detect calpain enzyme, currently being developed by Goryo, is a good example of the new endeavor by the company to expand its scope of R&D activities into new target fields other than cancer. To this end, Goryo has formalized a global license agreement for the ophthalmology area with Senju Pharmaceutical, Inc. on April 5, 2023 (refer to the press-release of the same date). In addition to the development of candidates for diagnostic use, Goryo is also engaged in developing new drug candidates for therapeutic use, by making the best use of its knowledge and know-how accumulated through developing fluorescent probe technology.

(Note 4) Fluorescence imaging: A technique that enables observation of the localization and movement of cells, specific proteins, etc. by shining a laser or other light on various fluorescent dyes and fluorescent proteins.

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