

## News Release

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March 1, 2024

Taiho Pharmaceutical Co., Ltd.

Haihe Biopharma Co., Ltd.

**Taiho Pharma Enters Exclusive License Agreement  
with Haihe Biopharma for Gumarontinib (SCC244),  
an Agent for Non-Small Cell Lung Cancer**

Taiho Pharmaceutical Co., Ltd. (hereinafter “Taiho”) and Haihe Biopharma Co., Ltd. (hereinafter “Haihe”) announced today that two companies have entered into an exclusive license agreement regarding the development, manufacturing and commercialization of gumarontinib (development code : SCC244), agent for non-small cell lung cancer, which application for marketing authorization has been submitted and is currently being reviewed in Japan by Haihe Biopharma K. K., fully owned affiliate of Haihe.

Under the license agreement, Taiho will obtain exclusive rights in Japan, Asia (excluding China) and Oceania to develop, manufacture and commercialize, gumarontinib, Haihe will receive an upfront payment, development and sales milestones, and royalty based on sales revenue from Taiho.

Gumarontinib is an oral, small molecule MET inhibitor discovered by Haihe. In September 2023, Haihe Biopharma K. K., submitted new drug application of gumarontinib in Japan for the treatment of unresectable, advanced or recurrent non-small cell lung cancer (NSCLC) with *MET* exon 14 (*MET*ex14) skipping mutations as possible indications. Gumarontinib has been approved in China in March 2023 by NMPA (National Medical Products Administration) for the treatment of non-small cell lung cancer (NSCLC) with *MET*ex14.

“We are pleased to announce that we will be entering into a partnership with

Haihe on gumarontinib, a new treatment option for the patients with non-small cell lung cancer. We will be preparing for the successful launch of gumarontinib with Haihe to contribute to the patients and healthcare professionals.” stated Masayuki Kobayashi, President and Representative Director of Taiho.

“We are pleased to announce that we are entering into partnership with Taiho, one of the leading companies of oncology in Japan. We hope our collaboration shall be able to provide a promising treatment option for the patients with non-small cell lung cancer.” stated Ruiping Dong, M.D., Ph.D., Chief Executive Officer of Haihe.

Taiho and Haihe through its alliance, will make every effort to deliver gumarontinib to patients and healthcare professionals as soon as possible.

### **About NSCLC with *MET*ex14 Skipping Mutations**

Primary lung cancer is the malignant tumor with one of the highest morbidity and mortality. Globally, the number of new patients with lung cancer is estimated to be 2.2 million/year and the number of deaths to be 1.79 million/year (2020)<sup>1</sup>. In Japan, the number of new patients with lung cancer is more than 120,000/year (2019) and the number of deaths is over 70,000. /year (2020)<sup>2</sup>. The proportion of non-small cell lung cancer among lung cancer patients in Japan is 88%, and the frequency of mesenchymal epithelial transforming factor (MET) gene exon 14 skipping mutation is about 3%<sup>3</sup>. Thus, in Japan, the number of patients eligible for treatment with this drug is estimated to be around 3,000/year.

### **About Taiho Pharmaceutical Co., Ltd. (Japan)**

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd. (<https://www.otsuka.com/en/>), is an R&D-driven specialty pharma focusing on the fields of oncology and immune-related diseases. Its corporate philosophy takes the form of a pledge: “We strive to improve human health and contribute to a society enriched by smiles.” In the field of oncology, in particular, Taiho Pharmaceutical is known as a leading company in Japan for developing innovative medicines for the treatment of cancer, a reputation that is rapidly expanding through their extensive global R&D efforts. In areas other than oncology, as well, the company creates and markets quality products that effectively treat medical conditions and can help improve people’s quality of life. Always putting customers first, Taiho Pharmaceutical also aims to offer

consumer healthcare products that support people's efforts to lead fulfilling and rewarding lives. For more information about Taiho Pharmaceutical, please visit <https://www.taiho.co.jp/en/>

### **About Haihe Biopharma Co., Ltd.**

Haihe Biopharma Co., Ltd is a global, values-based, R&D driven biopharmaceutical leader headquartered in China with operation centers in the US and Japan, and mainly focuses on innovative anti-tumor therapies. The company has the comprehensive capability of drug discovery, development, manufacturing and commercialization, and delivers life-saving therapies to cancer patients in China and around the world. As a R&D focused company with many experts skilled in developing new drugs, Haihe Biopharma is committed in-house innovation with global perspective management and R&D team. For more information about Haihe Biopharma, please visit <https://www.haihepharma.com/en>

Haihe Biopharma K. K. has been established as fully owned affiliate of Haihe Biopharma Co., Ltd. since 2021. Company shall introduce rich pipeline of novel anticancer drugs from Haihe Biopharma Co., Ltd. in Japan.

- 1) Sung H, Ferlay J, Siegel R L, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries[J]. CA: A Cancer Journal for Clinicians, 2021, 71(3): 209–249.
- 2) Cancer information service “Cancer Statistics” of National Cancer Institute as of 14th February 2024  
[https://ganjoho.jp/reg\\_stat/statistics/stat/cancer/12\\_lung.html](https://ganjoho.jp/reg_stat/statistics/stat/cancer/12_lung.html)
- 3) Frampton GM, Ali SM, Rosenzweig M, et al. Activation of MET via diverse exon 14 splicing alterations occurs in multiple tumor types and confers clinical sensitivity to MET inhibitors. Cancer Discov. 2015;5(8):850–859. doi:10.1158/2159-8290.