

## News Release

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September 24, 2024

Taiho Pharmaceutical Co., Ltd.

Haihe Biopharma Co., Ltd.

**Taiho Pharmaceutical and Haihe Biopharma Announce  
the Launch of MET Inhibitor HAIYITAN® Tablets 50mg in Japan**

Taiho Pharmaceutical Co., Ltd. (hereinafter “Taiho”) and Haihe Biopharma Co., Ltd. (hereinafter “Haihe”) announced today that the MET inhibitor, HAIYITAN® tablets 50mg (generic name: gumarontinib hydrate), is schedule for launch on October 11, 2024, in Japan.

In June 2024, Haihe Biopharma K. K., a fully owned affiliate of Haihe, obtained approval to manufacture and market HAIYITAN in Japan for the treatment of unresectable, advanced or recurrent non-small cell lung cancer with *MET* exon 14 skipping mutations.

HAIYITAN is an oral, small-molecule, receptor-type tyrosine kinase MET inhibitor developed by Haihe. HAIYITAN is expected to inhibit tumor growth by blocking MET phosphorylation and downstream signaling.<sup>1</sup> In China, HAIYITAN has been approved by the National Medical Products Administration (NMPA) for manufacturing and marketing in March 2023.

Taiho and Haihe, together with Haihe Biopharma K. K., will contribute to patients with non-small cell lung cancer and healthcare professionals by providing HAIYITAN as a new treatment option for non-small cell lung cancer.

## About Non-Small Cell Lung Cancer with *MET* exon 14 Skipping Mutations

Primary lung cancer is the second most common malignancy in the world and has the highest mortality rate.<sup>2</sup> In Japan, the number of new patients with lung cancer is reported to be more than 120,000/year (2019), and the number of deaths is over 70,000/year (2020).<sup>3</sup> The percentage of non-small cell lung cancer among patients with lung cancer in Japan is 88%, and the frequency of *MET* exon 14 skipping mutations is about 3%.<sup>4</sup> Thus, in Japan, the number of patients with *MET* exon 14 skipping gene mutations positive, unresectable, advanced or recurrent non-small cell lung cancer who are eligible for treatment with HAIYITAN is estimated to be around 1,200/year.

## About *MET* Tyrosine Kinase

*MET* gene encodes a receptor-type tyrosine kinase. Binding hepatocyte growth factor (HGF), a *MET* ligand, induces receptor dimerization and autophosphorylation of tyrosine residues in the kinase domain of *MET*, forming binding sites for various signaling factors. Subsequently, intracellular signaling cascades such as the RAS pathway are activated to stimulate tumor cell growth, migration, invasion, and angiogenesis in cancer.<sup>5</sup>

## Summary of Product Information in Japan

Brand name	HAIYITAN® tablets 50mg
Generic name	Gumarontinib hydrate
Indications	Unresectable, advanced or recurrent non-small cell lung cancer with <i>MET</i> exon 14 skipping mutations
Dosage and administration	Normally, for adults, oral administration in fasting condition of 300mg of gumarontinib once daily. Dosage should be reduced based on the patient's condition.
Date of manufacturing and marketing approval	June 24, 2024
Date listed in NHI reimbursement price listing	August 15, 2024
Date of initial marketing in Japan	October 11, 2024
NHI reimbursement price	JPY 4,382.30 / tablet
Packaging	PTP Packaging: 24 tablets (8 tablets x 3)

Manufacturer and distributor	Haihe Biopharma K. K.
Distributor	Taiho Pharmaceutical Co., Ltd.

### **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 an R&D focused company with many experts skilled in developing new drugs, Haihe Biopharma is committed to 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. The Company will introduce rich pipeline of novel anticancer drugs from Haihe Biopharma Co., Ltd. in Japan.

1. Ai J, Chen Y, Peng X, et al. Preclinical evaluation of SCC244 (Glumetinib), a novel, potent and highly selective inhibitor of c-Met in MET-dependent cancer models. *Mol Cancer Ther.* 2018;17(4):751–762
2. Sung, H, Ferlay J, Siegel RL, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of

Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin.* 2021;71(3): p. 209–249.

3. Cancer information service “Cancer Statistics” of National Cancer Institute as of 12th September 2024 [https://ganjoho.jp/reg\\_stat/statistics/stat/cancer/12\\_lung.html](https://ganjoho.jp/reg_stat/statistics/stat/cancer/12_lung.html)

4. Vuong HG, Ho ATN, Altibi AMA, et al. Clinicopathological implications of MET exon 14 mutations in non-small cell lung cancer - A systematic review and meta-analysis. *Lung Cancer.* 2018;123:76–82.

5. Tomoyuki Naito, et al. Treatment of Lung Cancer Targeting *MET* Alterations. *Japanese Journal of Lung Cancer.* 2021: 61: 273-281