

Ono Pharma Submits an Application for Approval of Ripretinib (DCC-2618) in Patients with Advanced Gastrointestinal Stromal Tumor in Japan

- Application submitted for manufacturing and marketing approval of ripretinib in Japan for the indication of “gastrointestinal stromal tumor that has progressed following cancer chemotherapy”
- Ripretinib has significantly prolonged the primary endpoint of progression-free survival compared to placebo in the INVICTUS study
- Already approved in the United States and Europe; recognized as a highly necessary medicine by the government review committee addressing drug loss in Japan

Osaka, Japan, March 26, 2026 - Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Toichi Takino; “Ono”) today announced that Ono submitted an application for the manufacturing and marketing approval of ripretinib (DCC-2618), developed by Deciphera Pharmaceuticals, Inc. (“Deciphera”), for the indication of “gastrointestinal stromal tumor that has progressed following cancer chemotherapy”.

This application is based on the results of the INVICTUS study, a global Phase 3 clinical study, evaluating the efficacy of ripretinib compared to placebo in patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. In this study, ripretinib significantly prolonged the primary endpoint of progression-free survival (PFS) compared to placebo.

“GIST is recognized as a rare disease worldwide, and ripretinib, developed by Deciphera, has already been approved in more than 40 countries and regions, including the United States and Europe. This application for approval of ripretinib represents a significant advancement for patients with GIST in Japan,” said Tatsuya Okamoto, Corporate Officer / Executive Director, Clinical Development of Ono. “Moving forward, we remain committed to developing and providing innovative medicines to meet the treatment needs of patients and the expectations of society.”

“The application submission brings us one step closer to providing patients in Japan with advanced GIST a potential new treatment option. We anticipate that this submission may help address the issue of delayed access to new medicines, which remains a significant challenge for patients in Japan,” said Ryota Udagawa, President and Chief Executive Officer of Deciphera. “As GIST is a rare type of tumor, the limited availability of disease information and current treatment options are likely to cause significant anxiety for patients. Together with our group companies, we will continue to make every effort to deliver ripretinib to patients in Japan suffering from advanced GIST as quickly as possible.”

About the INVICTUS Study

The INVICTUS Phase 3 clinical study is a randomized, double-blind, placebo-controlled, international, multicenter study conducted in 12 overseas countries including US and EU to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in 129 patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib. Patients

were randomized 2:1 to either 150 mg of ripretinib or placebo once daily.

In the INVICTUS study, ripretinib significantly prolonged the primary endpoint of PFS determined by independent central radiologic review (a median PFS of 6.3 months in ripretinib arm compared to 1.0 month in the placebo arm, HR of 0.15, $p < 0.0001$).¹⁾

About GIST

GIST is a mesenchymal tumor that arises from the muscular layer of the gastrointestinal tract and forms a mass that pushes up the mucosa from below. GIST is a rare disease, with an incidence of approximately 1 to 2 cases per 100,000 population per year. In Japan, the number of patients diagnosed with GIST between 2016 and 2018 was 4,475 over three years (approximately 1,492 cases per year; crude incidence rate: 1.18 cases per 100,000 population).²⁾ It is known that mutations in KIT (KIT proto-oncogene receptor tyrosine kinase) and PDGFR α (platelet-derived growth factor receptor α) are involved in the development of the majority of patients with GIST.

For unresectable, metastatic, or recurrent GIST, four agents—imatinib, sunitinib, regorafenib, and pimitespib—are currently approved in Japan. According to the Japanese clinical practice guidelines for GIST, these agents are recommended as first-line, second-line, third-line, and fourth-line treatments, respectively.³⁾

About ripretinib

Ripretinib is an orally administered, tyrosine kinase inhibitor developed by Deciphera. Ripretinib inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, which are involved in GIST. In addition, ripretinib inhibits primary PDGFR α mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, which is present in a subset of GIST. The INVICTUS study has demonstrated the significant efficacy of ripretinib in patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib. Ripretinib was launched in the U.S. in 2020 under the brand name QINLOCK[®]. As of March 2026, it is approved for the treatment of advanced GIST in more than 40 countries or regions, including the U.S. and European countries. In Japan, ripretinib was designated as an orphan drug by the Ministry of Health, Labour and Welfare on March 19, 2026, for the treatment of GIST that have progressed following cancer chemotherapy. In addition, ripretinib was determined as a drug with high medical needs at the "67th Evaluation Committee on Unapproved or Off-label Drugs with High Medical Needs" held by Ministry of Health, Labour and Welfare, aiming to eliminate drug losses in Japan.

About Deciphera Pharmaceuticals Inc.

Deciphera, a member of Ono Pharmaceutical Co., Ltd., is a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines and providing hope to people living with cancer, neurologic and autoimmune disease. Deciphera is leveraging its proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines.

In addition to advancing multiple product candidates from Deciphera's platform in clinical studies, QINLOCK[®] (ripretinib) is Deciphera's switch-control kinase inhibitor approved in many countries including the European Union and the United States for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib. ROMVIMZA[®] is a kinase inhibitor approved in the United States for adult patients with symptomatic

tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity, and in the European Union for adult patients with TGCT associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability. For more information, visit www.deciphera.com and follow us on [LinkedIn](#) and [X \(@Deciphera\)](#).

References:

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- 2) -CANCER STATISTICS IN JAPAN-2025. Available from: https://ganjoho.jp/public/qa_links/report/statistics/2025_jp.html
- 3) Japan Society of Clinical Oncology, ed. Japanese Clinical Practice Guidelines for Gastrointestinal Stromal Tumors (GIST), Fourth Edition, April 2022. KANEHARA & Co., Ltd. Available from: <http://www.jsco-cpg.jp/gist/>

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