Press Release

Deciphera Receives European Commission Approval of ROMVIMZA™ (vimseltinib) for the Treatment of Tenosynovial Giant Cell Tumor (TGCT)

Vimseltinib is the first and only therapy with marketing authorization for the treatment of TGCT in the European Union

Osaka, Japan and Waltham, Massachusetts, September 18, 2025 – Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President and COO: Toichi Takino; "Ono"), today announced that the European Commission (EC) has approved ROMVIMZA™ (vimseltinib) in the European Union (EU) for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability[1]

"The European Commission's approval of vimseltinib for TGCT is a significant milestone for Deciphera, Ono, and TGCT patients across the European Union who are in need of a non-invasive treatment option. We are excited to leverage our global commercial infrastructure to bring vimseltinib to these patients," said Ryota Udagawa, President and Chief Executive Officer of Deciphera. "We look forward to working with health authorities to ensure all eligible patients who can benefit from vimseltinib have access as quickly as possible."

"This is much news for the TGCT community as vimseltinib is now the first approved therapy for TGCT in Europe," said Jean-Yves Blay, M.D., Ph.D., Leon Berard Center. "TGCT can significantly impact the daily lives of patients by causing pain, stiffness and mobility limitations. Vimseltinib is a differentiated treatment that has demonstrated the ability to address these unmet patient needs while remaining well-tolerated."

The EC approval is supported by compelling efficacy and safety results from the pivotal Phase 3 MOTION study of vimseltinib in patients with TGCT not amenable to surgery with no prior anti-CSF1/CSF1R therapy (prior therapy with imatinib or nilotinib allowed), compared to placebo, as well as the Phase 1/2 study of vimseltinib[1]. The primary endpoint was supported by statistically significant and clinically meaningful improvements in active range of motion, patient-reported physical functioning, and patient-reported pain observed in the vimseltinib arm compared to the placebo arm at week 25[1]. The secondary endpoint was supported by statistically significant and clinically meaningful improvements versus placebo in all six key secondary endpoints assessed at Week 25 including objective response rate (ORR) by tumor volume score (TVS), active range of motion (ROM), physical function, stiffness, quality of life, and pain[1]. In a descriptive analysis at Week 97, 23% (n=19/83) of the patients randomized to receive vimseltinib had best overall response of complete response (CR) according to RECIST v1.1, as assessed by blind independent radiological review (IRR), with a median time to CR of 11.5 months[1]. The safety profile of vimseltinib is manageable and consistent with results previously disclosed in the Phase 1/2 clinical trial[1]. For a full list of side effects and information on dosage and administration and other precautions, please refer to the Summary of Product Characteristics for further information.

About Tenosynovial Giant Cell Tumor (TGCT)

TGCT is caused by a translocation in colony-stimulating factor 1 (CSF1) gene resulting in overexpression of CSF1 and recruitment of colony-stimulating factor 1 receptor (CSF1R)-positive inflammatory cells into the lesion[2]. TGCT is also known as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS), a diffuse-type of TGCT. TGCT is a rare locally aggressive neoplasm that can grow and cause damage to surrounding tissues and structures inducing pain, swelling, and limitation of movement of the joint. Surgery is the main treatment option; however, these tumors tend to recur, particularly in diffuse-type TGCT. If untreated or if the tumor continually recurs, damage and degeneration may occur in the affected joint and surrounding tissues, which may cause significant disability. For a subset of patients, surgical resection will potentially cause worsening functional limitation or severe morbidity, systemic treatment options are limited and a new therapeutic option for TGCT is needed[2,3].

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 to improve the lives of people with cancer. 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 gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. ROMVIMZA™ (vimseltinib) 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).

About Ono Pharmaceutical Co., Ltd

Ono Pharmaceutical Co., Ltd. delivers innovative therapies for patients worldwide. Upholding its philosophy of "Dedicated to the Fight against Disease and Pain," Ono targets areas with unmet medical needs including oncology, immunology, and neurology, and fosters partnerships with academic and biotech organizations to accelerate drug discovery. Through its affiliate, Deciphera Pharmaceuticals, Ono is accelerating clinical development and commercial operations in the US and Europe to drive global business expansion and further its commitment to patient care. For more information, please visit the company's website at https://www.ono-pharma.com/en .

Cautionary Note Regarding Forward-Looking Statements

In this press release, statements made with respect to current plans, estimates, strategies and beliefs, and other statements that are not historical facts are forward-looking statements about the future performance of the company. These statements are based on current assumptions and beliefs in light of the information currently available and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in the business environment in the pharmaceutical market and amendments to relevant laws and regulations, (ii) disruptions to product supply due to stagnation or delays in production caused by natural disasters, fires, etc., (iii) the possibility that sales activities for new and existing products may not achieve the expected results, (iv) the emergence of new side effects in post-marketing drugs, and (v) infringements of intellectual property rights by third parties. Information about pharmaceutical products included in this press release is not intended to constitute an advertisement or medical advice.

1. - ROMVIMZA™ EU Summary of Product Characteristics, September 2025.
2. - Gelderblom H, Bhadri V, Stacchiotti S, et al. Vimseltinib versus placebo for tenosynovial giant cell tumour (MOTION): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2024;403(10445):2709-2719. doi:10.1016/S0140-6736(24)00885-7
3. - Stacchiotti S, Dürr HR, Schaefer IM, et al. Best clinical management of tenosynovial giant cell tumour (TGCT): A consensus paper from the community of experts. *Cancer Treat Rev*. 2023;112:102491. doi:10.1016/j.ctrv.2022.102491

Contact:
Ono Pharmaceutical Co., Ltd.
Media:
media_inquiries@ono-pharma.com

Deciphera Pharmaceuticals, Inc.
Media:
David Rosen
Argot Partners
david.rosen@argotpartners.com
646-461-6387