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Press Release

Deciphera Presents 2-Year Efficacy and Safety Results from MOTION Phase 3 Study of ROMVIMZA™ (vimseltinib) in Patients with Tenosynovial Giant Cell Tumor (TGCT) at the European Society for Medical Oncology Congress 2025

– Vimseltinib demonstrated statistically significant and clinically meaningful benefit vs placebo in antitumor response –

Osaka, Japan and Waltham, Massachusetts, October 18, 2025 – Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President and COO: Toichi Takino; "Ono"), today announced the two-year efficacy and safety results from its MOTION Phase 3 study of vimseltinib in patients with TGCT in cases where surgical removal of the tumor is not an option will be presented as a poster during the 2025 European Society for Medical Oncology Congress (ESMO), taking place October 17-21 in Berlin, Germany.

"These long-term Phase 3 MOTION results add to the established body of evidence supporting vimseltinib as a best-in-class treatment for TGCT," said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. "TGCT often causes debilitating pain, stiffness and impaired mobility and these results demonstrate the durable benefit that vimseltinib can offer patients."

Summary of Data and Findings from the 2-year results of the MOTION Phase 3 Study

Methods

The global Phase 3 MOTION study (NCT05059262) aims to evaluate the efficacy and safety of vimseltinib for the treatment of TGCT in cases where surgical removal of the tumor is not an option.

The study consists of two parts. In Part 1, eligible study participants were assigned to receive either vimseltinib or matching placebo for 24 weeks. Participants assigned to placebo in Part 1 had the option to receive vimseltinib for Part 2. Part 2 was a long-term treatment phase in which all participants received open-label vimseltinib. Patients received vimseltinib 30 mg twice weekly in all periods. Objective response rate (ORR) based on best overall response was assessed by independent radiological review (IRR) per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) and per Tumor Volume Score (TVS). Duration of response (DOR) and safety were also evaluated.

Efficacy

In these two-year results from the MOTION Phase 3 trial, vimseltinib continued to demonstrate robust and durable antitumor efficacy with a manageable safety profile that was consistent with prior reports. These long-term results support vimseltinib as a treatment option for 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, where it is approved. These results are reported with two years of follow-up in patients randomized to vimseltinib in Part 1 and crossed over from placebo to vimseltinib in Part 2. The data cutoff for this analysis was February 22, 2025.

In total, 118 patients received vimseltinib. At data cutoff, 51% (60/118) remained on treatment. With at least 2 years of follow-up, results demonstrate robust and durable antitumor activity with vimseltinib per RECIST v1.1 and per TVS, including in patients who crossed over to vimseltinib in Part 2.

- Of 83 patients randomized to vimseltinib in Part 1, 73 continued open-label treatment in Part 2. Median (range) treatment duration was 23.6 months (2 to 36).
- Of the 40 patients randomized to placebo in Part 1, 35 crossed over to vimseltinib in Part 2. Median treatment duration for this group was 19.1 months (1 to 30).
- ORR on study per RECIST v1.1 was 48% (40/83) for patients randomized to vimseltinib and 54% (19/35) for those who crossed over to vimseltinib. ORR on study per TVS was 81% (67/83) for patients randomized to vimseltinib and 71% (25/35) for those who crossed over to vimseltinib.
- The corresponding median DOR per RECIST v1.1 and per TVS was still not reached.

Safety

Vimseltinib continued to have a manageable safety profile that was consistent with prior reports with no new safety signals.

- Most treatment-emergent adverse events (TEAEs) were grade 1/2, and grade 3/4 TEAEs were similar between randomized vimseltinib and crossover groups.
- There were no new TEAEs in ≥15% of patients receiving vimseltinib and no new serious adverse events in more than one patient.
- Serum enzyme elevations were consistent with the known mechanism of action of CSF1R inhibition, and there was no evidence of cholestatic hepatotoxicity or drug-induced liver injury.

About Vimseltinib

Vimseltinib is an oral, switch-control tyrosine kinase inhibitor specifically designed to selectively and potently inhibit CSF1R. Vimseltinib has been developed using Deciphera's proprietary switch-control kinase inhibitor platform. It has been approved in the United States for adult patients with symptomatic 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.

About Tenosynovial Giant Cell Tumor (TGCT)

TGCT is caused by a dysregulation in colony-stimulating factor 1 (CSF1) gene leading to overproduction of CSF1 and recruitment of colony-stimulating factor 1 receptor (CSF1R)-positive inflammatory cells into the lesion.[1] TGCT is also known as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS). 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 new therapeutic options are needed.[1,2]

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. 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
2. 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

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