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Press Release

U.S. FDA Grants Full Approval of Deciphera's ROMVIMZA™ (vimseltinib) for the Treatment of Symptomatic Tenosynovial Giant Cell Tumor (TGCT)

In the MOTION Phase 3 study, ROMVIMZA met primary endpoint of improved objective response rate (ORR) compared to placebo and all key secondary endpoints with statistically significant and clinically meaningful improvements in quality-of-life measures, and demonstrated well-tolerated safety profile

Osaka, Japan and Waltham, Massachusetts, February 14, 2025 – Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Toichi Takino; "Ono") announced that the U.S. Food and Drug Administration (FDA) has approved ROMVIMZA™ (vimseltinib), a kinase inhibitor, for adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity. The FDA previously granted Fast Track designation and Priority Review for ROMVIMZA, which was developed by Deciphera Pharmaceuticals, Inc. ("Deciphera"), a wholly owned subsidiary of Ono.

"The approval of ROMVIMZA provides a new, much-needed, well-tolerated, and effective treatment option for people suffering from TGCT," said Hans Gelderblom, M.D., Ph.D., Chair of the Department of Medical Oncology at Leiden University Medical Center. "TGCT adversely affects the lives of patients, causing significant pain, limited mobility, and stiffness. The MOTION Phase 3 study demonstrated ROMVIMZA's ability to shrink tumors along with being the first well-tolerated agent to demonstrate significant improvement in a number of other important quality-of-life measures without any observed liver injury as seen with other approved TGCT treatment. ROMVIMZA is a differentiated treatment that has the potential to address the significant unmet needs of the TGCT community."

"The FDA approval of ROMVIMZA for TGCT is a crucial advancement for the TGCT community and we believe ROMVIMZA has the potential to become the new standard of care for people with TGCT for which surgical resection will potentially cause worsening functional limitation or severe morbidity. This is also an important milestone for our organization, as it is the second approved therapy discovered using Deciphera's proprietary switch-control kinase inhibitor platform," said Ryota Udagawa, President and Chief Executive Officer of Deciphera Pharmaceuticals. "I'd like to extend my gratitude to the patients, families, caregivers, and healthcare providers who contributed to the success in ROMVIMZA's clinical studies. Their commitment, along with the dedication of the Deciphera and Ono teams, enabled us to advance this impactful new treatment, which we look forward to delivering to patients."

TGCT is a rare, non-malignant tumor that forms within or near joints. TGCT arises from the dysregulation of the CSF1 gene, resulting in an overproduction of CSF1. If left untreated or if the tumor repeatedly recurs, it can lead to damage and degeneration in the affected joint and

surrounding tissues, potentially causing significant disability.

The FDA approval was based on the efficacy and safety results from the pivotal Phase 3 MOTION study of ROMVIMZA 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 ROMVIMZA. In MOTION, ROMVIMZA demonstrated a statistically significant and clinically meaningful ORR at Week 25 in the intent-to-treat (ITT) population, as assessed by blinded independent radiologic review (IRR) per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1), versus placebo (40% in ROMVIMZA arm vs 0% in placebo arm, p <0.0001). 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. The safety profile of ROMVIMZA is manageable and consistent with results previously disclosed in the Phase 1/2 clinical trial.

Deciphera Pharmaceuticals plans to make ROMVIMZA commercially available in the U.S. next week. Learn more at www.ROMVIMZA.com.

In July of 2024, the Company announced the marketing authorization application (MAA) for ROMVIMZA for the treatment of patients with TGCT was accepted and is under review by the European Medicines Agency (EMA).

Deciphera is committed to supporting TGCT patients and providers in navigating coverage and access to ROMVIMZA. As part of that commitment, Deciphera AccessPoint™, a patient support program, is available to provide comprehensive access and financial assistance programs for eligible patients. For more information, visit DecipheraAccessPoint.com or call 1-833-4DACCES (1-833-432-2237), Monday-Friday, 8:00 AM to 8:00 PM Eastern Time (ET).

About MOTION Study

The MOTION study is a two-part, randomized, double-blind, placebo-controlled Phase 3 clinical study to assess the efficacy and safety of vimseltinib in patients with TGCT not amenable to surgery with no prior anti-CSF1/CSF1R therapy (prior therapy with imatinib or nilotinib allowed). The primary endpoint of the study is an objective response rate (ORR) at Week 25 in the intent-to-treat (ITT) population, as assessed by blinded independent radiologic review (IRR) per using Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1), versus placebo. The secondary endpoints include ORR per tumor volume score (TVS), active range of motion (ROM), physical function, stiffness, quality of life, and pain, all assessed at Week 25.

This study consists of two Parts. In Part 1, patients were randomized to receive either vimseltinib or placebo for 24 weeks. In Part 2, patients randomized to placebo in Part 1 have the option to receive vimseltinib, and all patients receive vimseltinib for a long-term period in an open-label setting.

ROMVIMZA (vimseltinib) capsules

INDICATIONS AND USAGE

ROMVIMZA is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity

- Cases of serious and fatal liver injury have occurred with the use of another kinase inhibitor that targets CSF1R. Serious and fatal liver injury have not been observed with ROMVIMZA.
- Elevated AST and ALT can occur with ROMVIMZA.
- Avoid ROMVIMZA in patients with pre-existing increased serum transaminases; total bilirubin or direct bilirubin (>ULN); or active liver or biliary tract disease, including ALP.
- Monitor liver function tests prior to initiation of ROMVIMZA, twice a month for the first two months and once every 3 months for the first year of therapy and as clinically indicated thereafter. Withhold and reduce the dose, or permanently discontinue ROMVIMZA based on the severity of the hepatotoxicity.

Embryo-Fetal Toxicity:

- ROMVIMZA may cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk to the fetus.
- Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with ROMVIMZA and for 1 month after the last dose.

Allergic Reactions to FD&C Yellow No.5 (Tartrazine) and No. 6 (Sunset Yellow FCF):

- ROMVIMZA 20 mg capsule contains FD&C Yellow No. 5 (tartrazine) which may cause allergic reactions (including bronchial asthma) in certain susceptible patients. FD&C Yellow No. 5 (tartrazine) sensitivity is frequently seen in patients who also have aspirin sensitivity.

- Advise patients that ROMVIMZA 14 mg and 20 mg capsules contain FD&C Yellow No.6 (Sunset Yellow FCF), which may cause allergic reactions.

Increased Creatinine without Affecting Renal Function:

- Increases in serum creatinine can occur with the use of ROMVIMZA. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon ROMVIMZA discontinuation. During ROMVIMZA treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Adverse Reactions:
The most common (≥20%) adverse reactions, including laboratory abnormalities that occurred in patients receiving ROMVIMZA were increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT.

Drug Interactions:

- P-glycoprotein (P-gp) substrates: Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use cannot be avoided, take ROMVIMZA at least 4 hours prior to P-gp substrates.
- Breast Cancer Resistance Protein (BCRP) substrates: Avoid concomitant use of ROMVIMZA with BCRP substrates.
- Organic Cation Transporter 2 (OCT2) substrates: Avoid concomitant use of ROMVIMZA with OCT2 substrates.
- Concomitant use of vimseltinib with P-gp substrates, BCRP substrates or OCT2 substrates may increase exposure of these substrates.

Lactation: Advise females not to breastfeed during treatment with ROMVIMZA.

Please see the accompanying full Prescribing Information.

About Tenosynovial Giant Cell Tumor (TGCT)

TGCT is a rare disease 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. TGCT is a rare, non-malignant tumor that develops inside or near joints. TGCT is caused by dysregulation of the CSF1 gene leading to overproduction of CSF1. TGCT is also known as giant cell tumor of the tendon sheath (GCT-TS) or

pigmented villonodular synovitis (PVNS), a diffuse-type of TGCT. Although non-malignant, these tumors 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.

About Deciphera Pharmaceuticals Inc.

(As of June 11, 2024, Deciphera became a member of Ono Pharmaceutical Co., Ltd.)
Deciphera is a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer. We are leveraging our 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 our platform in clinical studies, QINLOCK® (ripretinib) is Deciphera's switch-control inhibitor approved in many countries including the European Union and the United States for the treatment of fourth-line gastrointestinal stromal tumor (GIST). 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. For more information, visit www.deciphera.com and follow us on LinkedIn and Twitter (@Deciphera).

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.

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