Deciphera Pharmaceuticals Announces Oral Presentation of Results from MOTION Pivotal Phase 3 Study of Vimseltinib in Patients with Tenosynovial Giant Cell Tumor (TGCT) at the 2024 ASCO Annual Meeting and Online Publication in The Lancet

June 3, 2024

– MOTION Phase 3 Data Demonstrate Robust Efficacy, Clinically Meaningful Improvements in Quality-of-Life Measures, and Well-Tolerated Safety Profile, Positioning Vimseltinib as Potential New TGCT Treatment –

– Company Expects to Submit a New Drug Application (NDA) in the Second Quarter of 2024 and Marketing Authorisation Application (MAA) in the Third Quarter of 2024 –

WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 3, 2024-- Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer, today announced that results from the Company's MOTION pivotal Phase 3 study of vimseltinib in patients with TGCT are being highlighted in an oral presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago, Illinois, and have been published in *The Lancet.*

The article titled "Vimseltinib versus placebo for tenosynovial giant cell tumour (MOTION): a randomised phase 3 trial" is now available online and will be published in a future print issue of *The Lancet*.

"The results from the MOTION pivotal Phase 3 study provide compelling evidence that vimseltinib can address the unmet medical need in TGCT for an effective and well-tolerated therapy without cholestatic hepatotoxicity," said Hans Gelderblom, M.D., Ph.D., Chair of the Department of Medical Oncology at Leiden University Medical Center and senior author of the manuscript. "In addition to its robust antitumor activity and tolerability, vimseltinib also demonstrated clinically significant functional and symptomatic improvements in key quality-of-life measures, which can provide long-term, meaningful benefits to TGCT patients."

"Building upon the strong efficacy results disclosed previously at topline, we are excited to share details on the statistically significant and clinically meaningful improvements that vimseltinib offered TGCT patients across all six key secondary endpoints, along with its favorable safety profile," said Matthew L. Sherman, M.D., Executive Vice President and Chief Medical Officer of Deciphera. "We remain on track to submit an NDA for vimseltinib in the second quarter of 2024, and an MAA in the third quarter of 2024, and look forward to bringing this important new therapy to TGCT patients globally."

In addition to the results from the MOTION pivotal Phase 3 study, the Company will also be presenting a trial-in-progress poster for the ongoing Phase 1/2 study of DCC-3116 in combination with ripretinib at the 2024 ASCO Annual Meeting.

Both presentations are available on the Company's website at www.deciphera.com/presentations-publications. Presentation details are as follows:

Abstract Number: 11500
Title: Efficacy, safety, and patient-reported outcomes of vimseltinib in patients with tenosynovial giant cell tumor: Results from the phase 3 MOTION trial.
Presenter: William D. Tap, M.D., FASCO, Memorial Sloan Kettering Cancer Center
Presentation Date: Monday, June 3, 2024

Presentation Time: 3:00 – 3:12 PM CT
Key Highlights:

- Study Design: The MOTION pivotal Phase 3 study is a two-part, randomized, double-blind, placebo-controlled 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).
    - In Part 1, patients (n=123) were randomized two-to-one to receive either 30 mg twice weekly of vimseltinib (n=83) or placebo (n=40) for 24 weeks. The results for Part 1 of the study are based on a data cutoff date of August 22, 2023.
    - The open-label Part 2 portion of MOTION, in which patients from both the vimseltinib and placebo arms receive treatment with vimseltinib, remains ongoing.
- ORR: The primary endpoint of the study is ORR at Week 25 as measured by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 by blinded independent radiologic review (IRR).
    - The study met its primary endpoint in the intent-to-treat (ITT) population demonstrating statistically significant and clinically meaningful improvement versus placebo in ORR at Week 25 based on IRR per RECIST v1.1.
    - In the ITT population, the ORR at Week 25 was 40% (95% CI: 29%, 51%) for the vimseltinib arm and 0% (95% CI: 0%, 9%) for the placebo arm resulting in a response difference (vimseltinib versus placebo) of 40% (95% CI: 29%, 51%) ($p<0.0001$).
- Secondary Endpoints: In addition to meeting the primary endpoint, the study also achieved statistically significant and clinically meaningful improvements versus placebo in all six key secondary endpoints assessed at Week 25 including ORR by tumor volume score (TVS), active range of motion (ROM), physical function, stiffness, quality of life, and pain.
    - ORR by TVS: The ORR at Week 25 based on IRR per TVS was 67% (95% CI: 56%, 77%) for the vimseltinib arm and 0% (95% CI: 0%, 9%) for the placebo arm ($p<0.0001$).
    - Active ROM: Treatment with vimseltinib demonstrated an improvement in mean change from baseline in active ROM at Week 25 of 18.4% versus a 3.8% improvement for placebo ($p=0.0077$).
    - Physical Function by PROMIS-PF: Treatment with vimseltinib demonstrated an improvement in mean change from baseline in PROMIS-PF at Week 25 of 4.6 versus 1.3 for placebo ($p=0.0007$).
    - Worst Stiffness Numeric Rating Scale (NRS): Patients treated with vimseltinib reported a decrease of 2.1 versus 0.3 for placebo in worst stiffness ($p<0.0001$).
    - Quality of Life by EuroQol Visual Analogue Scale (EQ-VAS): The mean change from baseline for EQ-VAS was significantly higher with 13.5 in the vimseltinib arm versus 6.1 in the placebo arm ($p=0.016$).
    - Brief Pain Inventory (BPI) Worst Pain Response Rate: The BPI worst pain response rate was 48% for patients receiving vimseltinib versus 23% for placebo ($p=0.0056$).
- Safety and Tolerability:
    - Vimseltinib was well tolerated with most treatment-emergent adverse events (TEAEs) were grade 1 or 2.
    - There was no evidence of cholestatic hepatotoxicity, drug-induced liver injury, or hair hypopigmentation.
    - Serum enzyme elevations were consistent with the known mechanism of action of CSF1R inhibitors.
    - TEAEs leading to treatment discontinuation was 6% in the vimseltinib arm.
- If approved, vimseltinib offers an effective systemic treatment to patients with TGCT and provides proven functional health and symptomatic benefit to a population living with substantial morbidity and limited treatment options.

Abstract Number: TPS11587
Title: DCC-3116 in combination with ripretinib for patients with advanced gastrointestinal stromal tumor: A phase 1/2 study.
Presenter: Sreenivasa Chandana, M.D., Ph.D., START Midwest, The Cancer & Hematology Centers
Session Date: Saturday, June 1, 2024
Session Time: 1:30 – 4:30 PM CT
Key Highlights:

- This is a phase 1/2, multicenter study designed to evaluate the safety, tolerability, and efficacy of DCC-3116 in combination with ripretinib.
    - In Part 1, eligible patients will receive escalating oral doses of DCC-3116 combined with ripretinib 150 mg once daily (QD); the safety will be evaluated and the recommended phase 2 dose (RP2D) will be determined.
    - In Part 2, eligible patients will receive the RP2D of DCC-3116 in combination with ripretinib 150 mg QD; antitumor activity will be evaluated.
- The trial is currently enrolling in the phase 1 dose escalation portion.

About Deciphera Pharmaceuticals

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® is Deciphera's switch-control inhibitor for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the European Union, Hong Kong, Iceland, Israel, Liechtenstein, Macau, New Zealand, Norway, Singapore, Switzerland, Taiwan, The United Kingdom, and the United States. For more

information, visit https://www.deciphera.com/ and follow us on LinkedIn and X (@Deciphera).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations and timing regarding the potential for our preclinical and/or clinical stage pipeline assets to be first-in-class and/or best-in-class treatments, the timing of our NDA and MAA submissions for vimseltinib, and plans to present trial-in-progress poster for the ongoing Phase 1/2 study of DCC-3116 in combination with ripretinib at the 2024 ASCO Annual Meeting. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation: (i) risks associated with the timing of the closing of the proposed transaction, including the risks that a condition to closing would not be satisfied within the expected timeframe or at all or that the closing of the proposed transaction will not occur; (ii) uncertainties as to how many of Deciphera's stockholders will tender their shares in the offer; (iii) the possibility that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction; (iv) the possibility that competing offers will be made; (v) the outcome of any legal proceedings that may be instituted against the parties and others related to the merger agreement; (vi) unanticipated difficulties or expenditures relating to the proposed transaction, the response of business partners and competitors to the announcement of the proposed transaction, and/or potential difficulties in employee retention as a result of the announcement and pendency of the proposed transaction; (vii) Deciphera's ability to successfully demonstrate the efficacy and safety of its drug or drug candidates, and the preclinical or clinical results for its product candidates, which may not support further development of such product candidates; (viii) comments, feedback and actions of regulatory agencies; (ix) Deciphera's ability to commercialize QINLOCK® and execute on its marketing plans for any drugs or indications that may be approved in the future; (x) the inherent uncertainty in estimates of patient populations, competition from other products, Deciphera's ability to obtain and maintain reimbursement for any approved product and the extent to which patient assistance programs are utilized; and (xi) other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240603284422/en/

Investor Relations:
Maghan Meyers
Argot Partners
Deciphera@argotpartners.com
212-600-1902

Media:
David Rosen
Argot Partners
david.rosen@argotpartners.com
212-600-1902

Source: Deciphera Pharmaceuticals, Inc.