Deciphera Pharmaceuticals Announces Completion of Enrollment for Pivotal Phase 3 MOTION Study of Vimseltinib in TGCT

March 1, 2023

– Top-line Results Expected in the Fourth Quarter of 2023 –

– Phase 1/2 Data Demonstrated Vimseltinib's Best-in-Class Potential for the Treatment of TGCT –

WALTHAM, Mass.--(BUSINESS WIRE)--Mar. 1, 2023-- 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 the completion of enrollment in the pivotal Phase 3 MOTION study of vimseltinib in patients with tenosynovial giant cell tumor (TGCT) not amenable to surgery. Deciphera expects to report top-line results in the fourth quarter of 2023.

"The rapid enrollment of the pivotal Phase 3 MOTION study underscores both the substantial unmet medical need for a highly effective and well-tolerated drug for patients with TGCT and the best-in-class therapeutic potential of vimseltinib," said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. "Results from the Phase 1/2 study of vimseltinib have demonstrated not only its compelling clinical activity, but also the favorable safety and tolerability profile essential for TGCT patients. We look forward to reporting top-line results from the MOTION study later this year."

In September 2022, Deciphera presented updated results from the ongoing Phase 1/2 study of vimseltinib in TGCT at the European Society for Medical Oncology (ESMO) Congress. The results showed objective response rates of 69% in Phase 1, 53% in Phase 2 Cohort A, and 46% in Phase 2 Cohort B, with a demonstrated clinical benefit rate of 100% across all Phase 1/2 patients. Preliminary patient-reported outcome data in the Phase 2 portion demonstrated clinically meaningful improvements in pain and stiffness at week 25 compared to baseline. Treatment with vimseltinib across all Phase 1/2 patients was well-tolerated. The full Phase 1/2 data for vimseltinib in TGCT presented at ESMO can be accessed here: https://investors.deciphera.com/news-releases/news-release-details/deciphera-pharmaceuticals-inc-presents-updated-phase-12-data.

Phase 3 MOTION Study

The ongoing pivotal Phase 3 MOTION study of vimseltinib for the treatment of TGCT, which has completed enrollment, is a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with TGCT not amenable to surgery. The primary endpoint of the study is objective response rate at week 25 as measured by RECIST version 1.1 by blinded independent radiologic review. For more information about the clinical trial design, please visit https://www.clinicaltrials.gov/ct2/show/NCT05059262.

About Vimseltinib

Vimseltinib is an investigational, orally administered, potent and highly selective switch-control kinase inhibitor of CSF1R. It was discovered using Deciphera's proprietary drug discovery platform and was designed to selectively bind to the CSF1R switch pocket. Vimseltinib has demonstrated encouraging preliminary efficacy and safety data in patients with TGCT and is currently being evaluated in a Phase 1/2 clinical study. Phase 1 is the dose escalation portion of the study, Cohort A includes TGCT patients with no prior anti-CSF1/CSF1R therapy (previous therapy with imatinib or nilotinib is allowed) and Cohort B includes patients with prior anti-CSF1/CSF1R therapy. The Phase 3 MOTION study is a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with symptomatic TGCT who are not amenable to surgery, and has completed enrollment.

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, Israel, Macau, New Zealand, Switzerland, Taiwan, the United Kingdom, and the United States. For more information, visit www.deciphera.com and follow us on LinkedIn and Twitter (@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 vimseltinib to be a best-in-class treatment, if approved, and the topline readout for the pivotal Phase 3 MOTION study. 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, our ability to successfully demonstrate the efficacy and safety of our drug or drug candidates, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, comments, feedback and actions of regulatory agencies, our ability to commercialize QINLOCK and execute on our marketing plans for any drugs or indications that may be approved in the future, the inherent uncertainty in estimates of patient populations, competition from other products, our ability to obtain and maintain reimbursement for any approved product and the extent to which patient assistance programs are utilized and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Annual Report on Form 10-K for the year ended December 31, 2022, 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.

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