Deciphera Pharmaceuticals Presents Data from QINLOCK® and Rebastinib Programs at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting

June 4, 2021

– Exploratory Analysis of the INVICTUS Phase 3 Study Showed QINLOCK Dose Escalation After Disease Progression Provided Substantial Clinical Benefit in Advanced GIST –

– Rebastinib in Combination with Paclitaxel in a Phase 1b/2 Study Demonstrated Median Progression Free Survival of 6.2 Months in Heavily Pretreated Patients with Endometrial Cancer –

WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 4, 2021-- Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a commercial-stage biopharmaceutical company developing innovative medicines to improve the lives of people with cancer, today announced two e-poster presentations at the 2021 ASCO Annual Meeting. The presentations include intra-patient dose escalation (IPDE) data from the INVICTUS Phase 3 study of QINLOCK in patients with advanced gastrointestinal stromal tumor (GIST), as well as preliminary results from the Company's ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in patients with endometrial cancer.

Both e-poster presentations are now available on-demand via the ASCO Meeting Library and on the Company's website at www.deciphera.com/presentations-publications.

"We are committed to understanding the full benefit QINLOCK may provide to patients with GIST and the data presented at ASCO further demonstrate the important clinical benefits QINLOCK can provide in this population," said Matthew L. Sherman, MD, Executive Vice President and Chief Medical Officer of Deciphera. "Importantly, consistent with our Phase 1 data, these exploratory results from the Phase 3 study show that dose escalation to QINLOCK 150 mg BID after disease progression on QINLOCK 150 mg QD can offer substantial additional clinical benefit with a tolerable safety profile. As the body of data supporting QINLOCK's efficacy and safety continues to grow, we are pleased with QINLOCK's potential to offer clinically meaningful benefit for GIST patients in multiple settings of the disease."

Dr. Sherman continued, "Results presented today from the endometrial cancer cohort of the Phase 1b/2 study of rebastinib, our selective TIE2 inhibitor, in combination with paclitaxel continue to demonstrate rebastinib's anti-tumor activity as well as its evolving safety profile. We look forward to sharing updated data from the platinum-resistant ovarian cancer cohort of this study in the third quarter of 2021 and finalizing the pivotal development plan for rebastinib in combination with paclitaxel in the second half of 2021."

INVICTUS Dose Escalation Data

The INVICTUS Phase 3 clinical study is a randomized (2:1), double-blind, placebo-controlled, international, multicenter study to evaluate the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. The Company previously reported primary results from the randomized portion of the INVICTUS study, in which QINLOCK significantly improved PFS and showed a clinically meaningful overall survival (OS) benefit. An exploratory analysis was conducted to assess the safety and efficacy of QINLOCK dose escalation to 150 mg BID among patients randomized to QINLOCK 150 mg QD in the INVICTUS study.

As of an August 10, 2020 cutoff date, of the 85 patients randomized to QINLOCK 150 mg QD in the INVICTUS study, 43 dose escalated to 150 mg BID after disease progression by blinded independent central review using modified RECIST version 1.1.

- Among the 43 patients in the QINLOCK arm who dose escalated, initial median PFS, or mPFS1, was 4.6 months (95% CI 2.7–6.4) and the subsequent median PFS, or mPFS2, from the day of dose escalation to second disease progression or death was 3.7 months (95% CI 3.1–5.3). The ratio of mPFS2/mPFS1 was 80%.
- Median OS was 18.4 months in patients randomized to QINLOCK 150 mg QD with progressive disease and who dose escalated to 150 mg BID (n=43) and 14.2 months in those randomized to QINLOCK 150 mg QD with progressive disease and not dose escalating (n=22) (HR 0.74, 95% CI 0.37–1.49).
- QINLOCK 150 mg BID was well tolerated with a similar safety profile to QINLOCK 150 mg QD, with new or worsening Grade 3–4 TEAEs of anemia in 6 (14%) and abdominal pain in 3 (7%) patients.

Updated Preliminary Data from the Ongoing Phase 1b/2 Study of Rebastinib in Combination with Paclitaxel in Endometrial Cancer

The Phase 1b/2 study of rebastinib in combination with paclitaxel is a two-part, open-label, multicenter study assessing the safety, tolerability, anti-tumor activity, and pharmacokinetics of rebastinib in patients with advanced or metastatic solid tumors. As previously announced, both the endometrial and platinum-resistant ovarian cancer cohorts in Part 2 of the study advanced into the second stage of the Simon two-stage design based on demonstrating at least five responses in each cohort.

As of a March 19, 2021 cutoff date, 38 patients with endometrial cancer initiated treatment with rebastinib in combination with weekly paclitaxel 80 mg/m^2. All 38 patients received prior taxane, with 44% of patients having received four or more prior anti-cancer regimens, with a median of three prior therapies across all patients. 16 patients were treated with rebastinib at a starting dose of 100 mg BID (11 reduced to 50 mg BID) and 22 patients were treated with a starting dose of 50 mg BID. Of the 38 patients with endometrial cancer who initiated treatment with rebastinib, the median duration of treatment was 3.7 months.

Of the 33 patients in the modified intent-to-treat (mITT) population:

- There were 11 partial responses (8 confirmed) and 12 patients with stable disease for an objective response rate of 33% (unconfirmed and confirmed) and 24% (confirmed only) with a median duration of response of 7.4 months,
- The median progression-free survival (PFS) was 6.2 months.
- The majority of the common (≥15%) treatment-emergent adverse events (TEAEs) were Grade 2 or lower.
- Nine patients experienced SAEs at least possibly related to rebastinib including muscular weakness (n=3), nausea (n=2), acute myocardial infarction (n=1), atrial flutter (n=1), dehydration (n=1), noninfective encephalitis (n=1), peritonsillitis (n=1), and stress cardiomyopathy (n=1).

The Company expects to present updated data from the ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in the platinum-resistant ovarian cancer cohort in the third quarter of 2021 and finalize the pivotal development plan for rebastinib in combination with paclitaxel in the second half of 2021, subject to favorable data and discussions with regulators.

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 FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is also approved for fourth-line GIST in Canada, Australia, China, and Hong Kong. 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 regarding the potential benefit of QINLOCK, including, without limitation, on dose escalation and in multiple settings of GIST, presenting updated data from the Phase 1b/2 study of rebastinib in combination with paclitaxel for patients with platinum-resistant ovarian cancer and finalizing the pivotal study plan for the rebastinib/paclitaxel combination, subject to favorable data and discussions with regulators. 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, risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, our ability to successfully demonstrate the efficacy and safety of our drug candidates and in additional indications for our existing drug, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, 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, our ability to build and scale our operations to support growth in additional geographies, 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, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, and 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, 2021, 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. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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