Deciphera Announces Approval of QINLOCK® in the United Kingdom for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor

December 21, 2021

– QINLOCK Significantly Reduced the Risk of Disease Progression or Death by 85% and Showed Clinically Meaningful Overall Survival in the INVICTUS Phase 3 Study –

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 21, 2021-- Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a commercial-stage biopharmaceutical company developing innovative medicines to improve the lives of people with cancer, today announced that the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for QINLOCK® (ripretinib) in the UK for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib[1].

"The approval of QINLOCK in the UK is an important milestone for patients with advanced GIST who have been waiting for a new treatment option," said Steve Hoerter, President and Chief Executive Officer of Deciphera. "The results from the INVICTUS study underscore the potential for QINLOCK to transform the treatment of advanced GIST and establish a new standard of care in the UK for fourth-line GIST."

The QINLOCK approval was supported by efficacy results from the primary analysis of the pivotal Phase 3 INVICTUS study in patients with advanced GIST as well as combined safety results from INVICTUS and the Phase 1 study of QINLOCK. In INVICTUS, QINLOCK demonstrated a median progression-free survival of 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, p<0.0001)[2]. Secondary endpoints include Objective Response Rate (ORR) as determined by independent radiologic review using modified RECIST and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo (p =0.0504)[2] In addition, QINLOCK demonstrated a median overall survival of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36)[2].

The most frequently observed adverse drug reactions (≥25%) in a pooled safety population (n=392) treated with QINLOCK were fatigue, alopecia, nausea, myalgia, constipation, diarrhea, palmar-plantar erythrodysesthesia syndrome (PPES), weight decreased, and vomiting[1,2].

In the INVICTUS study, adverse reactions resulting in permanent discontinuation occurred in 8% of patients, dosage interruptions due to an adverse reaction occurred in 24% of patients and dose reductions due to an adverse reaction occurred in 7% of patients who received QINLOCK[2].

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRA mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation[3,4]. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST[3,4].

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[5], Canada[6], China[7], European Union[8], Hong Kong[7] Switzerland[10], Taiwan[9], and the United States[11]. 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 QINLOCK the transform the treatment of advanced GIST and establish a new standard of care in the UK for fourth-line GIST. 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 our ability to provide access to QINLOCK in European countries other than Germany and France through other channels, 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 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 Quarterly

Report on Form 10-Q for the quarter ended September 30, 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.

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