Deciphera Receives European Commission Approval of QINLOCK® for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor

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– 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)--Nov. 22, 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 European Commission (EC) has approved QINLOCK® (ripretinib) in the European Union (EU) 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 EC decision is applicable to all 27 European Union member states plus Iceland, Norway, and Liechtenstein. In September 2021, QINLOCK was added as a fourth-line treatment for GIST patients progressing or intolerant to imatinib, sunitinib, and regorafenib to the ESMO-EURACAN-GENTURIS clinical practice guidelines for GIST[2].

“The European Commission’s approval of QINLOCK marks the eighth regulatory approval of this transformative medicine worldwide and is an important milestone for patients with advanced GIST in the EU who are in need of a new treatment option,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “We look forward to working with health authorities to ensure that all eligible patients who can benefit from QINLOCK have access as rapidly as possible.”

“With a complex disease like advanced GIST, the availability of new efficacious and tolerable treatment options is critical for patients,” said Jean-Yves Blay, M.D., Ph.D., professor of Medicine at the Université Claude Bernard, Lyon, France. “The treatment of advanced GIST patients who initially respond to traditional tyrosine kinase inhibitors but eventually develop tumor progression due to secondary mutations has remained an area of high unmet medical need in Europe. In the INVICTUS study, QINLOCK demonstrated compelling clinical benefit in progression-free and overall survival and was well tolerated[3]. This product brings a new hope for those patients who failed currently approved kinase inhibitors.”

“For patients with advanced GIST, the EC approval of QINLOCK offers a much-needed therapeutic option for these patients for whom existing agents have only limited benefit,” said Sebastian Bauer, M.D., medical oncologist at the West German Cancer Center in Essen. “The INVICTUS study evaluated QINLOCK in patients who had exhausted all approved options. QINLOCK showed a highly meaningful benefit, not only in terms of disease control, but for the first time in a randomized GIST trial, also overall survival when compared to best supportive care. It is also noteworthy that QINLOCK maintained quality of life in this very advanced group of patients.”

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, $p<0.0001$)[3]. 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 ($p=0.0504$)[3]. 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)[3].

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[1,3].

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[3].

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[4,5]. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST[4,5].

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[6], Canada[7], China[8], European Union[1], Hong Kong[9], 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 working with health authorities to ensure that all eligible patients who can benefit from QINLOCK have access as rapidly as possible.. 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 including in additional indications for our existing drug such as second-line GIST patients in our INTRIGUE Phase 3 study, 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, the results of a review of our portfolio to determine how best to invest our significant resources to maximize shareholder value, 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 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. 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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