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

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– Seventh Approval Worldwide for QINLOCK and First European Approval –

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 12, 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 Swiss Agency for Therapeutic Products (Swissmedic) has granted approval for QINLOCK (ripretinib) 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].

"We are committed to delivering this much-needed medicine to patients globally, and are thrilled that we have received approval in Switzerland, which is our seventh approval worldwide and the first in Europe," said Steve Hoerter, President and Chief Executive Officer of Deciphera. "Following a positive opinion earlier this month from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), we look forward to a potential approval from the European Commission (EC) for QINLOCK in the fourth quarter of this year, and to ensuring that GIST patients across the EU have access to this treatment option designed specifically for their disease."

The application for QINLOCK approval was supported by efficacy results from the primary analysis of the pivotal Phase 3 INVICTUS study of QINLOCK 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). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) 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 (≥20%) in patients treated with QINLOCK were fatigue, alopecia, nausea, myalgia, constipation, diarrhea, palmar-plantar erythrodysesthesia syndrome (PPES), weight decreased, vomiting, lipase increased, muscle spasms, arthralgia, headache and dyspnoea[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 [1,2].

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. 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], Hong Kong[8], Switzerland[1], Taiwan[8], and the United States[9]. 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 potential European Commission decision on marketing approval for QINLOCK in fourth-line GIST and ensuring QINLOCK access for GIST patients in the European Union. 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 June 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.

References

1. Swiss medicinal product information.
2. Blay JY, Serrano C, Heinrich MC et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): A double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol* 2020; 21:923–934.
3. Smith B et al. Ripretinib (DCC-2618) is a switch control kinase inhibitor of a broad spectrum of oncogenic and drug-resistant KIT and PDGFRA variants. *Cancer Cell* 2019; 35:738–751.
4. Bauer S, Heinrich M, et al. Clinical activity of ripretinib in patients with advanced gastrointestinal stromal tumor harboring heterogenous KIT/PDGFRA mutations in the phase 3 INVICTUS study. *Clinical Cancer Research* [online] September 9, 2021. Available from: https://clincancerres.aacrjournals.org/content/early/2021/09/08/1078-0432.CCR-21-1864 [Last accessed: September 2021].
5. Deciphera Press Release: Deciphera Announces Australian Therapeutic Goods Administration's Approval of QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] July 14, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/deciphera-announces-australian-therapeutic-goods-administrations [Last accessed: September 2021].
6. Deciphera Press Release: Deciphera Announces Health Canada's Authorization of QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] June 22, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/deciphera-announces-health-canadas-authorization-qinlocktm [Last accessed: September 2021].
7. Zai Lab Press Release: China NMPA Approves QINLOCK® (Ripretinib) for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST) [online] March 31, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/china-nmpa-approves-qinlockr-ripretinib-treatment-advanced [Last accessed: September 2021].
8. Zai Lab Press Release: QINLOCK® (Ripretinib) Approved in Taiwan for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST) [online] September 1, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/qinlockr-ripretinib-approved-taiwan-treatment-advanced [Last accessed: September 2021].
9. Deciphera Press Release: FDA Grants Full Approval of Deciphera Pharmaceuticals' QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] May 15, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/fda-grants-full-approval-deciphera-pharmaceuticals-qinlocktm [Last accessed: September 2021].

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