Deciphera Pharmaceuticals Announces Presentations of Positive Patient Reported Outcomes Results from INVICTUS Phase 3 Study of QINLOCKTM (ripretinib) in Patients with Fourth-Line Advanced GIST at the ASCO 2020 Virtual Scientific Program

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-Patients Receiving QINLOCK for Fourth-line GIST Reported Improved Quality of Life and Better Physical and Role Functioning Compared with a Decline in Placebo-

WALTHAM, Mass.--(BUSINESS WIRE)--May 29, 2020-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced the presentation of quality of life and certain safety results from the INVICTUS pivotal Phase 3 study evaluating QINLOCK™ (ripretinib) in adult patients with fourth-line advanced gastrointestinal stromal tumor (GIST). These results were presented as part of the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program.

“The recent FDA approval of QINLOCK marked an important milestone for the entire GIST patient community who had been waiting for a new treatment option designed specifically for their disease,” said Matthew Sherman, M.D., Executive Vice President and Chief Medical Officer of Deciphera. “In addition to the impressive efficacy results shown in the INVICTUS Phase 3 study, QINLOCK was shown to have a favorable safety profile. Today’s ASCO presentations demonstrate that patients receiving QINLOCK rated their overall health, quality of life, and physical and role function as better than that of patients receiving placebo. These insights into the GIST patient experience are invaluable to us as we establish a new standard of care in this area of unmet medical need.”

Quality of Life and Self-Reported Function

In a poster presentation titled, “Quality of life (QoL) and self-reported function with ripretinib in ≥4th-line therapy for patients with gastrointestinal stromal tumors (GIST): Analyses from INVICTUS” (abstract 11535; poster 423), five key measures of quality of life and function were maintained in patients with fourth-line GIST receiving QINLOCK compared with declining measures in patients receiving placebo. Patients in the QINLOCK arm had consistently stable patient reported outcomes (PROs), and the measures suggest these patients were able to maintain quality of life while PROs declined sharply in the placebo arm. Additional highlights from the presentation include:

- QINLOCK was associated with an increase in the patients’ self-reported health status on the EuroQol-5D visual analogue scale (EQ-5D-5L VAS) while placebo was associated with a decline (p=0.004).
- Patients receiving QINLOCK reported better physical and role functioning on the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) compared with a decline observed in patients receiving placebo (p=0.004; p=0.001).
- Patients receiving QINLOCK had higher perceptions of their overall health and quality of life compared with patients receiving placebo (both p=0.001).
- Differences between treatment arms were clinically significant (using threshold for meaningful change).
- Patients receiving QINLOCK reported stable scores on all PRO measures out to cycle 10.

Safety and Impact on Patient Reported Outcomes

In a poster presentation titled, “Safety profile of ripretinib, including impact of alopecia and palmar-plantar erythrodysesthesia syndrome (PPES) on patient reported outcomes (PROs), in ≥4th-line advanced gastrointestinal stromal tumors (GIST): Analyses from INVICTUS” (abstract 11539; poster 427), when stratified by alopecia and PPES, patient-reported assessments of function, overall health, and overall quality of life were shown to be stable. This exploratory analysis demonstrates that alopecia and PPES were not associated with a negative effect on function, overall health, and quality of life. Additional highlights from the presentation include:

- For both alopecia and PPES, the majority of the events were of lower severity grades and did not generally worsen over time.
    - In the QINLOCK arm, grade 1-2 alopecia occurred in 44 patients (52%) and grade 1-2 PPES occurred in 18 patients (21%). No patients experienced grade 3 or higher PPES.
    - There were no serious adverse events of alopecia or PPES reported.
- In the QINLOCK arm, 8.2%, 24%, and 7.1% of patients experienced a treatment-emergent adverse event leading to treatment discontinuation, dose interruption, or dose reduction compared with 12%, 21%, and 2.3% in the placebo arm.

A copy of each presentation is available at www.deciphera.com/science/presentation-publications/.

About QINLOCK (ripretinib)

Indications and Usage

QINLOCK (ripretinib) is a kinase inhibitor indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. For more information visit QINLOCK.com.

Important Safety Information

There are no contraindications for QINLOCK.

Palmar-plantar erythrodysesthesia syndrome (PPES): In INVICTUS, Grade 1-2 PPES occurred in 21% of the 85 patients who received QINLOCK. PPES led to dose discontinuation in 1.2% of patients, dose interruption in 2.4% of patients, and dose reduction in 1.2% of patients. Based on severity, withhold QINLOCK and then resume at same or reduced dose.

New Primary Cutaneous Malignancies: In INVICTUS, cutaneous squamous cell carcinoma (cuSCC) occurred in 4.7% of the 85 patients who received QINLOCK with a median time to event of 4.6 months (range 3.8 to 6 months). In the pooled safety population, cuSCC and keratoacanthoma occurred in 7% and 1.9% of 351 patients, respectively. In INVICTUS, melanoma occurred in 2.4% of the 85 patients who received QINLOCK. In the pooled safety population, melanoma occurred in 0.9% of 351 patients. Perform dermatologic evaluations when initiating QINLOCK and routinely during treatment. Manage suspicious skin lesions with excision and dermatopathologic evaluation. Continue QINLOCK at the same dose.

Hypertension: In INVICTUS, Grade 1-3 hypertension occurred in 14% of the 85 patients who received QINLOCK, including Grade 3 hypertension in 7% of patients. Do not initiate QINLOCK in patients with uncontrolled hypertension. Monitor blood pressure as clinically indicated. Based on severity, withhold QINLOCK and then resume at same or reduced dose or permanently discontinue.

Cardiac Dysfunction: In INVICTUS, cardiac failure occurred in 1.2% of the 85 patients who received QINLOCK. In the pooled safety population, cardiac dysfunction (including cardiac failure, acute left ventricular failure, diastolic dysfunction, and ventricular hypertrophy) occurred in 1.7% of 351 patients, including Grade 3 adverse reactions in 1.1% of patients.

In INVICTUS, Grade 3 decreased ejection fraction occurred in 2.6% of the 77 patients who received QINLOCK and who had a baseline and at least one post-baseline echocardiogram. Grade 3 decreased ejection fraction occurred in 3.4% of the 263 patients in the pooled safety population who received QINLOCK and who had a baseline and at least one post-baseline echocardiogram.

In INVICTUS, cardiac dysfunction led to dose discontinuation in 1.2% of the 85 patients who received QINLOCK. The safety of QINLOCK has not been assessed in patients with a baseline ejection fraction below 50%. Assess ejection fraction by echocardiogram or MUGA scan prior to initiating QINLOCK and during treatment, as clinically indicated. Permanently discontinue QINLOCK for Grade 3 or 4 left ventricular systolic dysfunction.

Risk of Impaired Wound Healing: QINLOCK has the potential to adversely affect wound healing. Withhold QINLOCK for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of QINLOCK after resolution of wound healing complications has not been established.

Embryo-Fetal Toxicity: QINLOCK can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least 1 week after the final dose. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment and for at least 1 week after the final dose. QINLOCK may impair fertility in males of reproductive potential.

Adverse Reactions: The most common adverse reactions (≥20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, PPES, and vomiting. The most common Grade 3 or 4 laboratory abnormalities (≥4%) were increased lipase and decreased phosphate.

The safety and effectiveness of QINLOCK in pediatric patients have not been established.

Administer strong CYP3A inhibitors with caution. Monitor patients who are administered strong CYP3A inhibitors more frequently for adverse reactions. Avoid concomitant use with strong CYP3A inducers.

Please click here to see the full Prescribing Information for QINLOCK.

About the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomized, double-blind, placebo-controlled, international, multicenter clinical study evaluating the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK or placebo once daily. The primary efficacy endpoint is progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The median PFS in the study was 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 ($p =0.0504$). QINLOCK also demonstrated a median OS 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).

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. For more information, please visit the company's website at www.deciphera.com.

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 QINLOCK as a new standard of care, and patient reported outcomes in the INVICTUS study, and the potential benefit of QINLOCK to GIST patients. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "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, including, without limitation, commercial and clinical drug supply chain continuity and the commercial launch of QINLOCK, our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, the preclinical and 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, 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 and incidence and prevalence estimates, 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 make our investigational drugs and QINLOCK available to patients, and to derive revenue from product sales, 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, 2020, 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 its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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