



Deciphera Announces Presentation of Analysis of Crossover Population from the INVICTUS Phase 3 Study of QINLOCK™ (ripretinib) in Patients with Fourth-Line Advanced GIST

July 2, 2020

- Clinically Meaningful Benefit Observed in Patients Receiving QINLOCK Following Progression on Placebo -

- Data Featured at the ESMO World Congress on Gastrointestinal Cancer 2020 Virtual Meeting -

WALTHAM, Mass.--(BUSINESS WIRE)--Jul. 2, 2020-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced the presentation of new data from an exploratory analysis of progression-free survival (PFS) and overall survival (OS) for patients who crossed over to QINLOCK therapy following disease progression in the INVICTUS pivotal Phase 3 study. The INVICTUS study evaluated QINLOCK in adult patients with fourth-line gastrointestinal stromal tumor (GIST). The results were featured in an oral presentation at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal (GI) Cancer 2020 Virtual Meeting in a presentation titled, "Efficacy and safety of ripretinib as ≥4th-line therapy for patients with gastrointestinal stromal tumor (GIST) following crossover from placebo: Analyses from INVICTUS" (Abstract ID O-13). The data presented showed that patients who crossed over to the open-label extension to receive treatment with QINLOCK demonstrated a median PFS of 4.6 months and an OS benefit of 11.6 months.

"The data presented today further reinforce the potential of QINLOCK to provide meaningful clinical benefit to patients with advanced GIST," said César Serrano, MD, PhD, Head of the Sarcoma Translational Research Group at the Vall d'Hebron Institute of Oncology. "QINLOCK represents a new standard of care for patients with GIST who have received 3 prior treatments."

"On the heels of QINLOCK's recent approval in the U.S. and Canada in patients with fourth-line GIST, we are excited to add to the body of evidence supporting its potential as a new standard of care in this setting," said Matthew L. Sherman, MD, Executive Vice President and Chief Medical Officer of Deciphera. "GIST is a highly complex disease for which we specifically designed QINLOCK and we are committed to ensuring it is able to reach as many appropriate patients as possible."

INVICTUS Crossover Data Analysis

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 129 patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. The Company previously reported results from the randomized portion of the INVICTUS study, in which QINLOCK significantly improved PFS and showed a clinically meaningful OS benefit.

Following disease progression, patients randomized to the placebo arm were eligible to cross over to an open-label extension portion of the study to receive treatment with 150 mg of QINLOCK once daily. Of the 44 patients randomized to receive placebo during the double-blind treatment period, a total of 29 patients crossed over and were treated with QINLOCK. Based on an exploratory analysis of the data, patients treated in the open-label extension demonstrated a median PFS of 4.6 months, from initiation of treatment with QINLOCK to progression or death. Of note, two patients achieved partial responses, with responses observed as early as one month following initiation of QINLOCK therapy. In addition, patients who crossed over demonstrated an OS benefit of 11.6 months, as measured from initial study randomization and including all time periods, including dose escalations. Treatment with QINLOCK was generally well tolerated and the adverse events observed were consistent with those in the double-blind portion of INVICTUS. These exploratory results reinforce the potential for QINLOCK to provide meaningful benefit to GIST patients.

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

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 QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFR α mutated kinases by using a unique 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 involved in systemic mastocytosis, or SM. QINLOCK also inhibits primary PDGFR α mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

QINLOCK is approved by the U.S. FDA for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib, and by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib.

Deciphera Pharmaceuticals is developing QINLOCK for the treatment of KIT and/or PDGFR α -driven cancers, including GIST, SM, and other cancers. Deciphera Pharmaceuticals has an exclusive license agreement with Zai Lab (Shanghai) Co., Ltd. for the development and commercialization of QINLOCK in Greater China (Mainland China, Hong Kong, Macau, and Taiwan). Deciphera Pharmaceuticals retains development and commercial rights for QINLOCK in the rest of the world.

U.S. Indication and Important Safety Information About QINLOCK

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 ($\geq 20\%$) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, PPES, and vomiting. The most common Grade 3 or 4 laboratory abnormalities ($\geq 4\%$) 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 U.S. Prescribing Information for QINLOCK.

About GIST

Gastrointestinal stromal tumor (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST is the most common sarcoma of the gastrointestinal tract, with approximately 4,000 to 6,000 new GIST cases each year in the United States and a similar incidence rate in European and other countries. Most cases of GIST are driven by a spectrum of mutations. The most common primary mutations are in KIT kinase, representing approximately 80% of cases, or in PDGFR α kinase, representing approximately 6% of cases. Current therapies are unable to inhibit the full spectrum of primary and secondary mutations, which drives resistance and disease progression. Estimates for 5-year survival range from 48% to 90%, depending on the stage of the disease at diagnosis.

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, QINLOCKTM is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line GIST. 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 the potential benefit of QINLOCK to GIST patients, the potential for QINLOCK to become a standard of care in fourth-line GIST, and our commitment to ensuring appropriate patients receive QINLOCK. 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, 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, 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, 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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