Deciphera Announces Publication of QINLOCK™ (ripretinib) Phase 1 Study Results in Patients with Gastrointestinal Stromal Tumor in Journal of Clinical Oncology

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- Results Consistent with Those Presented at the 2019 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics and Support Ongoing INTRIGUE Phase 3 Clinical Study in Patients with Second-line GIST -

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 17, 2020-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), today announced that the *Journal of Clinical Oncology* has published results from its Phase 1 study of QINLOCK, the Company's switch-control tyrosine kinase inhibitor, in patients with second-line through fourth-line plus gastrointestinal stromal tumor (GIST). The article, entitled "Switch control inhibition of KIT and PDGFRA in patients with advanced gastrointestinal stromal tumor (GIST): a phase 1 study of ripretinib," is now available online and will be published in a future print issue of *Journal of Clinical Oncology*.

"QINLOCK continues to demonstrate encouraging clinical benefit in earlier lines of treatment following imatinib therapy," said Matthew L. Sherman, MD, Executive Vice President and Chief Medical Officer of Deciphera. "We believe that these positive results strongly support the ongoing INTRIGUE pivotal Phase 3 study, which is our registration-enabling study in patients with second-line GIST. We are committed to unlocking the full potential of QINLOCK to benefit patients and look forward to completion of enrollment in the INTRIGUE study, expected later this year."

The publication highlighted results from the Company's ongoing Phase 1 study of ripretinib in patients with second-line through fourth-line plus GIST. These published results are from 142 GIST patients receiving 150 mg of ripretinib once daily (QD) as the starting dose, which is the dose utilized in both of the Company's registration-enabling trials, INVICTUS and the ongoing INTRIGUE study, as of an August 31, 2019 data cutoff date. Results were consistent with those previously presented at the 2019 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

The table below includes local, investigator-assessed objective response rate (ORR) by best response as determined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, median duration of response, and median progression free survival (mPFS).

Line of Therapy	**2nd Line (n=31)**	**3rd Line (n=28)**	**≥4th Line (n=83)**
ORR (confirmed responses only)	19.4%	14.3%	7.2%
Median Duration of Response	18.4 months	NE(1)	17.5 months
mPFS	10.7 months	8.3 months	5.5 months

(1) NE = not estimable.

Ripretinib was generally well tolerated with adverse events consistent with previously presented Phase 1 data in patients with GIST. Grade 3 or 4 treatment-emergent adverse events (TEAEs) in >5% of patients were increase in lipase level (n=25; 18%), anemia (n=10; 7%), hypertension (n=8; 6%) and abdominal pain (n=13; 9%).

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRα 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 PDGFRα 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. It is also approved by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib and by the Australian Therapeutic Goods Administration for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

Deciphera Pharmaceuticals is developing QINLOCK for the treatment of KIT and/or PDGFRα-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 (≥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 U.S. 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 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 PDGFRα 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, QINLOCK™ is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is also approved for fourth-line GIST in Canada and Australia. 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 regarding Phase 1 data supporting and the timing of completion of enrollment in, our Phase 3 INTRIGUE 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, 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, 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 June 30, 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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Investor Relations:
Jen Robinson
Deciphera Pharmaceuticals, Inc
jrobinson@deciphera.com
781-906-1112

Media:
David Rosen
Argot Partners
David.Rosen@argotpartners.com
212-600-1902

Source: Deciphera Pharmaceuticals, Inc.