Deciphera Presents Data from QINLOCK® (Ripretinib) Program at the Connective Tissue Oncology Society (CTOS) 2020 Virtual Annual Meeting

November 11, 2020

– Deciphera Presents the First and Largest Baseline Genomic Analysis by Tumor and Liquid Biopsy in Fourth-line Patients with GIST –

– Results from an Exploratory Analysis of the Phase 3 INVICTUS Study in Fourth-line GIST Demonstrate the Broad Clinical Activity of QINLOCK Across Mutation Sub-groups –

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 11, 2020-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), today announced data presentations from clinical studies of QINLOCK, the Company's switch-control tyrosine kinase inhibitor approved in the U.S. for fourth-line gastrointestinal stromal tumor (GIST), to be presented at the CTOS 2020 Virtual Annual Meeting, being held November 18-21, 2020. Posters and presentations are available to meeting participants as of November 11, 2020. New data presented at the meeting included an oral presentation titled "Characterization of the extensive heterogeneity of KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: Genomic analysis of the phase 3 INVICTUS study" and a poster presentation titled "Ripretinib demonstrated activity across all KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: Analysis from the phase 3 INVICTUS study".

"We're pleased to share our findings from the largest dataset of tumor and plasma sequencing in the fourth-line and fourth-line plus setting in GIST, which highlight the broad spectrum of mutations that drive this disease," said Matthew L. Sherman, MD, Executive Vice President and Chief Medical Officer of Deciphera. "Data being presented at CTOS also provide further evidence that QINLOCK inhibits a broad spectrum of relevant mutations in patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib."

Characterization of the extensive heterogeneity of KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: Genomic analysis of the phase 3 INVICTUS study

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 patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. Baseline tumor and plasma samples were collected to investigate the genomic heterogeneity of resistance in the INVICTUS study.

- This is the first and largest baseline genomic analysis by tumor and liquid biopsy in fourth-line patients with GIST that failed prior treatment with at least imatinib, sunitinib, and regorafenib.
- In patients with fourth-line and fourth-line plus GIST, data demonstrated a complex and heterogenous mutational landscape.
- The most frequent primary mutations found were in KIT exon 11 and KIT exon 9.
- By tumor biopsy, secondary mutations were more diverse in KIT exons 17/18 (15 unique mutations) compared to KIT exons 13/14 (5 unique mutations).
- More mutations were detected by liquid biopsy compared with tumor biopsy, increasing the detection rate of secondary mutations from 15 to 26 unique mutations (73% increase) in KIT exons 17/18 and from 5 to 12 unique mutations (140% increase) in KIT exons 13/14.
- The heterogeneity of the KIT mutations highlight the need for therapies that are effective against a broad spectrum of mutations.

Ripretinib demonstrated activity across all KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: Analysis from the phase 3 INVICTUS study

Results from an exploratory analysis from the Phase 3 INVICTUS study showed that QINLOCK demonstrated clinically meaningful activity in patients with a broad spectrum of KIT and PDGFRA mutations. The data cutoff for this analysis was March 9, 2020.

In INVICTUS, QINLOCK demonstrated clinically meaningful activity in patients with fourth-line and fourth-line plus GIST (n=129) with multiple, heterogeneous genetic subsets of KIT/PDGFRA mutations. QINLOCK showed a median progression free survival (PFS) benefit of 6.3 months versus placebo of 1 month in all patients (hazard ratio = 0.16). Hazard ratios (HRs) of PFS by KIT mutation subgroup by combined tumor and liquid biopsy are below:

Mutation subgroup	QINLOCK 150 mg QD (N)	Placebo (N)	Hazard ratio (95% CI)
Any KIT exon 11[a]	52	34	0.13 (0.07, 0.24)
Any KIT exon 9[a]	16	7	0.22 (0.08, 0.63)
Any KIT exon 13	27	16	0.17 (0.08, 0.38)
Any KIT exon 17	44	27	0.14 (0.07, 0.28)

[a]One patient had both KIT exon 11 and KIT exon 9 mutations detected in liquid biopsy. N, number of patients.

The HRs of PFS within different mutation subgroups all favored treatment with QINLOCK, which is in line with the primary outcome of the INVICTUS study. These results support the proposed broad mechanism of action of QINLOCK with its specific receptor binding properties.

The Company also announced two encore presentations highlighting data from the QINLOCK program, one oral presentation and one poster presentation, which will be featured at the CTOS 2020 Virtual Annual Meeting. The oral presentation will focus on results from the ongoing Phase 1 study of QINLOCK in patients with second-line through fourth-line plus GIST. The results demonstrate that patients receiving QINLOCK who, upon disease progression, dose escalated to QINLOCK 150 mg twice daily experienced additional, clinically meaningful, PFS benefit across all lines of therapy. The poster presentation will feature the nine-month follow-up data from the Phase 3 INVICTUS study in patients with fourth-line and fourth-line plus GIST.

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.

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

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 (greater-than or equal to 20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, PPES, and vomiting. The most common Grade 3 or 4 laboratory abnormalities (greater-than or equal to 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 was 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 PDGFRA 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 the broad activity of QINLOCK in mutation subgroups of fourth-line and fourth-line plus 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 September 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 our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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