Deciphera Pharmaceuticals Announces Results from ctDNA Analysis from INTRIGUE Phase 3 Clinical Study Demonstrating Substantial Clinical Benefit of QINLOCK® in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18 Only

January 3, 2023

– Median Progression Free Survival for QINLOCK of 14.2 Months Versus Sunitinib of 1.5 Months; Hazard Ratio of 0.22, nominal p value <0.0001 –

– Objective Response Rate of 44.4% for QINLOCK Versus 0% for Sunitinib; nominal p value 0.0001 –

– Median Overall Survival for QINLOCK was Not Estimable Versus 17.5 Months for Sunitinib; Hazard Ratio of 0.34, nominal p value 0.0061 –

– Company Plans to Initiate the INSIGHT Pivotal Phase 3 Clinical Study in the Second Half of 2023 –

– Conference Call to be Held Today at 5:00 PM ET –

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 3, 2023-- Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer, today announced findings of a planned exploratory analysis of data from the INTRIGUE Phase 3 clinical study of QINLOCK using circulating tumor DNA (ctDNA) from a subgroup of patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib who harbor mutations in KIT exon 11 and 17/18 only.

“We are extremely pleased by the exploratory analysis showing that QINLOCK, already the standard of care for fourth-line GIST patients, provided substantial clinical benefit to this subgroup of second-line patients compared to sunitinib. We look forward to presenting additional data from the overall ctDNA analysis at a medical meeting later this month,” said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. “Given the strength of these results, and after consultation with the FDA, we plan to initiate our INSIGHT pivotal Phase 3 study in the second half of 2023. If positive, we believe this trial will transform the standard of care for this subgroup of second-line GIST patients based on their mutational profile.”

“The newly reported clinical results from INTRIGUE demonstrate the remarkable differential benefit of ripretinib in patients with unique molecular subtypes of GIST in the second-line setting, specifically patients with ctDNA demonstrating KIT exon 11 and 17/18 mutations,” said Suzanne George, M.D., Associate Division Chief, Sarcoma Center, Dana-Farber Cancer Institute, and the co-lead investigator on the INSIGHT study. “This data is potentially practice changing in second-line GIST and as ctDNA assays are increasingly optimized and utilized in the clinical arena, we must continue clinical drug development which aims to understand the impact of drugs in specific molecular subtypes of GIST with the goal to improve clinical outcomes by giving the right drug to the right patient at the right time.”

Planned Exploratory Efficacy Analysis using ctDNA in INTRIGUE Study

An exploratory objective in the INTRIGUE Phase 3 study in GIST patients previously treated with imatinib was to evaluate anti-tumor efficacy of QINLOCK according to baseline KIT primary and secondary mutation status. Baseline peripheral whole blood was analyzed by Guardant360, a 74-gene ctDNA next-generation sequencing liquid biopsy assay.

Of the 453 patients in the overall intent-to-treat population (ITT), baseline ctDNA was analyzed in 362 patients for whom evaluable samples were available. ctDNA was detected in 280 samples and KIT mutations were detected in 213 patients.

Primary mutations in KIT were detected in exon 11 in 157 patients and in exon 9 in 36 patients. Common resistance mutations in KIT were detected in exons 17/18 in 89 patients and in exons 13/14 in 81 patients.

In patients with a KIT exon 11 primary mutation, 52 patients had mutations in exon 17/18 only, 41 had mutations in exon 13/14 only, and 22 patients had mutations in both exon 13/14 and exon 17/18.

Patients with mutations in KIT exon 11 and exon 17/18 only had substantially improved progression-free survival (PFS), objective response rate (ORR), and overall survival (OS) with QINLOCK versus sunitinib. Efficacy results in patients with detectable ctDNA in KIT exon 11 and in the ITT populations were consistent with the primary analysis of the INTRIGUE study based on tumor data used for randomization. The subgroup safety profiles were consistent with the primary analysis.

Summary of INTRIGUE Efficacy Results of ctDNA Analysis for Patients with Mutations in KIT Exon 11 and 17/18 Only

	Ripretinib (n=27)	**Sunitinib (n=25)**	**Hazard Ratio/Response Difference (95% CI)**
Median Progression-Free Survival [(1)]	14.2 months	1.5 months	0.22 (0.11, 0.44), nominal p value <0.0001
Objective Response Rate [(1)]	44.4%	0%	44.4% (23.0%, 62.7%) nominal p value = 0.0001
Overall Survival [(2)]	Not Estimable	17.5 months	0.34 (0.15, 0.76), nominal p value = 0.0061

Notes: (1) Data cut as of September 1, 2021; (2) Data cut as of September 1, 2022.

Based on the results of the ctDNA analysis and discussions with regulators, the Company plans to initiate the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only. In the planned study, approximately 54 patients will be randomized 2:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. The primary endpoint will be PFS as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria. The Company expects to initiate the INSIGHT study in the second half of 2023.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, January 3, 2023, at 5:00 PM ET. The conference call may be accessed via this link: https://register.vevent.com/register/BI4841f7cb08a04e5ba80127e42e643432. A live webcast of the conference call will be available in the “Events and Presentations” page in the “Investors & News” section of the Company’s website at https://investors.deciphera.com/events-presentations. A replay will be available on the Company’s website approximately two hours after the conference call and will be available for 30 days following the call.

About the INSIGHT Study

The planned INSIGHT Phase 3 clinical study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib with mutations in KIT exon 11 and 17/18 only (excluding patients with mutations in KIT exons 9, 13, or 14). In the study, 54 patients will be randomized 2:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. The primary endpoint is PFS as determined by independent radiologic review using modified RECIST 1.1 criteria. Secondary endpoints include ORR as determined by independent radiologic review using modified RECIST 1.1 criteria and OS.

About the INTRIGUE Study

The INTRIGUE Phase 3 clinical study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib. In the study, 453 patients were randomized 1:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. As previously reported, the study did not achieve the primary efficacy endpoint of PFS as determined by independent radiologic review using modified RECIST 1.1 criteria. The statistical analysis plan included a hierarchical testing sequence that included testing patients with a KIT exon 11 primary mutation and then in the all patient intent-to-treat (AP) population. In patients with a KIT exon 11 primary mutation (n=327), QINLOCK demonstrated an mPFS of 8.3 months compared to 7.0 months for the sunitinib arm (hazard ratio (HR) 0.88, p=0.360). Although not formally tested due to the rules of the hierarchical testing sequence, in the AP population QINLOCK demonstrated a mPFS of 8.0 months compared to 8.3 months for the sunitinib arm (HR 1.05, nominal p=0.715). QINLOCK was generally well tolerated. Fewer patients in the QINLOCK arm experienced Grade 3-4 treatment-emergent adverse events compared to sunitinib (41.3% vs 65.6%).

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, Canada, China, the European Union, Hong Kong, Switzerland, Taiwan, the United Kingdom, and the United States. 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 our planned Phase 3 INISGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only, plans to initiate the INSIGHT study in the second half of 2023, our ability to improve clinical outcomes in second-line GIST patients with mutations in KIT exon 11 and 17/18 only, and the potential for QINLOCK to be an transformational therapy for this mutational subgroup. 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 or drug candidates and in additional indications for our existing drug, the preclinical or clinical results for our drug candidates, which may not support further development of such drug candidates, 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, 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 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, 2022, 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.

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