Deciphera Pharmaceuticals Presents Results from ctDNA Analysis of INTRIGUE Phase 3 Clinical Study at the American Society of Clinical Oncology Plenary Series Session

January 24, 2023

– Second-Line GIST Patients with Mutations in KIT Exon 11 + 17/18 Only Demonstrated Substantial Clinical Benefit from QINLOCK® but Not Sunitinib –

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

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 24, 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 the presentation of additional data from the planned exploratory analysis from the INTRIGUE Phase 3 clinical study of QINLOCK® using circulating tumor DNA (ctDNA) from patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib.

The presentation titled “Mutational heterogeneity of imatinib resistance and efficacy of ripretinib vs sunitinib in patients with gastrointestinal stromal tumor: ctDNA analysis from INTRIGUE” was presented by Sebastian Bauer, M.D., University Hospital Essen, University Duisburg-Essen and German Cancer Consortium at the American Society of Clinical Oncology (ASCO) Plenary Series Session and is available on the Company’s website at www.deciphera.com/presentations-publications.

“We are pleased with the exploratory analysis, which showed that QINLOCK provided clinically meaningful benefit for second-line GIST patients based on the mutational drivers of their disease. QINLOCK’s impressive median progression free survival of 14.2 months compared to 1.5 months for sunitinib underscores the potential of QINLOCK to become the standard-of-care for second-line GIST patients with mutations in KIT exon 11 and 17/18 only,” said Dr. Bauer. “I look forward to the upcoming INSIGHT pivotal Phase 3 study, which aims to provide more evidence of the potential benefit QINLOCK can offer to these post-imatinib patients.”

Results of ctDNA Analysis

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 mutational status. Baseline peripheral whole blood was analyzed by Guardant360, a 74-gene ctDNA next-generation sequencing liquid biopsy assay. Key highlights from the analysis presented today include the following:

Mutational Subgroups

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

Efficacy Results of ctDNA Analysis

- Patients with mutations in KIT exon 11 and exon 17/18 only derived substantially improved clinical benefit with QINLOCK versus sunitinib.
  - QINLOCK demonstrated a median PFS (mPFS) of 14.2 months compared to 1.5 months for the sunitinib arm (Hazard Ratio [HR] 0.22, nominal p value <0.0001).
  - QINLOCK demonstrated a confirmed objective response rate (ORR) of 44.4% (n=12 of 27) compared to 0% for sunitinib (nominal p value 0.0001).
  - OS for the QINLOCK arm has not reached a median, while patients randomized to the sunitinib arm had a median OS (mOS) of 17.5 months (HR 0.34, nominal p value 0.0061).
- Patients with mutations in KIT exon 11 and 13/14 only derived substantially improved clinical benefit with sunitinib versus QINLOCK.
  - QINLOCK demonstrated a mPFS of 4 months compared to 15 months for the sunitinib arm (HR 3.94, nominal p value 0.0005).
  - QINLOCK demonstrated a confirmed ORR of 9.5% (n=2 of 21) compared to 15% (n=3 of 20) for sunitinib (nominal p value 0.5922).
  - QINLOCK demonstrated a mOS of 24.5 months, while patients randomized to the sunitinib arm has not reached a median (HR 1.75, nominal p value 0.2085).

Safety and Tolerability

- QINLOCK was generally well-tolerated and the safety profiles were consistent with the primary analysis of the INTRIGUE study.
- For patients with mutations in KIT exon 11 and exon 17/18 only, fewer patients in the QINLOCK arm experienced Grade 3-4 treatment-related adverse events compared to sunitinib (33% vs 50%).

Based on the results of the ctDNA analysis and discussions with the U.S. Food and Drug Administration (FDA), 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.

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 (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, Israel, New Zealand, 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, the potential for the planned INSIGHT study to provide evidence of the benefit QINLOCK can offer to these post-imatinib patients, plans to initiate the INSIGHT study in the second half of 2023, our ability to offer clinically meaningful benefit for second-line GIST patients based on mutational drivers of their disease, and the potential for QINLOCK to become the standard-of-care for second-line GIST patients with mutations KIT exon 11 and 17/18 only. 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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