Deciphera Pharmaceuticals Presents Long-Term Follow-Up Results from INTRIGUE Phase 3 Clinical Study in Second-Line GIST Patients at the 2024 American Society of Clinical Oncology Gastrointestinal Cancers Symposium

January 18, 2024

– Median Overall Survival for QINLOCK® of 35.5 Months Versus 31.5 Months for Sunitinib in the All-Patient Intent-to Treat-Population –

– Long-Term Safety Profile Consistent with Primary Analysis Showing Fewer Patients with Grade 3/4 Treatment-Emergent Adverse Events (TEAEs) and Lower Rate of Treatment Discontinuations Due to TEAEs with QINLOCK Versus Sunitinib –

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 18, 2024-- 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 new long-term results from the INTRIGUE Phase 3 clinical study comparing QINLOCK® (ripretinib) versus sunitinib in patients with advanced gastrointestinal stromal tumor (GIST) previously treated with imatinib.

The presentation titled “Overall survival and long-term safety with ripretinib vs sunitinib in patients with advanced gastrointestinal stromal tumor previously treated with imatinib: final analyses from INTRIGUE” will be presented by John Zalcberg, M.D., Ph.D., Cancer Research Program, Monash University School of Public Health and Preventive Medicine and Department of Medical Oncology, Alfred Health, Melbourne, Victoria, Australia at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium and will be available on the Company’s website at www.deciphera.com/presentations-publications.

“These long-term clinical results demonstrate that the overall survival rate was similar for both QINLOCK and sunitinib, and that treatment with QINLOCK continued to show a favorable safety profile compared to treatment with sunitinib,” said Dr. Zalcberg. “In addition, the data show that patient outcomes in the third-line setting are comparable for patients that were treated with either QINLOCK or sunitinib in the second line.”

“The final results from INTRIGUE demonstrate the strong clinical activity of QINLOCK in the broader second-line GIST patient population,” said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. “Importantly, these results also indicate that third line treatment is not adversely impacted by treatment with QINLOCK in the second line and that QINLOCK continues to show a favorable safety profile compared to sunitinib.”

Results of INTRIGUE Study Long-Term Follow-Up

In INTRIGUE, 453 patients in the all-patient intent-to-treat population (AP-ITT) with second-line GIST were randomized 1:1 to receive QINLOCK 150 mg once daily (n=226) or sunitinib 50 mg once daily (4 weeks on/2 weeks off) (n=227) of which 444 patients received treatment.

In the primary analysis of the AP-ITT population based on a data cut of September 1, 2021, while the primary endpoint was not achieved, QINLOCK demonstrated similar efficacy with a median progression-free survival (PFS) of 8.0 months versus 8.3 months for sunitinib (hazard ratio [HR] 1.05, nominal p=0.72). There were fewer patients with Grade 3/4 drug-related treatment emergent adverse events (TEAE) with QINLOCK (26.5%) compared with sunitinib (55.2%). Based on the primary results from the INTRIGUE study, QINLOCK was included in the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology for GIST (version 1.2023) as a preferred second-line regimen for patients with advanced GIST who are intolerant to sunitinib.

The final analysis includes 18 months of additional follow up after the primary analysis based on a data cut of March 15, 2023. Key highlights from the final results presented include the following:

Overall Survival (OS)

- There were 211 OS events (46.6%) in the AP-ITT population with median duration of follow-up in the QINLOCK and sunitinib arms of 35.1 months and 34.1 months, respectively.
- Median OS in the AP-ITT population was similar with QINLOCK (35.5 months) versus sunitinib (31.5 months) (HR 0.86; 95% CI, 0.65 to 1.13; nominal p= 0.275).

Safety and Tolerability

- Among the 444 patients treated, 9.0% of patients remained on treatment at the time of data cutoff including 12.6% of 223 patients treated with QINLOCK and 5.4% of 221 patients treated with sunitinib.
- The long-term safety profile of QINLOCK was consistent with the primary analysis.
    - Fewer patients had Grade 3/4 drug-related TEAEs with QINLOCK (27.4%) versus sunitinib (57.9%).
    - Dose interruptions and reductions as well as treatment discontinuations due to TEAEs were lower with QINLOCK versus sunitinib. Fewer patients discontinued treatment due to any TEAE for QINLOCK (4.9%) versus sunitinib (9.0%).
- The most common TEAEs in the QINLOCK arm were alopecia, fatigue, and myalgia. The most common TEAEs in patients treated with sunitinib were palmar-plantar erythrodysesthesia syndrome, diarrhea, and hypertension.

Exploratory Analysis: Efficacy of Next-Line Therapy

- Median PFS on the next line of therapy after protocol treatment was similar for QINLOCK (7.7 months) versus sunitinib (7.4 months) in the AP-ITT population (HR 1.03; 95% CI, 0.78 to 1.35).
- Following study treatment discontinuation, the most common third-line therapy was sunitinib for patients in the QINLOCK arm (59.7%) and regorafenib for patients in the sunitinib arm (42.7%).
- Patients in the QINLOCK arm who received third-line sunitinib had a median PFS on next line of therapy of 8.5 months compared with 6.3 months for patients in the sunitinib arm who received third-line regorafenib (HR 0.90; 95% CI, 0.66 to 1.24).

Details of the poster presentation are as follows:

Title: Overall survival and long-term safety with ripretinib vs sunitinib in patients with advanced gastrointestinal stromal tumor previously treated with imatinib: final analyses from INTRIGUE
Author: John Zalcberg, M.D., Ph.D., Monash University School of Public Health and Preventive Medicine
Session: A: Cancers of the Esophagus and Stomach and Other GI Cancers
Abstract #: 748
Date and Time: Thursday January 18, 2024 11:45 AM – 1:15 PM PT

In January 2024, *Nature Medicine* published the results of the exploratory ctDNA analysis from INTRIGUE showing substantial clinical benefit of QINLOCK compared to sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only. Patients with mutations in KIT exon 11 and 17/18 had improved progression-free survival, objective response rate, and overall survival with QINLOCK versus sunitinib.

Based on the results of this prespecified exploratory objective in INTRIGUE, the Company is enrolling the INSIGHT pivotal Phase 3 clinical study of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18 only.

About the INSIGHT Study

The 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 (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 in patients with a KIT exon 11 primary mutation and then in the AP-ITT population. In patients with a KIT exon 11 primary mutation (n=327), QINLOCK demonstrated a median PFS 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-ITT population QINLOCK demonstrated a median PFS of 8.0 months compared to 8.3 months for the sunitinib arm (HR 1.05, nominal p=0.72). 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%). Similarly, there were fewer patients with Grade 3/4 drug-related TEAEs with QINLOCK (26.5%) compared with sunitinib (55.2%).

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, Iceland, Israel, Liechtenstein, Macau, New Zealand, Norway, Singapore, Switzerland, Taiwan, The United Kingdom, and the United States. For more information, visit www.deciphera.com and follow us on LinkedIn and X (@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 the potential for our preclinical and/or clinical stage pipeline assets to be first-in-class and/or best-in-class treatments, our Phase 3 INSIGHT clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 and plans to enroll the INSIGHT study as quickly as possible. 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, our ability to successfully demonstrate the efficacy and safety of our drug or drug candidates, the preclinical or clinical results for our product candidates, which may not support further development of such product 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, 2023, 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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