Deciphera Pharmaceuticals Announces Nature Medicine Publication of Results from Exploratory ctDNA Analysis from INTRIGUE Phase 3 Study Demonstrating Substantial Clinical Benefit of QINLOCK® in 2L GIST Patients with Mutations in KIT Exon 11 and 17/18

January 5, 2024

– Median Progression-Free Survival for QINLOCK® of 14.2 Months Versus 1.5 Months for Sunitinib –

– Objective Response Rate of 44.4% for QINLOCK Versus 0% for Sunitinib –

– Median Overall Survival for QINLOCK was Not Estimable Versus 17.5 Months for Sunitinib –

– Results Support Ongoing Pivotal Phase 3 INSIGHT Study –

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 5, 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 that *Nature Medicine* has published results from a circulating tumor DNA (ctDNA) analysis of the INTRIGUE Phase 3 study of QINLOCK (ripretinib) in GIST patients with mutations in KIT exon 11 and 17/18 only previously treated with imatinib.

The article, titled “Ripretinib versus sunitinib in gastrointestinal stromal tumor: ctDNA biomarker analysis of the phase 3 INTRIGUE trial” is now available online and will be published in a future print issue of *Nature Medicine.*

“The results published in *Nature Medicine* provide compelling evidence that QINLOCK may provide progression-free and overall survival benefit to second-line (2L) GIST patients in whom a liquid biopsy reveals primary KIT exon 11 mutations plus secondary mutations restricted to KIT exons 17 and 18. It is the first test that measures heterogeneity of resistance and may allow for a more optimized and targeted treatment plan for people living with this disease,” said Sebastian Bauer, M.D., Medical Oncologist at the West German Cancer Center in Essen and senior author of the manuscript. “This analysis is leading us to consider a new approach in GIST treatment using sensitive and minimally invasive blood tests to identify the specific secondary mutational profile for individual patients in order to tailor their therapy based on the differential activity of QINLOCK and sunitinib seen in the INTRIGUE subgroup analysis.”

“In second-line GIST patients with KIT exon 11 + 17/18 mutations only, treatment with QINLOCK resulted in a 78% reduction in the risk of disease progression and a 66% reduction in the risk of death compared to sunitinib, representing a substantial clinical benefit for these patients,” said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. “Our ongoing INSIGHT pivotal Phase 3 study is designed to confirm the exceptional efficacy we observed in this exploratory analysis from INTRIGUE. The INSIGHT study is now open at multiple sites and we are committed to enrolling the study as quickly as possible.”

INTRIGUE is an international, multi-center study conducted in 122 active sites across 22 countries, where 453 patients in the all patient intent-to-treat population (AP-ITT) with second-line GIST were randomized to receive ripretinib (n=226) or sunitinib (n=227).

In the AP-ITT population, QINLOCK demonstrated similar efficacy with a median progression-free survival (PFS) of 8.0 months versus 8.3 months for sunitinib (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 (version 1.2023) as the preferred second-line regimen for patients with advanced GIST who are intolerant to sunitinib.

A prespecified exploratory objective in INTRIGUE 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 in patients for whom evaluable samples were available (n=362) out of whom 280 patients had detectable ctDNA. In patients with a detectable KIT exon 11 primary mutation (n=157), 52 patients also had mutations in KIT exon 17/18 only and 41 had mutations in KIT exon 13/14 only.

Patients with mutations in KIT exon 11 and 17/18 only had improved progression-free survival (PFS), objective response rate (ORR), and overall survival (OS) with QINLOCK versus sunitinib while patients with mutations in KIT exon 11 and 13/14 only had improved PFS, ORR, and OS with sunitinib compared to QINLOCK.

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 cutoff as of September 1, 2021; (2) Data cutoff as of September 1, 2022.

The subgroup safety profile was consistent with the primary analysis in the AP-ITT population and demonstrated a more favorable safety profile for QINLOCK compared with sunitinib with fewer patients experiencing Grade 3-4 drug-related TEAEs (KIT exon 11 and 17/18 only: 33.3% for QINLOCK versus 50.0% for sunitinib).

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 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-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 ripretinib (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 kinase inhibitor for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the European Union, Hong Kong, Israel, Macau, New Zealand, 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; the potential for QINLOCK to provide a more optimized and targeted treatment plan for people living with GIST, the substantial clinical benefit that QINLOCK can potentially offer second-line GIST patients with KIT exon 11+17/18 mutations only; the exceptional efficacy in a sub-group of second-line GIST patients observed in the exploratory analysis from INTRIGUE, and plans to enroll the pivotal Phase 3 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, 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, including the FDA and the EMA, 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 and total addressable markets, 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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