Deciphera Pharmaceuticals to Present Data from INTRIGUE Phase 3 Study of QINLOCK® (ripretinib) and Trial-in-Progress Poster for INSIGHT Pivotal Phase 3 Study of QINLOCK® at the 2023 American Society of Clinical Oncology Annual Meeting

May 25, 2023

– Company Presents Poster on Overall Survival and Long-Term Safety Results from INTRIGUE Study; Second Poster Presents Analysis from INTRIGUE Patients without Detectable ctDNA at Baseline –

– Encore Oral Presentation of Results of ctDNA Analysis of INTRIGUE Phase 3 Study in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18 Which Demonstrated Substantial Clinical Benefit from QINLOCK but Not Sunitinib –

– Trial-in-Progress Poster Outlines Planned INSIGHT Pivotal Phase 3 Study of QINLOCK Versus Sunitinib in Second-Line GIST Patients with KIT Exon 11 and 17/18 Mutations, Expected to Initiate in the Second Half of 2023 –

WALTHAM, Mass.--(BUSINESS WIRE)--May 25, 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 four poster presentations at the upcoming 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago, Illinois on June 2-6, 2023.

“As we prepare to initiate our INSIGHT pivotal Phase 3 study of QINLOCK versus sunitinib in second-line GIST patients with KIT exon 11 and 17/18 mutations, we are excited to share details on the study design and additional supporting data from the INTRIGUE study. Our exploratory analysis from INTRIGUE using baseline circulating tumor DNA (ctDNA) showed that QINLOCK provided clinically meaningful benefit in patients with co-occurring KIT exon 11 and 17/18 mutations, with a median progression-free survival of 14.2 months compared to 1.5 months for sunitinib,” said Matthew L. Sherman, M.D., Executive Vice President and Chief Medical Officer of Deciphera. “QINLOCK has the clear potential to become the standard-of-care for these second-line GIST patients and provide exceptional clinical benefit compared to the current standard of care.”

Dr. Sherman continued, “We are also pleased to report overall survival and long-term safety data for our INTRIGUE Phase 3 study. In the all-patient intent-to-treat population, overall survival was 35.5 months in the QINLOCK arm and 30.9 months in the sunitinib arm. The favorable safety profile was consistent with our primary analysis, with fewer patients on QINLOCK experiencing Grade 3/4 treatment-emergent adverse events compared to sunitinib. Separately, our analysis from the INTRIGUE study showed better clinical outcomes for patients without detectable ctDNA at baseline, and among these patients without baseline ctDNA, ripretinib showed a median PFS of 16.6 months compared to 11.0 months for patients in the sunitinib arm.”

Copies of the posters are currently available on the Company’s website at www.deciphera.com/presentations-publications. Presentation details are as follows:

Abstract Number: 11524
Title: Overall survival and long-term safety in patients with advanced gastrointestinal stromal tumor previously treated with imatinib: Updated analyses from INTRIGUE.
Presenter: Robin L. Jones, M.D., Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research
Session Date: Saturday, June 3
Session Time: 1:15 – 4:15 PM CT

Poster Discussion Session: 4:30 – 6:00 PM CT
Key Highlights:

- INTRIGUE is a randomized, open-label, global, multicenter phase 3 study comparing the efficacy and safety of ripretinib vs. sunitinib in patients with GIST who had disease progression on, or were intolerant to, first-line treatment with imatinib
- 453 patients were randomized 1:1 to receive ripretinib 150 mg QD or sunitinib 50 mg QD (4 weeks on/2 weeks off) and were stratified by KIT mutational status and imatinib intolerance
- 51 of 444 treated patients (11.5%; intent-to-treat population (ITT)) remain on treatment; 33/223 (14.8%) on ripretinib and 18/221 (8.1%) on sunitinib
- Overall survival (OS) was measured at the second interim analysis (IA) as of September 1, 2022, with 185 OS events (41%) in the ITT population and 133/327 (41%) in the KIT exon 11 ITT population
- OS was similar with ripretinib vs. sunitinib in the ITT population (median 35.5 months vs. 30.9 months; HR 0.88; 95% CI, 0.66 to 1.18; nominal P = 0.39) and KIT exon 11 ITT population (median 34.0 months vs. 31.5 months; HR 1.05; 95% CI, 0.75 to 1.48; nominal P = 0.77)
- PFS on next line of therapy in the second IA was similar with ripretinib vs. sunitinib in the all patient (AP) ITT population (median 7.7 months vs. 6.5 months; HR 1.01; 95% CI, 0.76 to 1.34) and KIT exon 11 ITT population (median 8.2 months vs. 7.5 months; HR 1.14; 95% CI, 0.81 to 1.59)
- The updated safety profile was consistent with the primary analysis
    - Fewer patients had grade 3/4 treatment-emergent adverse events (TEAEs) with ripretinib vs. sunitinib (95 [42.6%] vs. 149 [67.4%])
    - Dose interruptions, and reductions, and treatment discontinuations due to TEAEs were lower with ripretinib vs. sunitinib
    - The most common TEAEs of any grade in the ripretinib arm were alopecia, fatigue, and myalgia, whereas the most common TEAEs of any grade in patients treated with sunitinib were palmar-plantar erythrodysesthesia syndrome, diarrhea, and hypertension

Abstract Number: 11536
Title: Outcomes in patients with advanced gastrointestinal stromal tumor who did not have baseline ctDNA detected in the INTRIGUE study
Presenter: Jonathan Trent, M.D., Ph.D., Associate Director for Clinical Research, Sylvester Comprehensive Cancer Center, University of Miami Health System
Session Date: Saturday, June 3
Session Time: 1:15 – 4:15 PM CT
Key Highlights:

- An exploratory objective in the INTRIGUE Phase 3 study was to evaluate anti-tumor efficacy of QINLOCK according to baseline KIT primary and secondary mutational status using circulating tumor DNA (ctDNA)
- Data cutoff was September 1, 2021 for all data except OS, which had a data cutoff of September 1, 2022
- Of the 453 patients in the ITT population, baseline ctDNA was analyzed in 362 patients for whom evaluable samples were available
    - Among 82 patients (22.7%) who had no detectable ctDNA (ctDNA-ND), 40 were in the ripretinib arm and 42 in the sunitinib arm
    - Among the 280 patients (77.3%) with ctDNA detected (ctDNA-D), 135 were in the ripretinib arm and 145 in the sunitinib arm
- Clinical efficacy was higher in patients with ctDNA-ND vs. ctDNA-D
    - Objective response rate (ORR) rate was higher in patients with ctDNA-ND (25.6%) vs. ctDNA-D (17.5%)
    - Progression-free survival (PFS) was higher in patients with ctDNA-ND (12.3 months) vs. ctDNA-D (6.8 months), HR 1.81; 95% CI, 1.28 to 2.56; nominal P = 0.0006
- Overall survival (OS) was higher in patients with ctDNA-ND (not estimable) vs. ctDNA-D (28.9 months), HR 4.69; 95% CI, 2.54 to 8.68; nominal P < 0.0001
- In the ctDNA-ND group, ripretinib demonstrated a numerically higher PFS vs. sunitinib (median 16.6 months vs. 11.0 months; HR 0.73; 95% CI, 0.39 to 1.39; nominal P = 0.3362) and in the ctDNA-D group. PFS was comparable between ripretinib and sunitinib (median 6.8 months vs. 6.9 months; HR 1.23; 95% CI, 0.92 to 1.64; nominal P = 0.1583)
- In the ctDNA-ND group, OS was similar with ripretinib vs. sunitinib (not estimable for both ripretinib and sunitinib; HR 0.84; 95% CI, 0.25 to 2.75; nominal P = 0.7674) and in the ctDNA-D group (median 27.7 months vs. 29.5 months; HR 1.05; 95% CI, 0.75 to 1.47; nominal P = 0.7609)
- Patients with ctDNA-ND were younger (median 55.5 years vs. 62.0 years) and had smaller sums of longest diameters of target lesions vs. patients with ctDNA-D
- Safety was similar between ctDNA groups and consistent with the primary analysis
    - Fewer patients had grade 3/4 TEAEs with ripretinib vs. sunitinib in both groups (ctDNA-ND, 14 [35.0%] vs. 29 [69.0%]; ctDNA-D, 56 [41.5%] vs. 94 [65.7%])
    - Dose interruptions, dose reductions, and treatment discontinuations due to TEAEs were lower with ripretinib vs. sunitinib

Abstract Number: TPS11582
Title: INSIGHT: A phase 3, randomized, multicenter, open-label study of ripretinib vs sunitinib in patients with advanced gastrointestinal stromal tumor previously treated with imatinib harboring KIT exon 11 + 17 and/or 18 mutations.
Presenter: Suzanne George, M.D., Associate Division Chief, Sarcoma Center, Dana-Farber Cancer Institute
Session Date: Saturday, June 3
Session Time: 1:15 – 4:15 PM CT
Key Highlights:

- INSIGHT is an international, Phase 3, randomized, multicenter, open-label study to evaluate the efficacy of ripretinib vs. sunitinib in patients with advanced GIST previously treated with imatinib and who have KIT exon 11 mutations and co-occurring mutations exclusively in KIT exon 17 and/or 18
- 54 participants will be randomized 2:1 to either ripretinib 150 mg once daily (QD; continuous) or sunitinib 50 mg QD (4 weeks on/2 weeks off) in 6-week cycles
- Patients will receive the study drug until disease progression determined by independent radiologic review (IRR) using modified Response Evaluation Criteria in Solid Tumors version 1.1 (mRECIST v.1.1), unacceptable toxicity, or withdrawal of consent
- Upon disease progression as determined by blinded IRR, patients in the sunitinib arm may crossover to receive ripretinib
- The primary outcome measure is progression-free survival based on blinded IRR

Abstract Number: 397784*
Title: Mutational heterogeneity of imatinib resistance and efficacy of ripretinib vs sunitinib in patients with gastrointestinal stromal tumor: ctDNA analysis from INTRIGUE
Presenter: Sebastian Bauer, M.D., Head of Sarcoma Center and Translational Sarcoma Research at the West German Cancer Center, University Hospital Essen, University Duisburg-Essen and German Cancer Consortium
Session Date: Saturday, June 3
Presentation Time: 1:54 – 2:00 PM CT
Key Highlights:

- In patients with a KIT exon 11 primary mutation identified by the planned exploratory analysis from INTRIGUE:
    - 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
- Patients with mutations in KIT exon 11 and exon 17/18 only derived substantially improved clinical benefit with ripretinib compared to sunitinib
    - Ripretinib demonstrated a median PFS (mPFS) of 14.2 months compared to 1.5 months for the sunitinib arm (HR 0.22, nominal P <0.0001)
    - Ripretinib demonstrated a confirmed objective response rate (ORR) of 44.4% (n=12 of 27) compared to 0% for sunitinib (nominal P = 0.0001)
    - OS for the ripretinib 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 = 0.0061)
- Patients with mutations in KIT exon 11 and 13/14 only derived substantially improved clinical benefit with sunitinib compared to ripretinib
    - Ripretinib demonstrated an mPFS of 4.0 months compared to 15.0 months for the sunitinib arm (HR 3.94, nominal P = 0.0005)
    - Ripretinib demonstrated a confirmed ORR of 9.5% compared to 15% for sunitinib (nominal P = 0.5922)
    - Ripretinib demonstrated a mOS of 24.5 months, while mOS for patients randomized to sunitinib was not estimable (HR 1.75, nominal P = 0.2085)

* *ASCO Plenary Series: Rapid Abstract Update*

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, Macau, 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 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18, 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 in KIT exon 11 and 17/18. 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, 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 March 31, 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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