Deciphera Pharmaceuticals Reports Positive Updated Phase 1 Data for Ripretinib in Gastrointestinal Stromal Tumors

August 13, 2019

- Data from Phase 1 Study Supports Ongoing INTRIGUE Phase 3 Clinical Study in Patients with Second-line GIST –

- Median Progression Free Survival (mPFS) Sustained across All Cohorts -

- Additional Phase 1 Results Expected to be Presented at Upcoming Medical Meeting -

- Company to Host Conference Call Today at 8:00 AM ET -

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 13, 2019-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today reported updated data from its ongoing Phase 1 clinical study of ripretinib, a broad-spectrum KIT and PDGFRα inhibitor, in patients with second-line through fourth-line plus gastrointestinal stromal tumors (GIST).

In a separate press release issued today, Deciphera announced positive top-line results from its INVICTUS pivotal Phase 3 clinical study supporting a potential new drug application (NDA) submission to the U.S. Food and Drug Administration (FDA) for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib. In addition to the INVICTUS data, Deciphera will also be submitting in its NDA supportive data from the ongoing Phase 1 clinical study, which will include the updated data from GIST patients at doses of ≥100mg of ripretinib. Additional results from the Phase 1 clinical study in these patients are expected to be presented at an upcoming medical meeting.

“We believe the updated data from our ongoing Phase 1 clinical study, with the additional six months of maturity from our last Phase 1 data cut-off, continue to support ripretinib’s potential across the broad range of KIT and PDGFRα mutations known to occur in patients with GIST following therapy with imatinib,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “In the updated data from the second-line cohort, we believe ripretinib has demonstrated encouraging clinical benefit based on the objective response rate, disease control rate and median progression free survival rates observed. These results strengthen our confidence in the INTRIGUE pivotal Phase 3 clinical study comparing ripretinib to sunitinib, the standard of care for patients receiving second-line treatment for GIST.”

Updated Phase 1 Data

Updated data from 178 GIST patients receiving ripretinib at doses of ≥100mg daily are noted in the table below as of March 1, 2019. The table includes investigator-assessed objective response rate (ORR) by best response, disease control rate (DCR) and median progression free survival (mPFS), all of which were determined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.

Line of Therapy[1]	Objective Response Rate by Best Response Includes Unconfirmed (Confirmed Only)	Disease Control Rate at 3 Months	Median Progression Free Survival (mPFS)	Censored Patients for mPFS	Mean Treatment Duration[2][3]
Second-Line (n=37)	30% (22%)	81%	42 weeks	38%	43 weeks
Third-Line (n=31)	23% (13%)	80%	40 weeks	32%	48 weeks
Fourth-Line (n=60)	15% (8%)	73%	30 weeks	30%	49 weeks
≥Fourth-Line (n=110)[4]	11% (7%)	66%	24 weeks	22%	41 weeks

(1) Overall number of patients (n=178) remains the same as prior data presented at ESMO 2018; based on additional data cleaning, one patient from each of 2nd line and 4th/≥4th line were reclassified as 3rd line patients; (2) Median treatment durations were: 2nd line = 44 weeks, 3rd line = 48 weeks, 4th line = 46 weeks and ≥4th line = 29 weeks; (3) Includes 60 patients who elected for intra-patient dose escalation from 150 mg QD to 150 mg BID; (4) Number of patients includes 60 patients from 4th line.

Ripretinib was generally well tolerated and the updated adverse events were consistent with previously presented Phase 1 data in patients with GIST. Grade 3 or 4 treatment-emergent adverse events (TEAEs) in >5% of patients were lipase increased (18%; n=33), anemia (11%; n=20), hypertension (7%; n=13) and abdominal pain (6%; n=11). 13% of patients (n=24) experienced TEAEs leading to study treatment discontinuation, 17% of patients (n=31) experienced TEAEs leading to dose reduction and 49% of patients (n=88) had TEAEs leading to study drug interruption.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement, as well as results from the INVICTUS Phase 3 clinical study, today,

August 13, 2019 at 8:00 AM ET. To access the live call by phone please dial 866-930-5479 (domestic) or 409-216-0603 (international); the conference ID is 8859018. A live audio webcast of the event and accompanying slides may also be accessed through the “Investors” section of Deciphera’s website at www.deciphera.com. A replay of the webcast will be available for 30 days following the event.

About GIST

Gastrointestinal stromal tumor (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST is the most common sarcoma of the gastrointestinal tract, with approximately 4,000 to 6,000 new GIST cases each year in the United States and a similar incidence rate in European and other countries. Most cases of GIST are driven by a spectrum of mutations. The most common primary mutations are in KIT kinase, representing approximately 75% to 80% of cases, or in PDGFRα kinase, representing approximately 5% to 10% of cases. Current therapies are unable to inhibit the full spectrum of primary and secondary mutations, which drives resistance and disease progression. Estimates for 5-year survival range from 48% to 90%, depending on the stage of the disease at diagnosis.

About Ripretinib

Ripretinib is an investigational KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including gastrointestinal stromal tumors, or GIST, systemic mastocytosis, or SM, and other cancers. Ripretinib was specifically designed to improve the treatment of patients with GIST by inhibiting a broad spectrum of mutations in KIT and PDGFRα. Ripretinib is a KIT and PDGFRα inhibitor that inhibits initiating and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, involved in GIST, as well as the primary D816V exon 17 mutation involved in SM. Ripretinib also inhibits primary PDGFRα mutations in exons 12, 14 and 18, including the exon 18 D842V mutation, involved in a subset of GIST. In June 2019, the U.S. FDA granted Fast Track Designation to ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib.

Deciphera Pharmaceuticals has an exclusive license agreement with Zai Lab (Shanghai) Co., Ltd. for the development and commercialization of ripretinib in Greater China (MainlandChina, Hong Kong, Macau and Taiwan). Deciphera Pharmaceuticals retains development and commercial rights for ripretinib in the rest of the world.

About the INTRIGUE Phase 3 Study

The INTRIGUE Phase 3 clinical study is an interventional, randomized, global, multicenter, open-label study to evaluate the safety, tolerability and efficacy of ripretinib compared to sunitinib in patients with GIST previously treated with imatinib. This study was designed to provide evidence of clinical benefit to support regulatory approvals in second-line GIST patients in the United States, Europe and other major markets. Patients will be randomized 1:1 to either 150 mg of ripretinib once daily or 50 mg of sunitinib once daily for four weeks followed by two weeks without sunitinib. The primary efficacy endpoint is median progression-free survival (mPFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) and Overall Survival (OS). See www.clinicaltrials.gov for further information (NCT03673501).

About Deciphera Pharmaceuticals

Deciphera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a “switched off” or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate and/or durability of their responses to treatment.

Availability of Other Information About Deciphera Pharmaceuticals

Investors and others should note that Deciphera Pharmaceuticals communicates with its investors and the public using its company website (www.deciphera.com), including but not limited to investor presentations and scientific presentations, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Deciphera Pharmaceuticals posts on these channels and websites could be deemed to be material information. As a result, Deciphera Pharmaceuticals encourages investors, the media and others interested in Deciphera Pharmaceuticals to review the information that it posts on these channels, including Deciphera Pharmaceuticals’ investor relations website, on a regular basis. This list of channels may be updated from time to time on Deciphera Pharmaceuticals' investor relations website and may include other social media channels than the ones described above. The contents of Deciphera Pharmaceuticals' website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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, statements regarding our expectations regarding reporting additional data from our Phase 1 study of ripretinib in GIST patients at an upcoming medical meeting, the potential for the results of our INVICTUS pivotal Phase 3 clinical study to support a NDA submission, our plans for and the data to be included in a NDA submission for ripretinib, the potential for ripretinib (DCC-2618) and our other drug candidates based on our kinase switch control inhibitor platform to provide clinical benefit and treat cancers such as GIST and other possible indications, the prospects for and initiation of and enrollment for our INTRIGUE pivotal Phase 3 study and our confidence in such trial, preparations for and timing of a possible NDA submission, and potential commercial launch of ripretinib in fourth-line and fourth-line plus GIST, if approved. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “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 delay of any current or planned clinical studies or the development of our drug candidates, including ripretinib, our ability to successfully demonstrate the efficacy and safety of our drug candidates

including in later-stage studies, the preclinical and clinical results for our drug candidates, which may not support further development of such drug candidates, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and regulatory development and other risks identified in our SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, 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. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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Source: Deciphera Pharmaceuticals, Inc.

Investor Relations:
Jen Robinson
Deciphera Pharmaceuticals, Inc.
jrobinson@deciphera.com
781-906-1112

Media:
David Rosen
Argot Partners
David.Rosen@argotpartners.com
212-600-1902