Deciphera Pharmaceuticals Announces Positive Top-line Results from INVICTUS Pivotal Phase 3 Clinical Study of Ripretinib in Patients with Advanced Gastrointestinal Stromal Tumors

August 13, 2019

- INVICTUS Achieved Primary Endpoint, Ripretinib Significantly Improved Progression Free Survival (PFS) Versus Placebo in Patients with Fourth-line and Fourth-line Plus GIST -

- Median PFS for Ripretinib of 6.3 Months Versus Placebo of 1.0 Month; Hazard Ratio of 0.15, p<0.0001-

- Company Expects to Submit an NDA to the FDA in 1Q 2020 for the Treatment of Patients with Advanced GIST who have Received Prior Treatment with Imatinib, Sunitinib and Regorafenib -

- 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 announced positive top-line data from the INVICTUS pivotal Phase 3 clinical study of ripretinib, a broad-spectrum KIT and PDGFRα inhibitor, in patients with fourth-line and fourth-line plus gastrointestinal stromal tumors (GIST).

“There is a dire unmet need for new therapies that can deliver effective disease control for patients with advanced GIST who have failed currently approved treatment options,” said Margaret von Mehren, MD, Department of Medical Oncology, Fox Chase Cancer Center, Philadelphia, Pennsylvania. “These top-line data from a Phase 3, randomized, placebo-controlled study are highly impressive and suggest that ripretinib’s approach of targeting the broad spectrum of KIT and PDGFRα mutations known to drive GIST can significantly improve progression free survival in the most heavily pretreated patients. Particularly notable is the magnitude of benefit observed for overall survival in this study.”

The INVICTUS Phase 3 clinical study is a randomized (2:1), double-blind, placebo-controlled, international, multicenter study to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in 129 patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. The INVICTUS study achieved its primary endpoint of improved PFS as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.

In the INVICTUS study, ripretinib demonstrated a median PFS of 6.3 months (27.6 weeks) compared to 1.0 month (4.1 weeks) in the placebo arm and significantly reduced the risk of disease progression or death by 85% (HR of 0.15, p<0.0001) compared to placebo.

For the key secondary endpoint of objective response rate (ORR), as determined by blinded independent central radiologic review using modified RECIST version 1.1, ripretinib demonstrated an ORR of 9.4% compared with 0% for placebo (p-value=0.0504), which was not statistically significant. Ripretinib in this study also showed a clinically meaningful improvement over placebo in terms of the secondary endpoint overall survival (OS) (median OS 15.1 months vs. 6.6 months, HR = 0.36, nominal p-value=0.0004). Since statistical significance was not achieved for ORR, the hypothesis testing of OS was not formally performed. According to the pre-specified hierarchical testing procedure of the endpoints, the hypothesis testing of OS cannot be formally conducted unless the test of ORR is statistically significant. The OS data for the placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment.

Ripretinib was generally well tolerated and the adverse event results in INVICTUS were consistent with data from previously presented Phase 1 study results. Grade 3 or 4 treatment-emergent adverse events (TEAEs) occurred in 42 (49%) patients on the ripretinib arm compared to 19 (44%) on the placebo arm. Grade 3 or 4 TEAEs >5% of patients in the ripretinib arm were anemia (9%; n=8), abdominal pain (7%; n=6) and hypertension (7%; n=6). Grade 3 or 4 TEAEs >5% of patients in the placebo arm were anemia (14%; n=6). The below table lists TEAEs >15% in the ripretinib arm compared to placebo.

INVICTUS Phase 3 Clinical Study		
Treatment Emergent Adverse Event	**Placebo (N=43)[(1)]**	**Ripretinib 150mg Daily (N=85)[(1)]**
Any event	42 (98%)	84 (99%)
Alopecia	2 (5%)	44 (52%)
Fatigue	10 (23%)	36 (42%)
Nausea	5 (12%)	33 (39%)
Abdominal pain	13 (30%)	31 (36%)
Constipation	8 (19%)	29 (34%)

Myalgia	5 (12%)	27 (32%)
Diarrhea	6 (14%)	24 (28%)
Decreased appetite	9 (21%)	23 (27%)
Palmar-plantar erythrodysaesthesia syndrome	0	18 (21%)
Vomiting	3 (7%)	18 (21%)
Headache	2 (5%)	16 (19%)
Weight decreased	5 (12%)	16 (19%)
Arthralgia	2 (5%)	15 (18%)
Blood bilirubin increased	0	14 (16%)
Oedema peripheral	3 (7%)	14 (16%)
Muscle spasms	2 (5%)	13 (15%)

Notes to table: (1) Safety population includes 128 patients. One patient was randomized to placebo but did not receive study drug.

“Today’s announcement represents a significant milestone in our mission to deliver important new medicines for the treatment of cancer,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “On behalf of the entire Deciphera team, I would like to thank the patients, their caregivers and the healthcare professionals who participated in the INVICTUS study. The data from INVICTUS reinforce our belief that ripretinib has the potential to transform the treatment of GIST, and our focus now turns to working closely with the FDA as they evaluate ripretinib for those patients with GIST who, having failed all currently approved therapies, are in desperate need of a treatment option.”

Based on the positive INVICTUS data, the Company expects to submit a New Drug Application (NDA) 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 the first quarter of 2020.

Additional results from the INVICTUS Phase 3 clinical study are expected to be presented at an upcoming medical meeting.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss the results of 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 the INVICTUS Phase 3 Study

The INVICTUS Phase 3 clinical study is a randomized, double-blind, placebo-controlled, international, multicenter study to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib. This study was designed to provide evidence of clinical benefit in fourth-line and fourth-line plus patients with GIST that would be required to secure a regulatory approval. Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily. The primary efficacy endpoint is progression-free survival (PFS) 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), Time to Tumor Progression (TTP) and Overall Survival (OS). See www.clinicaltrials.gov for further information (NCT03353753).

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 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 INVICTUS pivotal Phase 3 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, the timing of our planned NDA submission for fourth and fourth-line plus GIST, the potential for ripretinib 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, and preparations for seeking regulatory approval for and making ripretinib available to patients with 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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