Deciphera Pharmaceuticals Announces Late-Breaking Oral Presentation at the ESMO 2019 Congress Demonstrating Positive Results from INVICTUS Pivotal Phase 3 Study of Ripretinib in Patients with Advanced Gastrointestinal Stromal Tumors

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WALTHAM, Mass.--(BUSINESS WIRE)--Sep. 30, 2019-- Deciphera Pharmaceuticals, Inc. (Nasdaq:DCPH), a clinical-stage biopharmaceutical company addressing key mechanisms of tumor drug resistance, today announced the late-breaking presentation of results from the INVICTUS pivotal Phase 3 clinical study of ripretinib in patients with advanced gastrointestinal stromal tumors (GIST) in an oral session at the European Society for Medical Oncology (ESMO) 2019 Congress.

“For GIST patients who have failed currently approved agents, there exists an urgent need for effective and well-tolerated treatment options,” said Margaret von Mehren, MD, Department of Medical Oncology, Fox Chase Cancer Center, Philadelphia, Pennsylvania. “With a statistically significant improvement observed in progression free survival compared with placebo, and a clinically meaningful increase in overall survival compared with placebo, ripretinib represents a potential standard of care for patients harboring a broad spectrum of mutations known to drive GIST in patients who have no approved treatment options.”

“Results from the INVICTUS study support our belief that ripretinib has the potential to transform the current treatment landscape for advanced GIST,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “We are now working with the FDA as we prepare the NDA submission for ripretinib, which we expect in the first quarter of 2020.”

Today’s presentation featured new data as well as top-line results previously announced by the Company in August 2019. A copy of the presentation will be available following the session at www.deciphera.com.

INVICTUS Study Results

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. As previously reported, the study achieved the primary endpoint of improved progression free survival (PFS) compared to placebo in patients with fourth-line and fourth-line plus GIST, as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.

Progression Free Survival (PFS)

Ripretinib significantly reduced the risk of disease progression or death by 85% compared to placebo and demonstrated a median PFS of 6.3 months compared to 1.0 month in the placebo arm (HR=0.15, 95% CI (0.09,0.25), p<0.0001). This PFS benefit was consistent across all assessed patient subgroups.

Objective Response Rate (ORR) and Duration of Response

Eight patients (9.4%) had a confirmed objective response with ripretinib (p=0.0504) compared to no confirmed responses in the placebo arm, as measured by blinded independent central review, which was not statistically significant. As of the cutoff date of May 31, 2019, the median duration of response had not been reached with seven of the eight patients still responding to treatment. All responders had partial responses.

Overall Survival (OS)

Ripretinib reduced the risk of death by 64% compared to placebo and demonstrated a median OS of 15.1 months vs. 6.6 months in the placebo arm (HR=0.36, 95% CI (0.20,0.62), nominal p=0.0004). Since statistical significance was not achieved for the secondary endpoint of 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 for ORR is statistically significant.

Safety

Ripretinib was generally well tolerated and the adverse events observed in INVICTUS were consistent with data from previously presented Phase 1 study results. Treatment-emergent adverse events (TEAEs) occurred in 99% of patients on the ripretinib arm compared to 98% on the placebo arm. Grade 3 or 4 TEAEs occurred in 49% of patients on the ripretinib arm compared to 44% on the placebo arm. Grade 3 or 4 TEAEs greater than 5% of patients on the ripretinib arm were anemia (9%), abdominal pain (7%) and hypertension (7%). Grade 3 or 4 TEAEs greater than 5% of patients on the placebo arm were anemia (14%). TEAEs leading to dose reduction occurred in 7% of patients on the ripretinib arm compared to 2% on the placebo arm. TEAEs leading to dose interruption occurred in 24% of patients on the ripretinib arm compared to 21% on the placebo arm. TEAEs leading to study treatment discontinuation occurred in 8% of patients on the ripretinib arm compared to 12% of patients on the placebo arm. TEAEs leading to death occurred in 6% of patients on the ripretinib arm compared to 23% on the placebo arm.

New Drug Application (NDA) Submission

Based on the positive INVICTUS data, the Company expects to submit an 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.

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 Ripretinib

Ripretinib is an investigational tyrosine kinase switch control inhibitor that was engineered to broadly inhibit KIT and PDGFRα mutated kinases by using a unique dual mechanism of action that regulates the kinase switch pocket and activation loop. Ripretinib is currently 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 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 (Mainland China, 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 addressing 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.

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 the potential for the results of our INVICTUS pivotal Phase 3 clinical study to support an 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, impact current treatment paradigms and landscape 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, our ability to timely complete and prepare the information required for and file an NDA for ripretinib, our ability to manage and our reliance on third parties such as our third party drug substance and drug product contract manufacturers, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain regulatory approval, if at all, and make our investigational drugs available to patients, 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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