



## **Deciphera Pharmaceuticals Initiates Pivotal Phase 3 Clinical Study of Ripretinib (DCC-2618) in Second-line Patients with Gastrointestinal Stromal Tumors (“INTRIGUE” Study)**

December 20, 2018

*- The Efficacy and Tolerability Profile of Ripretinib Will Be Compared to Sunitinib in Second-line GIST Patients Regardless of KIT or PDGFR $\alpha$  Mutational Status -*

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 20, 2018-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today announced that it has initiated a pivotal Phase 3 clinical study, “INTRIGUE”, to evaluate the efficacy and tolerability of ripretinib (DCC-2618), a broad-spectrum KIT and PDGFR $\alpha$  inhibitor, compared to sunitinib in second-line gastrointestinal stromal tumor (GIST) patients.

“We are extremely pleased that the INTRIGUE Phase 3 study of ripretinib is now open to enroll second-line GIST patients, regardless of their mutational status, who have progressed on, or are intolerant to front-line therapy with imatinib,” said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. “If successful, we believe this Phase 3 study could serve as the basis for a regulatory submission for broad use in all second-line GIST patients.”

“INTRIGUE is the second pivotal Phase 3 study of ripretinib that Deciphera has initiated in less than one year. As recently announced, we expect to report top-line data from our first Phase 3 clinical study, INVICTUS, in fourth-line and fourth-line-plus GIST patients in mid-2019,” continued Dr. Taylor.

“While imatinib is an effective treatment for most patients with early-stage GIST, in almost all patients the disease will eventually progress due to the development of secondary drug resistance mutations,” said Professor Michael Heinrich, MD, Cell and Developmental Biology, OHSU Knight Cancer Institute. “A well-tolerated therapy with broad coverage and efficacy across the spectrum of KIT and PDGFR $\alpha$  mutations would represent a much-needed improvement over currently approved therapies for patients with GIST.”

### **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 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](http://www.clinicaltrials.gov) for further information (NCT03673501).

### **About the INVICTUS Phase 3 Study**

The INVICTUS Phase 3 clinical study is a randomized, double-blind, placebo-controlled, global, multicenter trial to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. This fully enrolled study was designed to support regulatory approvals in fourth-line and fourth-line-plus GIST patients in the United States, Europe and other major markets. Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily. 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), Time to Tumor Progression (TTP), and Overall Survival (OS). See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for further information (NCT03353753).

### **About Ripretinib**

Ripretinib (DCC-2618) is an investigational KIT and PDGFR $\alpha$  kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFR $\alpha$ -driven cancers, including gastrointestinal stromal tumors, or GIST, systemic mastocytosis, or SM, and other cancers. Ripretinib is specifically designed to improve the treatment of GIST patients by inhibiting a broad spectrum of mutations in KIT and PDGFR $\alpha$ . Ripretinib is a KIT and PDGFR $\alpha$  inhibitor that blocks 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 PDGFR $\alpha$  mutations in exons 12, 14 and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

### **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](http://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 timing of reporting top-line data from our INVICTUS pivotal Phase 3 study, our expectations regarding data from our second pivotal Phase 3 INTRIGUE study supporting regulatory approvals for broad use in second-line GIST patients who have progressed or are intolerant to front-line therapy with imatinib, the potential for ripretinib to treat cancers such as GIST, and other business strategies. 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, rebastinib, and DCC-3014, our advancement of multiple early-stage and later-stage efforts, 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 efforts to scale up drug product manufacturing, our ability to implement commercial readiness, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and other risks identified in our SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, 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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