

# Deciphera Pharmaceuticals Initiates Phase 3 Clinical Study with DCC-2618 in Patients with Advanced Gastrointestinal Stromal Tumors ("INVICTUS" study)

- Pivotal Study to Evaluate the pan-KIT and PDGFRα inhibitor, DCC-2618, in Heavily Pretreated Patients with GIST, for Whom There Are No Approved Treatment Options -

- Top-line Data from the INVICTUS Study Expected in 2019 -

Waltham, MA – January 4, 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 Phase 3 clinical study to evaluate the safety and efficacy of DCC-2618, a pan-KIT and PDGFR $\alpha$  inhibitor, in patients with advanced gastrointestinal stromal tumors (GIST).

"We are extremely pleased to initiate the INVICTUS study with DCC-2618 in heavily pretreated GIST patients, specifically fourth-line and fourth-line plus patients," said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. "We expect to report top-line results in 2019 and, if successful, this pivotal Phase 3 study could serve as the basis for a New Drug Application (NDA), providing a much-needed therapeutic option for these patients for whom there are no approved treatments. We also plan to initiate a second Phase 3 study later this year evaluating DCC-2618 in second-line GIST patients who have progressed or are intolerant to front-line therapy with imatinib."

"While effective treatments are available for patients with early-stage GIST, in 9 out 10 patients the disease will eventually progress due to the development of secondary drug resistance mutations," said Professor Jean-Yves Blay, Medical Oncologist, General Director Centre Léon Bérard, Comprehensive cancer Centre of Lyon, France. "A therapy with the potential to provide broad coverage across the full spectrum of KIT and PDGFR $\alpha$  mutations would represent a much-needed improvement over currently approved treatment options for patients with later-stage GIST."

Initiation of the INVICTUS study follows results from the ongoing Phase 1 clinical trial presented at the European Society for Medical Oncology (ESMO) Congress in September 2017, in which durable disease control by DCC-2618 was observed in heavily pretreated patients with GIST.

## INVICTUS Phase 3 Study

The INVICTUS Phase 3 clinical study is a randomized, double-blind, placebo-controlled, international, multicenter trial to evaluate the safety, tolerability, and efficacy of DCC-2618 compared to placebo in patients with advanced GIST patients whose previous therapies have included imatinib, sunitinib, and regorafenib. The trial is expected to enroll approximately 120 patients randomized 2:1 to either 150 mg once daily of DCC-2618 or placebo. The primary efficacy endpoint is median 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 <u>www.clinicaltrials.gov</u> for further information (NCT03353753).

#### About DCC-2618



DCC-2618 is a pan-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, glioblastoma multiforme and systemic mastocytosis. DCC-2618 was specifically designed to improve the treatment of GIST patients by inhibiting the full spectrum of mutations in KIT and PDGFR $\alpha$ . DCC-2618 is a pan-KIT and pan-PDGFR $\alpha$  inhibitor that blocks initiating KIT mutations in exons 9, 11, 13, 14, 17, and 18, known to be present in GIST patients and the D816V exon 17 mutation known to be present in ASM patients. DCC-2618 inhibits PDGFR $\alpha$  mutations in exon 18, including the D842V mutation that drives 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), 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 the potential for DCC-2618 to treat GIST; statements regarding the potential benefits to patients of DCC-2618; statements regarding plans and timelines for the clinical development of DCC-2618; and Deciphera Pharmaceuticals' strategy, business plans and focus. 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, statements regarding the potential for DCC-2618 to treat GIST; statements regarding the potential benefits to patients of DCC-2618; statements regarding plans and timelines for the clinical development of DCC-2618; and Deciphera Pharmaceuticals' strategy, business plans and focus. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Deciphera Pharmaceuticals' most recent quarterly report on Form 10-Q, and other filings that Deciphera Pharmaceuticals may make with the SEC in the future. Any forward-looking statements contained in this press release represent Deciphera Pharmaceuticals' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Deciphera Pharmaceuticals explicitly disclaims any obligation to update any forward-looking statements.

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