



## **Deciphera Pharmaceuticals Completes Enrollment in the INVICTUS Pivotal Phase 3 Clinical Study of DCC-2618 in Patients with Advanced Gastrointestinal Stromal Tumors**

November 15, 2018

*- Company Expects to Report Top-line Data in Mid-2019 and is Building the Commercial Capabilities to Support the Planned Launch of DCC-2618 in the United States -*

*- Initiation of a Second Pivotal Phase 3 Study of DCC-2618 Across All Second-line GIST Patients Including Those with Any KIT or PDGFR $\alpha$  Mutation ("INTRIGUE" Study) Expected in 4Q 2018 -*

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 15, 2018-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today announced completion of enrollment in the INVICTUS pivotal Phase 3 clinical study evaluating the safety and efficacy of DCC-2618, a broad-spectrum KIT and PDGFR $\alpha$  inhibitor, in fourth-line and fourth-line-plus gastrointestinal stromal tumor (GIST) patients.

"We are very pleased to have completed enrollment in the INVICTUS pivotal Phase 3 study, initiated in January 2018. We expect to report top-line data from this randomized, double-blind study in mid-2019 and, if successful, we believe the results would support a New Drug Application (NDA) for full approval in fourth-line and fourth-

line-plus GIST patients,” said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. “Currently there are no treatments approved for fourth-line and fourth-line-plus GIST and we are grateful to those patients who participated in our study and to the GIST community for its support. In addition, we look forward to initiating later this year a second pivotal Phase 3 study, the INTRIGUE study, in second-line GIST patients who have progressed or are intolerant to front-line therapy with imatinib, including those with any KIT or PDGFR $\alpha$  mutation.”

On October 19, 2018, Deciphera presented updated data from its ongoing Phase 1 clinical trial of DCC-2618 in patients with GIST at the European Society of Medical Oncology (ESMO) 2018 Congress in Munich, Germany.

<https://investors.deciphera.com/news-releases/news-release-details/deciphera-pharmaceuticals-reports-updated-preliminary-phase-1>.

#### About the 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 whose previous therapies have included imatinib, sunitinib, and regorafenib. This study was designed to provide the definitive evidence of clinical benefit in fourth-line and fourth-line-plus GIST patients that would be required to secure a full regulatory approval. Patients were randomized 2:1 to either 150 mg of DCC-2618 or placebo once daily. 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 [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for further information (NCT03353753).

#### About DCC-2618

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. DCC-2618 was specifically designed to improve the treatment of GIST

patients by inhibiting a broad spectrum of mutations in KIT and PDGFR $\alpha$ . DCC-2618 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. DCC-2618 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 an NDA for full approval in fourth-line-plus GIST patients, the planned initiation of our second pivotal Phase 3 INTRIGUE study in second-line GIST patients who have progressed or are intolerant to front-line therapy with imatinib, the potential for DCC-2618 to treat cancers such as GIST, our commercial readiness planning, 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 DCC-2618, 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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Source: Deciphera Pharmaceuticals, Inc.

Media:

Gina Nugent, The Yates Network

[gina@theyatesnetwork.com](mailto:gina@theyatesnetwork.com)

617-460-3579

Investor Relations:

Laura Perry or Sam Martin, Argot Partners

[Laura@argotpartners.com](mailto:Laura@argotpartners.com) or [Sam@argotpartners.com](mailto:Sam@argotpartners.com)

212-600-1902

Company:

Christopher J. Morl, Chief Business Officer

Deciphera Pharmaceuticals, LLC

[cmorl@deciphera.com](mailto:cmorl@deciphera.com)

781-209-6418