Deciphera Pharmaceuticals, Inc. Reports Updated Data from Ongoing Phase 1 Clinical Trial of DCC-2618 at 2018 American Association for Cancer Research (AACR) Annual Meeting

April 16, 2018

- Pharmacokinetic (PK), Safety, and Tolerability Profile of DCC-2618 in a Phase 1 Clinical Trial Supports 150mg QD Selected for a Pivotal Phase 3 Study in Gastrointestinal Stromal Tumor (GIST) -

WALTHAM, Mass.--(BUSINESS WIRE)--Apr. 16, 2018-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today announced the presentation of updated data from its ongoing Phase 1 clinical trial of DCC-2618, the Company’s broad spectrum KIT and PDGFRα inhibitor, in patients with gastrointestinal stromal tumors (GIST). Filip Janku, M.D., Ph.D., Assistant Professor, The University of Texas MD Anderson Cancer Center presented the poster titled “Pharmacokinetic (PK), safety, and tolerability profile of DCC-2618 in a phase 1 trial supports 150 mg QD (once daily) selected for a pivotal phase 3 trial in gastrointestinal stromal tumors (GIST)” at the 2018 American Association for Cancer Research (AACR) Annual Meeting in Chicago, IL. The poster includes an assessment of the safety and tolerability profile of DCC-2618 in 100 GIST patients treated at the recommended Phase 2 dose (RP2D) of 150 mg QD, which supports the selection of this dose for the ongoing pivotal, randomized Phase 3 INVICTUS study (NCT03353753).
“The data presented at AACR provides a robust assessment of the safety and tolerability profile of DCC-2618 in GIST patients at the 150 mg QD dose selected for the INVICTUS pivotal Phase 3 study in fourth-line and fourth line plus GIST, which we initiated in January 2018,” said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. “If successful, the INVICTUS 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 treatment options. We also plan to initiate a second Phase 3 registration study later this year, evaluating DCC-2618 in second-line GIST patients who have progressed, or are intolerant to front-line therapy with imatinib.”

The poster presentation includes the following highlights:

- Safety and tolerability of DCC-2618 on 100 GIST patients treated at the 150 mg QD dose out of the total of 169 patients treated with DCC-2618, as of the cut-off date of January 18, 2018.
- As of March 19, 2018, 81 of 137 GIST patients enrolled at the cut-off date and treated at 100 mg or more per day, remained on study treatment. In addition, 46 patients were treated for more than 6 months, including 10 patients who were treated for more than 12 months.
- Employing a population pharmacokinetic (PK) model based on steady state exposure to DCC-2618 and the active metabolite, DP-5439, increasing doses of DCC-2618 resulted in dose proportional increases in the combined exposure.
- Preliminary data from the 12 GIST patients dose escalated from 150 mg QD to 150 mg BID following progression by RECIST (Response Evaluation Criteria in Solid Tumors) are immature and do not currently support a conclusion regarding a benefit from intra-patient dose escalation.
- Based on the 100 GIST patients treated at the RP2D dose of 150 mg QD, DCC-2618 was well-tolerated, supporting the use of this dose in the pivotal, randomized Phase 3 trial, INVICTUS (NCT03353753).

About DCC-2618

DCC-2618 is a KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including gastrointestinal
stromal tumors, systemic mastocytosis and glioblastoma multiforme. DCC-2618 was specifically designed to improve the treatment of GIST patients by inhibiting a broad spectrum of mutations in KIT and PDGFRα. DCC-2618 is a KIT and PDGFRα inhibitor that blocks initiating 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 PDGFRα 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), 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 annual report on Form 10-K, 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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Source: Deciphera Pharmaceuticals, Inc.

Media:
The Yates Network
Gina Nugent, 617-460-3579
gina@theyatesnetwork.com
or
Investor Relations:
Argot Partners
Laura Perry or Sam Martin, 212-600-1902
Laura@argotpartners.com or Sam@argotpartners.com
or
Company:
Deciphera Pharmaceuticals, Inc.
Christopher J. Morl, 781-209-6418
Chief Business Officer
cmorl@deciphera.com