



Deciphera Pharmaceuticals, Inc. to Present Data from DCC-3014 and Ripretinib Programs at the Connective Tissue Oncology Society (CTOS) 2019 Annual Meeting

November 13, 2019

- Preliminary Anti-tumor Activity Observed in Initial Diffuse-type TGCT Patients Treated with DCC-3014 in Ongoing Phase 1 Study -

- DCC-3014 was Generally Well Tolerated with No Reported Grade 3 or Higher TEAEs in Initial Diffuse-Type TGCT Patients -

- Encore Presentation of Results from the INVICTUS Pivotal Phase 3 Study of Ripretinib in Advanced GIST to be Featured in Oral Presentation Session -

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 13, 2019-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced preliminary data from the ongoing Phase 1 study of DCC-3014, an oral inhibitor of CSF1R, including initial data in diffuse-type tenosynovial giant cell tumor (TGCT) patients as well as an encore presentation of the INVICTUS pivotal Phase 3 study of ripretinib, a broad-spectrum KIT and PDGFR α inhibitor, in patients with advanced gastrointestinal stromal tumors (GIST). Results from these programs will be presented at the Connective Tissue Oncology Society (CTOS) 2019 Annual Meeting being held November 13-16 in Tokyo, Japan.

"We are excited to share preliminary data from the initial TGCT patients enrolled in the ongoing Phase 1 study of DCC-3014. While this program in TGCT is in its early stages, we are encouraged by the preliminary evidence of anti-tumor activity and emerging tolerability profile," said Matthew L. Sherman, M.D., Executive Vice President and Chief Medical Officer of Deciphera. "We plan to continue to enroll TGCT patients to further explore the potential of DCC-3014, with the goal of making a meaningful impact on disease progression and, importantly, quality of life for patients with TGCT."

Preliminary Data from DCC-3014 in Initial TGCT Patients

The Company's Phase 1 study of DCC-3014 was designed to evaluate the safety, pharmacokinetics, and pharmacodynamics of multiple doses of DCC-3014 in patients with advanced solid tumors and TGCT. Tumor reductions from baseline were determined by investigator assessment by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. The CTOS presentation highlights preliminary results from the initial three TGCT patients enrolled in the dose-escalation portion of the Phase 1 study. Safety, pharmacokinetic, and pharmacodynamic data were analyzed as of September 10, 2019, with additional anti-tumor activity data reported as of November 8, 2019.

- All three patients with diffuse-type TGCT treated as of the data analyses dates showed preliminary anti-tumor activity.
 - As of their first tumor assessment at Cycle 3 Day 1, tumor reductions from baseline of 48%, 25% and 24%, respectively, were observed.
 - One patient had a confirmed partial response, which has been sustained for nine months and is ongoing as of the most recent investigator report, with a tumor reduction from baseline of 84% as of Cycle 10 Day 1.
- Symptomatic improvements in mobility and reduced pain, as reported by the investigator, were observed.
- These patients were enrolled in Cohort 5 (30 mg loading dose daily for 5 days followed by a maintenance dose of 30 mg twice a week).
- DCC-3014 was generally well-tolerated, with no grade 3 or higher treatment-emergent adverse events (TEAEs) observed.
- Two patients remained on study as of the November data analyses date. One patient discontinued in Cycle 4 due to relocation outside of the U.S.
- Dose-escalation evaluation is ongoing to determine the recommended Phase 2 dose for advanced solid tumors and diffuse-type TGCT.

Results from the INVICTUS Pivotal Phase 3 Study of Ripretinib

An encore presentation of results from the INVICTUS pivotal Phase 3 study of ripretinib in advanced GIST will be featured during an oral presentation session. INVICTUS 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 RECIST version 1.1.

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 prior treatment with imatinib, sunitinib and regorafenib in the first quarter of 2020.

Presentation Details

Poster Presentation:

Poster Title: Phase 1 study of DCC-3014 to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics, in patients with malignant solid and diffuse-type tenosynovial giant cell tumor

Author: Breelyn Wilky, M.D., Associate Professor, Department of Medicine, Division of Medical Oncology, University of Colorado Cancer Center, University of Colorado School of Medicine

Poster Viewing Reception Date and Time: Thursday, November 14, 2019, 5:30 – 6:30 PM JST

Location: 3rd Floor, Hilton Tokyo Hotel

Abstract Number: 3241734

Oral Presentation:

Poster Title: INVICTUS: A Phase 3, interventional, double-blind, placebo-controlled study to assess the safety and efficacy of ripretinib (DCC-2618) in patients with advanced gastrointestinal stromal tumors (GIST) who have received treatment with prior anticancer therapies (NCT03353753)

Session Title: GIST

Author: Jean-Yves Blay, M.D., General Director, Centre Léon Bérard and Université Claude Bernard Lyon 1, Lyon, France

Presentation Date and Time: Friday, November 15, 2019, 1:00- 1:12 PM JST

Location: Kiku Ballroom, Hilton Tokyo Hotel

Abstract Number: 3254072

A copy of each presentation is available at www.deciphera.com/science/presentation-publications/.

About DCC-3014

DCC-3014 is an investigational, orally administered, potent and highly selective inhibitor of CSF1R. DCC-3014 was designed using the Company's proprietary switch control kinase inhibitor platform to selectively bind to the CSF1R switch pocket. DCC-3014 has greater than 100-fold selectivity for CSF1R over other closely related kinases and has an even greater selectivity for CSF1R over approximately 300 other human kinases. CSF1R controls the differentiation and function of macrophages including tumor-associated macrophages (TAMs) whose density within certain tumors including cancers of the breast, cervix, pancreas, bladder and brain, as well as tenosynovial giant cell tumors (TGCT), correlates with poor prognosis. Tumors induce TAMs to suppress a natural immune response mediated by cytotoxic T-cells, a type of lymphocyte that would otherwise eradicate the tumor; a process known as macrophage checkpoints. Through inhibition of CSF1R, DCC-3014 has in preclinical studies demonstrated potent macrophage checkpoint inhibition as both a single agent and in combination with PD1 inhibitors. DCC-3014 is currently being evaluated in a Phase 1 clinical study. For more information about the clinical trial design please visit www.clinicaltrials.gov (NCT03069469).

About Ripretinib

Ripretinib is an investigational tyrosine kinase switch control inhibitor that was engineered to broadly inhibit KIT and PDGFR α 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 PDGFR α -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 PDGFR α 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. In October 2019, FDA granted Breakthrough Therapy Designation (BTD) for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib. For more information about the Company's clinical trials with ripretinib, please visit www.clinicaltrials.gov.

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 product 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, and agents designed to inhibit reprogramming of cancer cell metabolism. We have used our platform to develop a diverse pipeline of tumor-targeted, immuno-targeted, and metabolism-targeted product 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 our expectations regarding our ongoing Phase 1 study of DCC-3014, our plans to continue to enroll TGCT patients in this study, the potential benefits of DCC-3014 in patients with TGCT and other cancers, our planned potential NDA submission with FDA for ripretinib for patients with advanced GIST and the timing of such filing, the breakthrough therapy designation of ripretinib for patients with advanced GIST, and the potential of our pipeline product candidates to improve the lives of patients with cancer. 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 product candidates, including ripretinib, our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, the preclinical and clinical results for our product candidates, which may not support further development of

such product candidates, the possibility that results experienced in early, preliminary, top-line or initial data, including preliminary data from initial TGCT patients in our Phase 1 study of DCC-3014, may not be indicative of the results experienced in final data, our ability to timely complete and prepare the information required for and file an NDA for ripretinib, the fact that receipt of a breakthrough therapy designation for a product candidate, such as ripretinib, may not result in us receiving any of the benefits of such designation, 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 September 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20191113005738/en/>

Source: Deciphera Pharmaceuticals, Inc.

Investor Relations:

Jen Robinson
Deciphera Pharmaceuticals, Inc
jrobinson@deciphera.com
781-906-1112

Media:

David Rosen
Argot Partners
David.Rosen@argotpartners.com
212-600-1902