Deciphera Pharmaceuticals Presents Data from Rebastinib and DCC-3116 Programs at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

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- Combination of Rebastinib and Paclitaxel Exhibited Encouraging Preliminary Anti-tumor Activity Across Treatment Arms in the Ongoing Phase 1b/2 Clinical Study -

- DCC-3116 Represents a Differentiated Approach to Autophagy Inhibition and a First-in-Class Opportunity for a New Therapeutic Modality in Mutant RAS Cancers -

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 28, 2019-- Deciphera Pharmaceuticals, Inc. (Nasdaq:DCPH), a clinical-stage biopharmaceutical company addressing key mechanisms of tumor drug resistance, today presented data from its ongoing Phase 1b/2 clinical study of rebastinib, an oral TIE2 kinase inhibitor, in combination with paclitaxel at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston. In addition, the Company also presented data from preclinical studies of DCC-3116, a potential first-in-class autophagy inhibitor to treat mutant RAS cancers.

“Both of these datasets highlight the broad applicability of Deciphera’s kinase switch control platform and our potential to address unmet needs in oncology,” said Matthew L. Sherman, M.D., Executive Vice President and Chief Medical Officer of Deciphera. “We look forward to continuing Part 2 of our Phase 1b/2 study of rebastinib in combination with paclitaxel with the insights garnered from Part 1 of the study. We also look forward to advancing the IND-enabling studies for DCC-3116.”

Rebastinib

The Phase 1b/2 study of rebastinib in combination with paclitaxel is a two-part, open-label, multicenter study assessing the safety, tolerability, anti-tumor activity and pharmacokinetics of multiple doses of rebastinib in patients with advanced or metastatic solid tumors. Data presented today are from 43 patients from Part 1 of the study, including 24 patients from the rebastinib 50 mg oral twice a day (BID) with paclitaxel 80 mg/m^2 IV cohort and 19 patients from the rebastinib 100 mg oral BID with paclitaxel 80 mg/m^2 IV cohort. Preliminary results from Part 1 included:

- Encouraging preliminary anti-tumor activity was observed in both dose cohorts, with objective responses seen across a heavily pre-treated patient population, including patients with prior exposure to paclitaxel. Objective responses were seen in eight patients including ovarian (3), breast (2), carcinosarcoma (2), and peritoneal mesothelioma (1), seven of whom had prior therapy with paclitaxel or docetaxel. A best response of partial response (PR) was observed in 5 of 24 patients in the 50 mg BID dose cohort and 3 of 19 patients in the 100 mg BID dose.
- Exposure to rebastinib was dose-proportional at the 50 mg BID and 100 mg BID doses when given in combination with paclitaxel.
- Mean circulating Ang-2 levels increased with exposure to higher doses of rebastinib in combination with paclitaxel, indicating TIE2 inhibition.
- Rebastinib in combination with paclitaxel was generally well-tolerated, with similar frequency of treatment-emergent adverse events (TEAEs) between the two dose cohorts, and most TEAEs were consistent with first-in-human studies of rebastinib or known to be associated with treatment with paclitaxel.
- Based on the observed frequency of muscular weakness in preliminary data from the ongoing Part 2 portion of the study with the 100 mg BID dose, the recommended phase 2 dose (RP2D) was changed to 50 mg BID.

DCC-3116

DCC-3116 is designed as a potential autophagy inhibitor by selectively targeting ULK kinase. Autophagy is a cellular pathway that has been shown to be upregulated in mutant RAS cancers and that also mediates resistance to inhibitors of the RAS signaling pathway. Subject to favorable investigational new drug (IND)-enabling studies and filing and activation of an IND application, Deciphera intends to develop DCC-3116 for the potential treatment of mutant RAS cancers in combination with inhibitors of downstream effector targets including RAF, MEK, or ERK inhibitors (MAPK inhibitors) as well as with direct inhibitors of mutant RAS. Preclinical data presented today included the following:

- DCC-3116 was shown to be a potent, selective, and tight-binding inhibitor of ULK kinase.
- DCC-3116 inhibited phosphorylation of the ULK substrate ATG13 in cancer cells and exhibited synergy *in vitro* in combination with MAPK inhibitors in inhibiting cancer cell growth.
- Oral doses of DCC-3116 led to sustained inhibition of ULK activity as shown by the inhibited phosphorylation of the ULK substrate ATG13 *in vivo.*

- DCC-3116 exhibited synergy with MAPK inhibitors in tumor growth inhibition in mouse models.

A copy of each poster presentation is available at www.deciphera.com.

About Rebastinib

Rebastinib is an investigational, orally administered, potent and selective inhibitor of the TIE2 kinase, the receptor for angiopoietins, an important family of vascular growth factors in the tumor microenvironment that also activate pro-tumoral TIE2 expressing macrophages. In a Phase 1 clinical study, biomarker data have demonstrated rebastinib-induced increases in the TIE2 ligand angiopoietin 2, providing evidence of TIE2 inhibition. Rebastinib is currently being evaluated in a Phase 1b/2 clinical study in combination with paclitaxel (NCT03601897) and in a Phase 1b/2 clinical study in combination with carboplatin (NCT03717415).

About DCC-3116

DCC-3116 is a potential first-in-class small molecule designed to inhibit cancer autophagy, a key tumor survival mechanism, by inhibiting the ULK kinase. Subject to favorable investigational new drug (IND)-enabling studies and filing and activation of an IND application, expected in mid-2020, Deciphera intends to develop DCC-3116 for the potential treatment of mutant RAS cancers in combination with inhibitors of downstream RAS effector targets including RAF, MEK, or ERK inhibitors as well as with direct inhibitors of mutant RAS.

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 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, 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 drug 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 the broad applicability of our kinase switch control platform, the potential of our drug candidates to address unmet needs in oncology, continuation of Part 2 of our Phase 1b/2 study of rebastinib in combination with paclitaxel, advancing DCC-3116 through IND-enabling studies, and the timing of the potential filing of an IND for DCC-3116, subject to favorable IND enabling studies. 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, 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, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and regulatory development and other risks identified in our SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended June 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.

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