Deciphera Pharmaceuticals Initiates a Phase 1b/2 Clinical Trial of Rebastinib in Combination with Carboplatin in Patients with Advanced or Metastatic Solid Tumors

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- Rebastinib is a Potent and Selective Inhibitor of the TIE2 kinase, the Receptor for Angiopoietins, an Important Family of Vascular Growth Factors Involved in Tumor Growth, Survival and Metastasis -

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 3, 2019-- 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 an open-label, multicenter, Phase 1b/2 study of rebastinib, the Company's investigational small molecule switch control inhibitor of TIE2 kinase, in combination with carboplatin in patients with advanced or metastatic solid tumors.

"We are extremely pleased with the recent progress made on our rebastinib program, including today's announcement that we have initiated a second Phase 1b/2 clinical study of rebastinib in combination with chemotherapy," said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. "This second clinical study will evaluate rebastinib in combination with carboplatin, a treatment regimen that, based on preclinical observations, we believe has the potential to be an important new approach to treating patients with advanced solid tumors."

Part 1 (3+3 dose escalation) of this two part study is designed to evaluate the safety, tolerability and pharmacokinetics of 50 mg and 100 mg rebastinib twice daily (BID) when administered in combination with carboplatin, and to determine the recommended phase 2 dose (RP2D) of rebastinib in combination with carboplatin, in patients with advanced or metastatic solid tumors that are refractory to standard therapies. In part 2, the safety, tolerability and efficacy of the RP2D of rebastinib in combination with carboplatin administered once every 3 weeks will be assessed across multiple disease cohorts, including: breast cancer, ovarian cancer, and mesothelioma. This trial is expected to enroll up to 117 patients in total, with approximately 18 patients in part 1 and up to 99 patients in part 2. For more information about the clinical trial design please visit www.clinicaltrials.gov (NCT03717415).

"The biological mechanisms by which tumors co-opt the surrounding microenvironment to grow, survive and become more invasive, are becoming better understood. Recent research indicates that TIE2 kinase is involved in multiple mechanisms favoring a pro-tumoral microenvironment, including the regulation of a population of immunosuppressive macrophages, promotion of tumor angiogenesis, and function of perivascular pumps that lead to tumor cell recruitment and metastasis," said Daniel L. Flynn, Ph.D., Chief Scientific Officer of Deciphera. "In addition, use of chemotherapeutic agents are believed to enhance the recruitment of these macrophages, leading to increased tumor vascularization and dissemination. In preclinical studies rebastinib has been shown to block these unintended effects of chemotherapy, providing rationale for the potential combination of rebastinib with chemotherapy."

Preclinical information on the role of TIE2 kinase was published in Molecular Cancer Therapeutics, 2017; 16: 2486-2501 and Science Translational Medicine, July 5, 2017; 9: eaan0026.
(www.deciphera.com/science/presentation-publications/)

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, secondary to TIE2 inhibition. Rebastinib is currently being evaluated in a Phase 1b/2 clinical study in combination with paclitaxel (NCT03601897), in a Phase 1b/2 clinical study in combination with carboplatin (NCT03717415), and in an investigator sponsored Phase 1b trial in patients with metastatic breast cancer in combination with paclitaxel or eribulin (NCT02824575).

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 our expectations of our clinical trials with our investigational agent rebastinib, including, without limitation, our study of rebastinib in combination with carboplatin, and the potential for rebastinib, alone or in combination with other agents or chemotherapy to treat cancers. 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 (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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