Deciphera Pharmaceuticals Provides Corporate Update and Highlights Key 2020 Milestones

January 13, 2020

- Ripretinib Marketing Applications Submitted to Health Canada and Australia's Therapeutic Goods Administration for Patients with Advanced GIST via the U.S. FDA's Project Orbis Pilot Program -

- Commercial Preparations Underway to Support Potential Approval and Launch of Ripretinib in the U.S. for Patients with Advanced GIST -

- INTRIGUE Pivotal Phase 3 Study of Ripretinib in 2nd line GIST Expected to Complete Enrollment in the Second Half of 2020 -

- Additional Pipeline Development Milestones Expected in Second Half of 2020 -

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 13, 2020-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today provided a corporate update and highlighted key 2020 milestones in conjunction with its presentation at the 38th Annual J.P. Morgan Healthcare Conference in San Francisco. The Company will webcast its presentation today at 11:00 a.m. PT (2:00 p.m. ET) at https://investors.deciphera.com/news-events/events-presentations.

"2019 was a year of many exciting accomplishments for Deciphera as we submitted our first New Drug Application (NDA) to the FDA for ripretinib in advanced gastrointestinal stromal tumors (GIST) based on positive results from the INVICTUS pivotal Phase 3 study and advanced our portfolio of wholly-owned product candidates," said Steve Hoerter, President and Chief Executive Officer of Deciphera. "We are preparing for a potential commercial launch in the U.S. and working to bring ripretinib to other parts of the world."

The Company announced today that two additional marketing applications have been submitted for ripretinib as part of the U.S. Food and Drug Administration's (FDA) Project Orbis pilot program. The marketing applications of ripretinib for advanced GIST in Canada and Australia have both received priority review designations. The Project Orbis pilot program, an initiative of the FDA Oncology Center of Excellence, is designed to provide a framework for concurrent submission and review of oncology products among international partners. Additional information about Project Orbis can be found at: https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis.

Mr. Hoerter continued, "In parallel with these efforts, we have laid the groundwork for further expansion across our pipeline of novel agents. We continued to activate sites and enroll patients in the INTRIGUE Phase 3 study in the 2nd line GIST patient population, advanced the DCC-3014 and rebastinib clinical development programs, and added a new internally-discovered candidate, DCC-3116, to our pipeline. We look forward to building on our momentum in 2020 as we work with the FDA towards a potential approval of ripretinib in advanced GIST and rapidly advance our additional programs."

In 2020, the Company seeks to achieve the following milestones:

Ripretinib
- Potential FDA approval and commercial launch of ripretinib in advanced GIST.
- Submit marketing authorization application to European Medicines Agency.
- Complete enrollment of INTRIGUE Phase 3 study in 2nd line GIST.
- Present Phase 1 study expansion data.

DCC- 3014
- Select Phase 2 dose for tenosynovial giant cell tumor (TGCT) patients and open expansion cohort.
- Provide update on Phase 1 data in TGCT patients.

Rebastinib
- Selected Phase 2 dose of 100 mg BID of rebastinib and activated Part 2 of Phase 1b/2 study in combination with carboplatin. (Completed January 2020)
- Present Phase 1b/2 data in combination with carboplatin.
- Present Phase 1b/2 data in combination with paclitaxel.

DCC-3116
- Submit an Investigational New Drug (IND) application to FDA.

Presentation at 38th Annual J.P. Morgan Healthcare Conference

Deciphera will webcast its corporate presentation from the 38th Annual J.P. Morgan Healthcare Conference in San Francisco on Monday, January 13, 2020 at 11:00 a.m. PT (2:00 p.m. ET). A live webcast of the presentation can be accessed under "Events & Presentations" in the Investors section of the Company's website at deciphera.com. A replay of the webcast will be archived on the Deciphera website for at least two weeks following the presentation. In conjunction with the conference, the Company has also updated its corporate presentation which can be found here: https://investors.deciphera.com/news-events/events-presentations.

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 goal of bringing ripretinib to patients with advanced GIST, the potential for ripretinib to serve as an important new treatment option for people with advanced GIST, working with the FDA through its review of our NDA application via the FDA's Real-Time Oncology Review pilot program, working with the FDA, Health Canada and the Therapeutic Goods Administration on our Canadian and Australian regulatory approval filings under the Project Orbis pilot program, and the possible benefits of those pilot programs and breakthrough therapy designation, receipt of priority review, preparing for the potential launch of ripretinib in the United States, if approved, and corporate guidance for 2020, including related to our expectations and timing for an MAA submission to the EMA for ripretinib in advanced GIST patients, presentation of additional Phase 1 ripretinib expansion data, completion of enrollment in the INTRIGUE Phase 3 study, selection of a recommended Phase 2 dose for DCC-3014 and opening a TGCT expansion cohort in such trial, the timing of and our expectations regarding our product candidates, including data for DCC-3014 from TGCT patients, data updates for rebastinib and submitting an IND for DCC-3116. 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 may not be indicative of the results experienced in final data, our ability to work with the FDA under its RTOR pilot program and our ability to work with the FDA, Health Canada and the TGA under the Project Orbis pilot program and timely respond to information requests or requirements in connection with our recently-filed NDAs and marketing approval applications in Canada and Australia for ripretinib in advanced GIST, that acceptance into the RTOR and Project Orbis pilot programs does not guarantee or influence approvability of our NDAs for ripretinib in advanced GIST, which are subject to the standard benefit-risk evaluation by FDA, Health Canada and the TGA, and that we may not derive any benefit from inclusion in the RTOR or Orbis pilot programs, including, but not limited to, a more efficient review process compared to investigational drugs evaluated without these pilot programs or under standard FDA, Health Canada or TGA procedures, the fact that these pilot programs are being tested by FDA, are not formal regulatory pathways with regulatory process, regulations or procedures, and may be suspended or halted at any time, including, without limitation, because FDA decides not to continue these pilots, or because FDA determines that our application no longer meets its criteria for inclusion in one or both of these pilot programs, 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 such as a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, the fact such designation does not assure ultimate approval by FDA and is subject to the risk FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened, the fact that any priority review received may not result in any more efficient review or other benefits, our ability to manage and our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, actions of regulatory agencies, our ability to plan for potential commercialization of our product candidates, such as ripretinib, and if approved execute on our marketing plans, the inherent uncertainty in estimates of patient populations and incidence and prevalence estimates, competition from other products, our ability to obtain and maintain reimbursement for any approved product and the extent to which patient assistance programs are utilized, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, 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, including ripretinib, available to patients, and, once commercial, to derive revenue from product sales, 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.

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