



Deciphera Presents Data from Rebastinib, its TIE2 Inhibitor Program, at the European Society for Medical Oncology (ESMO) Virtual Congress 2020

September 17, 2020

- Rebastinib Combined with Paclitaxel Showed Encouraging Preliminary Clinical Benefit and Favorable Tolerability in Patients with Platinum-resistant Ovarian Cancer -

- Rebastinib Combined with Carboplatin was Well-tolerated in Patients with Metastatic Solid Tumors and Showed Initial Clinical Activity -

WALTHAM, Mass.--(BUSINESS WIRE)--Sep. 17, 2020-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), today announced the presentation of data from the ovarian cancer cohort in Part 2 of the ongoing Phase 1b/2 study of rebastinib, the Company's selective TIE2 inhibitor, in combination with paclitaxel and from Part 1 of the Phase 1b/2 study of rebastinib in combination with carboplatin. The E-poster presentations, titled "A phase 1b/2 study of rebastinib and paclitaxel in advanced or metastatic platinum-resistant ovarian cancer" and "A phase 1 study of rebastinib and carboplatin in patients with metastatic solid tumors," were featured at the ESMO Virtual Congress 2020, being held September 19-21, 2020.

"Data presented today continue to support the potential of the TIE2 inhibitor rebastinib when combined with paclitaxel or carboplatin across a broad spectrum of solid tumor types," said Matthew L. Sherman, MD, Executive Vice President and Chief Medical Officer of Deciphera. "Earlier this year we presented promising data supporting the combination of rebastinib and paclitaxel in patients with endometrial cancer. We are pleased that the preliminary data with this combination in patients with ovarian cancer has also demonstrated encouraging efficacy, with a 38% objective response rate, confirmed and unconfirmed, and a clinical benefit rate at eight weeks of 88% in the modified intent-to-treat population. In addition, the combination of rebastinib and carboplatin in Part 1 of the ongoing Phase 1b/2 study was generally well tolerated and showed initial clinical activity with the combination in a heterogeneous, heavily pre-treated group of patients with advanced solid tumors."

Phase 1b/2 Study of Rebastinib and Paclitaxel in Advanced or Metastatic Platinum-resistant Ovarian Cancer

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 rebastinib in patients with advanced or metastatic solid tumors. As previously announced, a recommended Phase 2 dose of rebastinib 50 mg twice-daily (BID) in combination with paclitaxel was selected, based on activity observed in Part 1 of the study, and both the endometrial and ovarian cancer cohorts in Part 2 of the study advanced into Stage 2 of the Simon two-stage design based on demonstrating at least five responses in each cohort in Stage 1.

Data [previously presented](#) from the endometrial cancer cohort showed encouraging preliminary anti-tumor activity and favorable tolerability with an objective response rate of 39% (confirmed and unconfirmed) and a clinical benefit rate of 72% at eight weeks in the modified intent-to-treat population of 18 patients.

Data presented at the ESMO Virtual Congress 2020 are from a total of 29 patients in the platinum-resistant ovarian cancer expansion cohort in Part 2 of the study who initiated treatment as of June 3, 2020, with follow-up data through July 31, 2020. Ten patients were treated at the starting dose of rebastinib 100 mg BID + weekly paclitaxel 80 mg/m² (three patients remained at this dose and seven patients reduced to rebastinib 50 mg BID) and 19 patients were treated at a starting dose of rebastinib 50 mg BID + weekly paclitaxel 80 mg/m². Preliminary efficacy results are from 24 of the 29 patients that met the modified intent-to-treat (mITT) criteria.

Preliminary results from Part 2 included:

- Of the 24 patients in the mITT population, there were nine partial responses (3 confirmed, 3 to be confirmed at future follow-up, and 3 unable to be confirmed) and 12 patients with stable disease, for an objective response rate of 38% and a clinical benefit rate, defined as the proportion of patients with best overall response of complete response, partial response, or stable disease per RECIST v1.1, of 88% at eight weeks.
- Median treatment duration for the mITT population was 4.2 months.
- A CA-125 response, as defined by the Gynecological Cancer Intergroup CA-125 criteria, occurred in 10 of 17 (59%) evaluable patients.
- Treatment with rebastinib 50 mg BID in combination with paclitaxel was generally well-tolerated, with treatment-emergent adverse events (TEAEs) consistent with findings from Part 1 of the study and consistent with the first-in-human study of rebastinib, or known to be associated with treatment with paclitaxel.
- TEAEs occurring in ≥25% of patients regardless of causality were fatigue (41%), dry mouth (38%), nausea (34%), diarrhea (31%), stomatitis (31%), abdominal pain (28%), and peripheral sensory neuropathy (28%). Eleven patients (38%) had a TEAE of Grade ≥3.
- Two patients experienced serious adverse events at least possibly related to rebastinib: muscular weakness/fatigue (starting dose rebastinib 100 mg BID and resolved with drug interruption) and urinary tract infection (starting dose rebastinib 50 mg BID).

Enrollment in Stage 2 of the platinum-resistant ovarian cancer cohort at the rebastinib 50 mg BID dose is near completion and further efficacy and

safety evaluation is ongoing.

Phase 1b/2 Study of Rebastinib and Carboplatin in Patients with Metastatic Solid Tumors

The ongoing Phase 1b/2 study of rebastinib in combination with carboplatin is a two-part, open-label, multicenter study assessing the safety, tolerability, anti-tumor activity, and pharmacokinetics in patients with advanced or metastatic solid tumors. Data presented at the ESMO Virtual Congress 2020 are from 22 patients with advanced or metastatic solid tumors enrolled into Part 1 of the study. Patients were enrolled into one of three dose escalation cohorts of rebastinib in combination with carboplatin administered once every three weeks (Q3W): rebastinib 50 mg BID + carboplatin area under the plasma concentration-time curve (AUC) 5 (n=3), rebastinib 100 mg BID + carboplatin AUC5 (n=14), rebastinib 100 mg BID + carboplatin AUC6 (n=5).

Preliminary results from Part 1 included:

- Rebastinib in combination with carboplatin was generally well-tolerated. The majority of TEAEs were Grade 1 and Grade 2. One patient (rebastinib 50 mg BID) experienced a rebastinib-possibly related serious adverse event (Grade 2 retinal vascular disorder).
- Based on a higher observed frequency of reversible muscular weakness (Grade 1–2) in preliminary data from the ongoing Part 2 portion of the study phase at rebastinib 100 mg BID, the recommended Phase 2 dose was changed to rebastinib 50 mg BID + carboplatin AUC5 Q3W.
- The clinical benefit rate, defined as the proportion of patients with best overall response of complete response, partial response, or stable disease per RECIST v1.1, was 50% at six weeks and 36% at twelve weeks, and the median duration of treatment was 7.8 weeks.
- One patient (4.5%) had a partial response (unconfirmed) and 10 patients (46%) had stable disease as best response in this heterogeneous, heavily-treated population where all patients received at least two or more prior anti-cancer regimens and 50% received four or more prior regimens.
- At the rebastinib 50 mg BID dose level, the exposure of rebastinib was generally comparable to previously published data.
- Mean circulating Ang-2 levels increased after eight days of treatment for all doses, indicating TIE2 inhibition.

The Part 2 portion of the ongoing Phase 1/2 study is currently enrolling and will evaluate the safety and efficacy of rebastinib at the recommended Phase 2 dose in combination with carboplatin in patients with triple-negative breast cancer, recurrent platinum-sensitive ovarian cancer, and mesothelioma.

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 Deciphera Pharmaceuticals

Deciphera is a biopharmaceutical company focused on discovering, developing and commercializing important new medicines to improve the lives of people with cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from our platform in clinical studies, QINLOCK™ is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is also approved for fourth-line GIST in Canada and Australia. For more information, visit www.deciphera.com and follow us on [LinkedIn](#) and Twitter (@Deciphera).

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, our expectations regarding the potential benefit of rebastinib in combination with paclitaxel or carboplatin in solid tumor patients, including in cancers such as endometrial cancer and PROC. 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 severity and duration of the impact of COVID-19 on our business and operations, our ability to successfully demonstrate the efficacy and safety of our drug candidates and in additional indications for our existing drug, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, our ability to manage 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 commercialize QINLOCK and execute on our marketing plans for any drugs or indications that may be approved in the future, the inherent uncertainty in estimates of patient populations, 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 additional regulatory approvals, and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, 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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