# Deciphera Pharmaceuticals Presents New Clinical Study Results Across Pipeline at the European Society for Medical Oncology (ESMO) Congress 2021

September 17, 2021

*– Rebastinib in Combination with Paclitaxel Demonstrated Progression Free Survival of 9.1 months in Heavily Pretreated Patients with Platinum-Resistant Ovarian Cancer (PROC) –*

*– Pivotal Phase 3 Study of Rebastinib plus Paclitaxel in PROC Planned to Initiate in 2022 Subject to Regulatory Feedback –*

*– Updated Results for Vimseltinib Showed Objective Response Rate of 47% in Patients with Tenosynovial Giant Cell Tumor (TGCT) –*

*– Pivotal Phase 3 Study of Vimseltinib in TGCT Expected to Initiate in the Fourth Quarter of 2021 –*

*– Company to Host Virtual Investor Event to Discuss Rebastinib and Vimseltinib Results Today at 10 AM ET –*

WALTHAM, Mass.--(BUSINESS WIRE)--Sep. 17, 2021-- Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a commercial-stage biopharmaceutical company developing innovative medicines to improve the lives of people with cancer, today announced four e-poster presentations at the ESMO Congress 2021. The presentations include updated preliminary results from the ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in patients with PROC and updated preliminary results from the ongoing Phase 1/2 study of vimseltinib in patients with TGCT. A long-term update on the Phase 3 INVICTUS study of QINLOCK® (ripretinib) in patients with advanced gastrointestinal stromal tumors (GIST), and results from the expansion phase of the Phase 1 study of ripretinib in patients with KIT-altered metastatic melanoma will also be presented.

All e-poster presentations are now available on-demand via the ESMO website and on the Company's website at www.deciphera.com/presentations-publications. Deciphera will also host an investor event featuring key opinion leaders to discuss the rebastinib and vimseltinib data today, September 17, 2021, at 10 AM ET. A live webcast of the event may be accessed through the "Investors" section of Deciphera's website at www.deciphera.com. A replay of the webcast will be available following the event.

"We are excited to present strong results at this year's ESMO Congress, which support both our plans to initiate a Phase 3 pivotal study for rebastinib pending regulatory feedback, and our plans to initiate a Phase 3 pivotal study for vimseltinib. The updated safety and efficacy results for rebastinib in combination with paclitaxel show highly encouraging results, including a median progression free survival of 9.1 months, in heavily pretreated patients with PROC where additional treatment is heterogeneous and single agent paclitaxel retreatment has historically shown only 3-4 months of PFS. Based on these impressive results in patients with a significant unmet medical need, we have begun planning for a pivotal Phase 3 study that we plan to initiate in 2022 following regulatory feedback," said Matthew L. Sherman, MD, Executive Vice President and Chief Medical Officer of Deciphera. "We are equally encouraged by the tolerability and efficacy data presented today from the Phase 1/2 study of vimseltinib in TGCT. The data presented today with vimseltinib in TGCT reinforce its potential to be a best-in-class treatment for this disease. We are rapidly moving forward with this program and we expect to initiate our Phase 3 study, MOTION, in the fourth quarter of this year."

Dr. Sherman continued, "In addition to rebastinib and vimseltinib, we presented positive results from the Phase 1 study of ripretinib in patients with KIT-altered metastatic melanoma, and a long-term update from the Phase 3 INVICTUS study of QINLOCK, which shows further prolonged clinically meaningful median overall survival among patients receiving QINLOCK. Finally, we look forward to our Phase 3 INTRIGUE readout later this year in patients with second-line GIST."

**Updated Preliminary Data from the Ongoing Phase 1b/2 Study of Rebastinib in Combination with Paclitaxel in PROC**

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. The data presented today is from the second stage of Part 2 of the Simon two-stage design in PROC.

As of the June 22, 2021 cutoff date, 38 patients with PROC initiated treatment with rebastinib and paclitaxel and are included in the safety population and 34 patients that met the criteria for the modified intent-to-treat population (mITT) are included in the efficacy analysis.

- The median progression-free survival (PFS) was 9.1 months.
- There were 13 patients with objective responses (10 confirmed) for an objective response rate (ORR) of 38% (confirmed and unconfirmed) and 29% (confirmed only) with a median duration response of 5.5 months.
- The clinical benefit rate at 16 weeks was 76%.
- A CA-125 response occurred in 19 of 26 patients (73%).
- Rebastinib in combination with paclitaxel was generally well tolerated at 50 mg BID, and most common (≥15%) treatment-emergent adverse events (TEAEs) were Grade 1 or 2.
- Four patients experienced serious adverse events (SAEs) at least possibly related to rebastinib including reversible muscular weakness (n=2), constipation (n=1), fatigue (n=1), and urinary tract infection (n=1).

Based on the strength of these findings, the Company has begun planning for a pivotal study in PROC that is anticipated to start in 2022, subject to feedback from regulators.

**Updated Preliminary Data from the Ongoing Phase 1/2 Study of Vimseltinib in TGCT**

The Phase 1/2 study of vimseltinib is an open-label, multicenter study evaluating the safety, efficacy, pharmacokinetics, and pharmacodynamics of vimseltinib in patients with solid tumors and TGCT. The data today is from patients with TGCT in both the Phase 1 dose escalation portion of the study and from cohort A in the Phase 2 expansion portion of the study. Cohort A includes TGCT patients with no prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib is allowed) and cohort B includes patients with prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib are not eligible).

As of the June 7, 2021 cutoff date, 68 TGCT patients were treated with vimseltinib and included in the safety population, including 32 TGCT patients enrolled in the Phase 1 dose escalation portion of the study and 36 TGCT patients enrolled in cohort A in the Phase 2 portion of the study. Efficacy data presented today is from 51 TGCT patients, including all 32 TGCT patients enrolled in the Phase 1 dose escalation portion of the study and 19 TGCT patients enrolled in cohort A in the Phase 2 portion of the study that were evaluable for efficacy as of the cutoff date.

Dose Cohorts and Demographics:

- 32 patients enrolled in Phase 1 (dose escalation) and 36 patients enrolled in Phase 2 cohort A (expansion):
  - Phase 1 cohort 5 (n=8): 30 mg loading dose daily for five days followed by a maintenance dose of 30 mg twice a week.
  - Phase 1 cohort 8 (n=12): 30 mg loading dose daily for three days followed by a maintenance dose of 10 mg daily.
  - Phase 1 cohort 9 (n=12): 20 mg loading dose daily for three days followed by a maintenance dose of 6 mg daily.
  - Phase 2 cohort A (n=36): 30 mg twice weekly (no loading dose).
- 12 out of 32 patients (38%) in Phase 1 and 32 out of 36 patients (89%) in Phase 2 cohort A had at least one prior surgery; five patients (16%) in Phase 1 and two patients (6%) in Phase 2 cohort A had received at least one prior systematic therapy.
- 51 patients were evaluable for efficacy by Response Evaluation Criteria In Solid Tumors (RECIST) v1.1 at the data cutoff in Phase 1 across all dose cohorts and in Phase 2 cohort A; response data is based on independent central radiologic review with the exception of one patient who had a local assessment, and for whom no central assessment was performed.

Updated Preliminary Efficacy and Duration of Treatment:

- Of the 51 efficacy-evaluable patients in Phase 1 across all dose cohorts and in the Phase 2 cohort A, 24 patients had a response resulting in an ORR of 47%.
  - Of the 32 patients in Phase 1, 16 patients achieved an objective response for an ORR of 50% with durable responses observed across all dose cohorts, including one complete response in cohort 5. The median duration of treatment for all patients was 10.1 months. 72% of patients remain active in the study as of the data cutoff date.
  - Of the 36 patients enrolled in Phase 2 cohort A, 19 patients were evaluable for efficacy, of which there were eight patients with an objective response for an ORR of 42%. Of the 19 patients, 10 had more than one follow-up imaging assessment and two responses occurred at later scans. The median duration of treatment for all patients was 1.9 months. The study is ongoing and follow-up evaluation is continuing with 83% of patients remaining active as of the data cutoff date.

Safety and Tolerability:

- In both Phase 1 and Phase 2 cohort A, treatment with vimseltinib was generally well tolerated in patients with TGCT. Two patients (6%) discontinued treatment due to a TEAE in Phase 1 and one patient (3%) discontinued treatment due to an TEAE in Phase 2 cohort A.
- Two patients experienced SAEs at least possibly related to vimseltinib, including metabolic encephalopathy and vaginal hemorrhage in Phase 1; no treatment-related SAEs were reported in Phase 2 cohort A.
- The majority of the common (≥15%) TEAEs were Grade 2 or lower.
- Observed transaminase, pancreatic, and creatine phosphokinase enzyme elevations were mostly low grade, asymptomatic, and consistent with mechanism of action of CSF1R inhibitors.
- No abnormalities in bilirubin levels were reported.

**Phase 3 MOTION Study**

Based on the positive results of the ongoing Phase 1/2 study, the Company plans to advance vimseltinib into a pivotal Phase 3 study in patients with TGCT. The MOTION study is two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with symptomatic TGCT who are not amenable to surgery. In Part 1 of the study, eligible study participants will be assigned to receive either vimseltinib or matching placebo for 24 weeks. Participants assigned to placebo in Part 1 will have the option to receive vimseltinib for Part 2 of the study. Part 2 is a long-term treatment phase in which all participants receive open-label vimseltinib. The primary endpoint of the study is ORR at 25 weeks as measured by RECIST v1.1 by blinded independent central review. The Company expects to initiate the MOTION study in the fourth quarter of this year.

**Long-term Update from Phase 3 INVICTUS Study of QINLOCK in Patients with Advanced GIST**

The INVICTUS Phase 3 clinical study is a randomized (2:1), double-blind, placebo-controlled, international, multicenter study to evaluate the safety,

tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. The Company previously reported primary results from the randomized portion of the INVICTUS study, in which QINLOCK significantly improved PFS and showed a clinically meaningful overall survival (OS) benefit.

An exploratory evaluation of primary and secondary endpoints in the Phase 3 INVICTUS study, with a cutoff date of January 15, 2021, an additional 19 months after the primary analysis, demonstrates consistent PFS with no change since the primary data cut off, and improved median OS among patients receiving ripretinib.

- Median PFS was 6.3 months with QINLOCK compared to 1.0 month with placebo.
- Median OS was 18.2 months with QINLOCK compared to 6.3 months with placebo.
- Median OS was 10 months in placebo patients who crossed over to QINLOCK.
- Median ORR was 11.8% with QINLOCK compared to 0% with placebo.
- Median duration of response with QINLOCK was 14.5 months.

Safety findings were consistent with the primary analysis results and most TEAEs were Grade 1 or 2. Increases in TEAEs and TEAEs leading to dose modifications in the additional 19 months of follow up were minimal.

These more mature results continue to support the clinically meaningful benefit in PFS and OS for QINLOCK with an acceptable safety profile in patients with advanced GIST treated with three or more prior lines of therapy.

**Phase 1 Study of Ripretinib in Patients with KIT-altered Metastatic Melanoma**

As part of the expansion phase of the Phase 1 study, 26 patients with KIT-altered metastatic melanoma were treated with ripretinib at the recommended Phase 2 dose of 150 mg daily in repeated 28-day cycles. Tumor progression was assessed by the investigator using computed tomography/magnetic resonance imaging according to RECIST v1.1 on day 1 of cycles 3, 5, 7, and every three cycles thereafter, and a final study visit. ORR was confirmed with follow-up imaging approximately 28 days later. Patients who had disease progression at ripretinib 150 mg daily were allowed to dose escalate to 150 mg twice daily.

- Ripretinib demonstrated encouraging efficacy in patients with KIT-altered metastatic melanoma with a confirmed ORR of 23%, median duration of response of 9.1 months, and median PFS of 7.3 months. In addition, there were two unconfirmed partial responses resulting in an ORR of 31% (confirmed and unconfirmed).
- Tyrosine kinase inhibitor (TKI)-naïve patients had a greater response (confirmed ORR of 29% and median PFS of 10.2 months) to ripretinib than those with prior TKI treatment (confirmed ORR of 11% and median PFS of 2.9 months).
- Ripretinib had an acceptable safety profile in KIT-altered metastatic melanoma consistent with the approved indication in GIST.

**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 Australia, Canada, China, Hong Kong, and Taiwan. 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 and timing regarding top-line data from our Phase 3 INTRIGUE study in second-line GIST, pivotal study plans and timing of study initiation for vimseltinib in TGCT patients and for the rebastinib/paclitaxel combination in platinum-resistant ovarian cancer patients, subject to feedback from regulators, and the potential for vimseltinib to be a best-in-class treatment for TGCT. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "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, comments, feedback and 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, our ability to build and scale our operations to support growth in additional geographies, 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, 2021, 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 our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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