Deciphera Pharmaceuticals Announces Planned 2023 Corporate Milestones to Support Continued Evolution to Multi-Product Company

January 3, 2023

– Plans to Initiate Pivotal Phase 3 INSIGHT Study of QINLOCK® Versus Sunitinib in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18 Only in the Second Half of 2023 Based on ctDNA Analysis from INTRIGUE Study –

– Expects to Complete Enrollment in the Pivotal Phase 3 MOTION Study of Vimseltinib in the First Half of 2023 and Announce Top-line Results in the Fourth Quarter of 2023 –

– Expects to Evaluate DCC-3116 in a Combination Study with Encorafenib and Cetuximab in Patients with Colorectal Cancer; Announces Clinical Trial Collaboration and Supply Agreement for Encorafenib with Pfizer –

– Preliminary Unaudited Revenue of Approximately $36 Million for the Fourth Quarter 2022 and Approximately $134 Million for the Full Year 2022; Cash, Cash Equivalents, and Marketable Securities Approximately $339 million as of December 31, 2022 –

– Conference Call to be Held Today at 5:00 PM ET –

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 3, 2023-- Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer, today highlighted its strategic outlook for 2023 and planned 2023 corporate milestones, and announced preliminary unaudited fourth quarter and full year 2022 revenue.

In a separate press release issued today, Deciphera announced results from an exploratory analysis of circulating tumor DNA (ctDNA) from the INTRIGUE Phase 3 clinical study of QINLOCK in patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib, demonstrating substantial clinical benefit of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18 only. The Company also announced plans to initiate the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in this patient population in the second half of 2023.

“We are extremely proud of the significant progress made across our pipeline in 2022 and are in a strong position to build upon this momentum in 2023 with key commercial, clinical, and preclinical milestones on the horizon,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “We believe that Deciphera is on track to become a company with multiple approved products, and that QINLOCK and vimseltinib together have the potential to exceed one billion dollars in global revenue annually. At the same time, we continue to complement these commercial goals with research and development innovation powered by our proprietary switch-control discovery platform to drive new growth opportunities with potential first-in-class or best-in-class kinase inhibitors.”

Business updates and planned 2023 corporate milestones include:

QINLOCK® (ripretinib)

- Present additional data from the INTRIGUE Phase 3 exploratory ctDNA analysis at a medical meeting in January 2023.
- Initiate the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only in the second half of 2023.

- Continue European geographic expansion of QINLOCK in 2023, with planned commercial launches following conclusion of pricing and reimbursement negotiations in key European markets.

Vimseltinib

- Complete enrollment for the pivotal Phase 3 MOTION study of vimseltinib, an investigational, orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R for the potential treatment of tenosynovial giant cell tumor (TGCT), in the first half of 2023 and announce top-line results from the study in the fourth quarter of 2023.
- Present updated data from the Phase 1/2 study of vimseltinib in the second half of 2023.

DCC-3116

- Present updated data from the single agent dose escalation phase and initial data from the combination dose escalation cohorts of the Phase 1/2 study of DCC-3116, an investigational switch-control kinase inhibitor of ULK1/2 designed to inhibit autophagy, in the second half of 2023.
- Initiate one or more expansion cohorts in the ongoing Phase 1/2 study of DCC-3116 in the second half of 2023 in combination with the MEK inhibitors trametinib or binimetinib, or the $KRAS^{G12C}$ inhibitor sotorasib.
- Initiate a new dose escalation combination study evaluating DCC-3116 in combination with encorafenib and cetuximab in patients with colorectal cancer in the second half of 2023. Under the terms of the clinical trial collaboration and supply agreement with Pfizer, Inc., Deciphera will sponsor the trial and Pfizer will supply encorafenib at no cost.
- Present preclinical data on new clinical combinations with DCC-3116 in the first half of 2023.

DCC-3084

- Submit an investigational new drug (IND) application with the FDA for DCC-3084, a potential best-in-class pan-RAF inhibitor, in the second half of 2023.
- Present *in vitro* and *in vivo* data demonstrating a preclinical profile as a potent and selective inhibitor of BRAF/CRAF kinases, with optimized pharmaceutical properties for development in both single-agent and combination opportunities, in the first half of 2023.

Kinase Switch-Control Research Engine

- Nominate a new development candidate from Deciphera's proprietary discovery engine of novel switch-control inhibitors in the first half of 2023.
- Present new preclinical data from research programs at medical meetings in 2023.

Preliminary 2022 Financial Results

Based on preliminary unaudited financial information, Deciphera expects total fourth quarter 2022 revenue to be approximately $36 million and total full year 2022 revenue to be approximately $134 million. QINLOCK net product revenue is estimated to be approximately $33 million, including approximately $26 million in U.S. net product revenue and approximately $7 million in international net product revenue, in addition to approximately $3 million in collaboration revenue. International and total net product revenue for the fourth quarter includes a one-time reserve for QINLOCK product sales in Germany due to a change in German law effective retroactively as of November 2022 shortening the free pricing period to six months from twelve months.

In addition, cash, cash equivalents, and marketable securities was approximately $339 million as of December 31, 2022. Based on its current operating plans, Deciphera expects its current cash, cash equivalents, and marketable securities together with anticipated product, royalty, and supply revenues, but excluding any potential future milestone payments under its collaboration or license agreements, will enable the Company to fund its operating and capital expenditures into 2025.

Preliminary selected financial information presented in this release are unaudited, subject to adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results expected in February 2023.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss the ctDNA analysis results from the INTRIGUE Phase 3 clinical study, its planned 2023 corporate milestones and a general business update, today, January 3, 2023, at 5:00 PM ET. The conference call may be accessed via this link: https://register.vevent.com/register/BI4841f7cb08a04e5ba80127e42e643432. A live webcast of the conference call will be available in the "Events and Presentations" page in the "Investors & News" section of the Company's website at https://investors.deciphera.com/events-presentations. A replay will be available on the Company's website approximately two hours after the conference call and will be available for 30 days following the call.

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 switch control inhibitor for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the European Union, Hong Kong, Switzerland, Taiwan, the United Kingdom, and the United States. 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 the potential for our preclinical and/or clinical stage pipeline assets to be first-in-class and/or best-in-class treatments, our planned Phase 3 INSIGHT clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only, our plans to present results from the Phase 3 INTRIGUE ctDNA analysis, our plans to continue our geographic expansion of QINLOCK in key European markets; the vimseltinib enrollment and topline readout for the pivotal Phase 3 MOTION study and our phase 1/2 study of vimseltinib, each in TGCT patients; plans to present updated data from the dose escalation phase and initial data from the combination dose escalation cohorts of the Phase 1 study of DCC-3116, plans to initiate one or more combination cohorts in the Phase 1/2 study of DCC-3116, plans to initiate a new dose escalation cohort evaluating DCC-3116 in combination with encorafenib and cetuximab in patients with colorectal cancer in the second half of 2023, the benefits anticipated pursuant to our collaboration and supply agreement with Pfizer, plans to present additional preclinical data for DCC-3116; plans to submit an IND for DCC-3084 and present preclinical data for DCC-3084; plans to nominate a development candidate from our proprietary discovery engine of novel switch control inhibitors; statements regarding the Company's preliminary unaudited fourth quarter, year-end, and net product revenue for the quarter and year-ended December 31, 2022 and preliminary unaudited cash, cash equivalents, and marketable securities for the quarter and year-ended December 31, 2022. 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 or drug candidates, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, 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, 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 and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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.

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