UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): January 3, 2023

Deciphera Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38219**	**30-1003521**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Smith Street, Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (781) 209-6400

(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 203.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Common Stock, $0.01 Par Value	DCPH	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On January 3, 2023, Deciphera Pharmaceuticals, Inc. (the "Company") disclosed that it had a preliminary unaudited amount of net product revenue of approximately $36 million for the fourth quarter ended December 31, 2022, and approximately $134 million for the full year ended December 31, 2022. QINLOCK net product revenue is estimated to be approximately $33 million, including approximately $26 million in U.S. QINLOCK® (ripretinib) net product revenue and approximately $7 million in international QINLOCK net product revenue, in addition to approximately $3 million in collaboration revenue. The Company also disclosed that it had a preliminary unaudited amount of cash, cash equivalents, and marketable securities of approximately $339 million as of December 31, 2022, which is expected to fund the operating and capital expenditure plans into 2025. These amounts are preliminary and are subject to completion of financial closing procedures. As a result, these amounts may differ materially from the amounts that will be reflected in the Company's consolidated financial statements for the year ended December 31, 2022. A copy of the press release disclosing this information is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

The preliminary financial data included in this Current Report on Form 8-K has been prepared by, and is the responsibility of, the Company's management. PricewaterhouseCoopers LLP has not audited, reviewed, examined, compiled, nor applied agreed-upon procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

The information in Item 2.02 of this Current Report on Form 8-K is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

The information provided in Item 2.02 above is incorporated herein by reference.

In addition, on January 3, 2023, the Company issued a separate press release announcing results of a planned exploratory analysis of data from the Company's INTRIGUE Phase 3 clinical study using circulating tumor DNA and plans to initiate the Company's INSIGHT Phase 3 clinical study of QINLOCK versus sunitinib in second-line gastrointestinal stromal tumor (GIST) patients with mutations in KIT exon 11 and 17/18 only. A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the Company's preliminary unaudited amount of net product revenue for the fourth quarter and year ended December 31, 2022 and preliminary unaudited cash, cash equivalents, and marketable securities for the year ended December 31, 2022, and the Company's expectations and timing regarding its planned Phase 3 INISGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only. 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. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to preliminary financial results, including the risks that actual product and collaboration revenues may differ from the Company's current expectations, and risks that the

preliminary financial results reported herein reflect information available to the Company only at this time and may differ from actual results, including in connection with the Company's completion of financial closing procedures, as well as other risks detailed in the Company's recent filings on Forms 10-K and 10-Q with the Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release titled "Deciphera Pharmaceuticals Announces Planned 2023 Corporate Milestones to Support Continued Evolution to Multi-Product Company" issued by Deciphera Pharmaceuticals, Inc. on January 3, 2023, furnished herewith.
99.2	Press Release titled "Deciphera Pharmaceuticals Announces Results from ctDNA Analysis from INTRIGUE Phase 3 Clinical Study Demonstrating Substantial Clinical Benefit of QINLOCK® in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18 Only" issued by Deciphera Pharmaceuticals, Inc. on January 3, 2023, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 3, 2023

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter
Name: Steven L. Hoerter
Title: President and Chief Executive Officer

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

– 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, MA – January 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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Deciphera Pharmaceuticals Announces Results from ctDNA Analysis from INTRIGUE Phase 3 Clinical Study Demonstrating Substantial Clinical Benefit of QINLOCK® in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18 Only

– Median Progression Free Survival for QINLOCK of 14.2 Months Versus Sunitinib of 1.5 Months; Hazard Ratio of 0.22, nominal p value <0.0001 –

– Objective Response Rate of 44.4% for QINLOCK Versus 0% for Sunitinib; nominal p value 0.0001 –

– Median Overall Survival for QINLOCK was Not Estimable Versus 17.5 Months for Sunitinib; Hazard Ratio of 0.34, nominal p value 0.0061 –

– Company Plans to Initiate the INSIGHT Pivotal Phase 3 Clinical Study in the Second Half of 2023 –

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

Waltham, MA – January 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 announced findings of a planned exploratory analysis of data from the INTRIGUE Phase 3 clinical study of QINLOCK using circulating tumor DNA (ctDNA) from a subgroup of patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib who harbor mutations in KIT exon 11 and 17/18 only.

“We are extremely pleased by the exploratory analysis showing that QINLOCK, already the standard of care for fourth-line GIST patients, provided substantial clinical benefit to this subgroup of second-line patients compared to sunitinib. We look forward to presenting additional data from the overall ctDNA analysis at a medical meeting later this month,” said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. “Given the strength of these results, and after consultation with the FDA, we plan to initiate our INSIGHT pivotal Phase 3 study in the second half of 2023. If positive, we believe this trial will transform the standard of care for this subgroup of second-line GIST patients based on their mutational profile.”

“The newly reported clinical results from INTRIGUE demonstrate the remarkable differential benefit of ripretinib in patients with unique molecular subtypes of GIST in the second-line setting, specifically patients with ctDNA demonstrating KIT exon 11 and 17/18 mutations,” said Suzanne George, M.D., Associate Division Chief, Sarcoma Center, Dana-Farber Cancer Institute, and the co-lead investigator on the INSIGHT study. “This data is potentially practice changing in second-line GIST and as ctDNA assays are increasingly optimized and utilized in the clinical arena, we must continue clinical drug development which aims to understand the impact of drugs in specific molecular subtypes of GIST with the goal to improve clinical outcomes by giving the right drug to the right patient at the right time.”

Planned Exploratory Efficacy Analysis using ctDNA in INTRIGUE Study

An exploratory objective in the INTRIGUE Phase 3 study in GIST patients previously treated with imatinib was to evaluate anti-tumor efficacy of QINLOCK according to baseline KIT primary and secondary mutation status. Baseline peripheral whole blood was analyzed by Guardant360, a 74-gene ctDNA next-generation sequencing liquid biopsy assay.

Of the 453 patients in the overall intent-to-treat population (ITT), baseline ctDNA was analyzed in 362 patients for whom evaluable samples were available. ctDNA was detected in 280 samples and KIT mutations were detected in 213 patients.

Primary mutations in KIT were detected in exon 11 in 157 patients and in exon 9 in 36 patients. Common resistance mutations in KIT were detected in exons 17/18 in 89 patients and in exons 13/14 in 81 patients.

In patients with a KIT exon 11 primary mutation, 52 patients had mutations in exon 17/18 only, 41 had mutations in exon 13/14 only, and 22 patients had mutations in both exon 13/14 and exon 17/18.

Patients with mutations in KIT exon 11 and exon 17/18 only had substantially improved progression-free survival (PFS), objective response rate (ORR), and overall survival (OS) with QINLOCK versus sunitinib. Efficacy results in patients with detectable ctDNA in KIT exon 11 and in the ITT populations were consistent with the primary analysis of the INTRIGUE study based on tumor data used for randomization. The subgroup safety profiles were consistent with the primary analysis.

Summary of INTRIGUE Efficacy Results of ctDNA Analysis for Patients with Mutations in KIT Exon 11 and 17/18 Only

	Ripretinib (n=27)	Sunitinib (n=25)	Hazard Ratio/Response Difference (95% CI)
Median Progression-Free Survival [1]	14.2 months	1.5 months	0.22 (0.11, 0.44), nominal p value <0.0001
Objective Response Rate [1]	44.4%	0%	44.4% (23.0%, 62.7%) nominal p value = 0.0001
Overall Survival [2]	Not Estimable	17.5 months	0.34 (0.15, 0.76), nominal p value = 0.0061

Notes: (1) Data cut as of September 1, 2021; (2) Data cut as of September 1, 2022.

Based on the results of the ctDNA analysis and discussions with regulators, the Company plans to 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 planned study, approximately 54 patients will be randomized 2:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. The primary endpoint will be PFS as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria. The Company expects to initiate the INSIGHT study in the second half of 2023.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement 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 the INSIGHT Study

The planned INSIGHT Phase 3 clinical study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib with mutations in KIT exon 11 and 17/18 only (excluding patients with mutations in KIT exons 9, 13, or 14). In the study, 54 patients will be randomized 2:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. The primary endpoint is PFS as determined by independent radiologic review using modified RECIST 1.1 criteria. Secondary endpoints include ORR as determined by independent radiologic review using modified RECIST 1.1 criteria and OS.

About the INTRIGUE Study

The INTRIGUE Phase 3 clinical study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib. In the study, 453 patients were randomized 1:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. As previously reported, the study did not achieve the primary efficacy endpoint of PFS as determined by independent radiologic review using modified RECIST 1.1 criteria. The statistical analysis plan included a hierarchical testing sequence that included testing patients with a KIT exon 11 primary mutation and then in the all patient intent-to-treat (AP) population. In patients with a KIT exon 11 primary mutation (n=327), QINLOCK demonstrated an mPFS of 8.3 months compared to 7.0 months for the sunitinib arm (hazard ratio (HR) 0.88, p=0.360). Although not formally tested due to the rules of the hierarchical testing sequence, in the AP population QINLOCK demonstrated a mPFS of 8.0 months compared to 8.3 months for the sunitinib arm (HR 1.05, nominal p=0.715). QINLOCK was generally well tolerated. Fewer patients in the QINLOCK arm experienced Grade 3-4 treatment-emergent adverse events compared to sunitinib (41.3% vs 65.6%).

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 our planned Phase 3 INISGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only, plans to initiate the INSIGHT study in the second half of 2023, our ability to improve clinical outcomes in second-line GIST patients with mutations in KIT exon 11 and 17/18 only, and the potential for QINLOCK to be an transformational therapy for this mutational subgroup. 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 and in additional indications for our existing drug, the preclinical or clinical results for our drug candidates, which may not support further development of such drug 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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