

**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 24, 2022

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

Delaware
(State or other jurisdiction
of incorporation)

001-38219
(Commission
File Number)

30-1003521
(IRS Employer
Identification No.)

200 Smith Street, Waltham, Massachusetts
(Address of principal executive offices)

02451
(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 7.01 Regulation FD Disclosure.

On January 24, 2022, Deciphera Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the presentation of results from the Company’s INTRIGUE Phase 3 clinical study at the American Society of Clinical Oncology Plenary Series Session. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) 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, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on January 24, 2022, 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 24, 2022

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter

Name: Steven L. Hoerter

Title: President and Chief Executive Officer



Deciphera Pharmaceuticals Presents Results from the INTRIGUE Phase 3 Clinical Study at the American Society of Clinical Oncology Plenary Series Session

– Efficacy Observed with QINLOCK® was Comparable to Sunitinib with a More Favorable Safety and Tolerability Profile in GIST Patients Previously Treated with Imatinib –

Waltham, MA – January 24, 2022 – Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a commercial-stage biopharmaceutical company developing innovative medicines to improve the lives of people with cancer, announced the presentation of results from the INTRIGUE Phase 3 study of QINLOCK (ripretinib) in patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib at the American Society of Clinical Oncology (ASCO) Plenary Series Session. The presentation, which follows the announcement in November 2021 of the top-line results, is titled “INTRIGUE: A phase III, randomized, open-label study to evaluate the efficacy and safety of ripretinib vs sunitinib in patients with advanced gastrointestinal stromal tumor previously treated with imatinib” and is available on the Company’s website at www.deciphera.com/presentations-publications.

ASCO will be hosting a livestream event on Tuesday, January 25, 2022 at 3:00 PM ET featuring presentation of the abstract by Michael Heinrich, M.D., FACP, Professor of Medicine at Oregon Health & Science University followed by a discussion of the abstract by George D. Demetri, M.D., FASCO, FACP, Dana-Farber Cancer Institute, as well as a panel discussion with Drs. Heinrich and Demetri and Vicki Keedy, M.D., MSCI, Vanderbilt University Medical Center. To participate in the free and open session participants may register and login at <https://www.asco.org/meetings-education/monthly-plenary-series/program>.

“Patients with GIST in the post-imatinib setting are in need of additional treatment options for their disease, and the results from INTRIGUE demonstrate that ripretinib is an active and well-tolerated agent. Although the INTRIGUE study did not meet its primary endpoint of superiority in progression-free survival versus sunitinib, the efficacy of ripretinib appears comparable to sunitinib in 2nd line patients. In addition, ripretinib had a more favorable safety profile than sunitinib with fewer Grade 3/4 adverse events and patients reported less deterioration in role functioning and several other key patient-reported outcome measures of tolerability.” said Dr. Heinrich. “It is important to provide the detailed results of this study to the oncology community to help treating physicians make well-informed decisions on the best treatment options for their patients with advanced GIST.”

In patients with GIST who progressed on or were intolerant to imatinib, the efficacy of QINLOCK and sunitinib were comparable, although progression-free survival (PFS) of QINLOCK as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST) did not meet the study’s primary endpoint of superiority compared to sunitinib. The statistical analysis plan included a hierarchical testing sequence that included evaluation of patients with a KIT exon 11 primary mutation (Exon 11) and then of the all patient (AP) population. Key highlights from the study presented today include the following:

- An international, multicenter study conducted in 122 active sites across 22 countries, 453 patients were randomized to ripretinib (n = 226; Exon 11, n = 163) or sunitinib (n = 227; Exon 11, n = 164).
- In patients with a *KIT* exon 11 primary mutation, ripretinib demonstrated a median PFS (mPFS) of 8.3 months compared to 7.0 months for the sunitinib arm (Hazard Ratio [HR] 0.88, p=0.36). In the AP population (n=453), ripretinib demonstrated an mPFS of 8.0 months compared to 8.3 months for the sunitinib arm (HR 1.05, nominal p value=0.72).



- In patients with a *KIT* exon 11 primary mutation, ripretinib demonstrated an objective response rate (ORR) of 23.9% (n=39 of 163) compared to 14.6% (n=24 of 164) for sunitinib (nominal p value=0.03). In the AP population ripretinib demonstrated an ORR 21.7% (n=49 of 226) compared to 17.6% (n=40 of 227) for sunitinib (nominal p value=0.27).
- Ripretinib was generally well tolerated. Fewer patients in the ripretinib arm experienced Grade 3-4 treatment-emergent adverse events compared to sunitinib (41.3% vs 65.6%).
- Patients receiving sunitinib were three times more likely to develop Grade 3 hypertension compared to patients receiving ripretinib (26.7% vs. 8.5%) and patients receiving sunitinib were seven times more likely to develop Grade 3 palmar-plantar erythrodysesthesia compared to patients receiving ripretinib (10.0% vs. 1.3%).
- Patient reported outcome measures also showed a more favorable tolerability profile for patients receiving ripretinib compared to patients receiving sunitinib. Patients receiving ripretinib experienced less deterioration in their ability to engage in either work or leisure activities during treatment and fewer patients receiving ripretinib experienced moderate to extremely large impact on their lives due to skin toxicity across treatment cycles compared to patients receiving sunitinib.

QINLOCK is approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The new drug application (NDA) for QINLOCK was based on positive results from the Phase 3 INVICTUS trial in patients with fourth-line and fourth-line plus GIST¹. QINLOCK is also approved for the treatment of fourth-line GIST in Australia, Canada, China, the European Union, Hong Kong, Switzerland, Taiwan, and the United Kingdom.

About QINLOCK (ripertinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit *KIT* and *PDGFRA* mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK inhibits primary and secondary *KIT* mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation^{2,3}. QINLOCK also inhibits primary *PDGFRA* mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST^{2,3}.

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 regarding QINLOCK and our INTRIGUE study. 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 our ability to provide access to QINLOCK in European countries other than Germany and France through other channels, 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, 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.

Deciphera, the Deciphera logo, QINLOCK, and the QINLOCK logo are registered trademarks of Deciphera Pharmaceuticals, LLC.

References

1. Blay JY, Serrano C, Heinrich MC et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): A double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol* 2020; 21:923–934.
2. Smith B et al., Ripretinib (DCC-2618) is a switch control kinase inhibitor of a broad spectrum of oncogenic and drug-resistant KIT and PDGFRA variants. *Cancer Cell* 2019; 35:738–751.
3. Bauer S, Heinrich M, et al. Clinical activity of ripretinib in patients with advanced gastrointestinal stromal tumor harboring heterogenous KIT/PDGFRA mutations in the phase 3 INVICTUS study. *Clinical Cancer Research* 2021; 27:6333-6342.

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