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): November 5, 2021

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 7.01 Regulation FD Disclosure.

On November 5, 2021, Deciphera Pharmaceuticals, Inc. (the "Company") issued a press release announcing top-line results from the INTRIGUE Phase 3 clinical study of QINLOCK in patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib. A copy of the press release issued by the Company in connection with the announcement 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 (the "Exchange Act"), except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On November 5, 2021, the Company announced top-line results from the INTRIGUE Phase 3 clinical study of QINLOCK in patients with GIST previously treated with imatinib. The study did not meet the primary endpoint of improved progression free survival (PFS) compared with the standard of care sunitinib.

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.

The study did not achieve the primary efficacy endpoint of median progression-free survival (mPFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The statistical analysis plan included a hierarchical testing structure that included testing patients with a KIT exon 11 primary mutation and in the all patient intent-to-treat (AP) population. In patients with a KIT exon 11 primary mutation, (n=327), QINLOCK demonstrated a mPFS of 8.3 months compared to 7.0 months for the sunitinib arm (HR of 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 of 1.05, nominal p=0.715).

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, our expectations and timing regarding presenting the full results from the INTRIGUE Phase 3 clinical study and our commitment to ensuring patients around the world in the fourth-line GIST treatment setting have access to QINLOCK. 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 report 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 report, 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 including in additional indications for our existing drug such as second-line GIST patients in our INTRIGUE Phase 3 study, 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 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. Any forward-looking statements contained in this report 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on November 5, 2021, 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: November 5, 2021

DECIPHERA PHARMACEUTICALS, INC.

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

Exhibit 99.1

Deciphera Pharmaceuticals Announces Top-line Results from the INTRIGUE Phase 3 Clinical Study

– Study Did Not Achieve Primary Efficacy Endpoint of Improved Progression-Free Survival Versus Standard of Care Sunitinib in Patients with Second-line GIST –

– Conference Call to be Held Today at 8:00 AM ET –

Waltham, MA – November 5, 2021 – Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a commercial-stage biopharmaceutical company developing innovative medicines to improve the lives of people with cancer, today announced top-line results from the INTRIGUE Phase 3 clinical study of QINLOCK in patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib. The study did not meet the primary endpoint of improved progression-free survival (PFS) compared with the standard of care sunitinib.

“While we are disappointed with these results, which we learned yesterday, we believe this was a robust, well-designed, and well-executed study. The full results from the INTRIGUE Phase 3 clinical study are expected to be presented at an upcoming medical meeting,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “On behalf of the entire Deciphera team, I would like to thank the patients, their caregivers, and the healthcare professionals who participated in the INTRIGUE study. QINLOCK remains the standard of care and only approved therapy in patients with fourth-line GIST, and we are committed to ensuring that patients around the world in the fourth-line GIST treatment setting have access to QINLOCK.”

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.

The study did not achieve the primary efficacy endpoint of progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). 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 a median PFS (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).

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, November 5, 2021 at 8:00 AM ET. To access the live call by phone please dial (866) 930-5479 (domestic) or (409) 216-0603 (international); the conference ID is 3072405. A live audio webcast of the event may also be accessed through the “Investors” section of Deciphera’s website at www.deciphera.com. A replay of the webcast will be available for 30 days following the event.

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. The primary endpoint is progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST) in the pre-specified subgroup of patients with a KIT exon 11 mutation (exon 11) and then in the all patient intent-to-treat (AP) population. Secondary endpoints include Objective Response Rate (ORR) as determined by independent radiologic review using modified RECIST and Overall Survival (OS) in both the exon 11 and AP groups. The study is being conducted at 122 investigational sites in 22 countries.

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop[1,2].

Important Safety Information

There are no contraindications for QINLOCK.

Palmar-plantar erythrodysesthesia syndrome (PPES): In INVICTUS, Grade 1-2 PPES occurred in 21% of the 85 patients who received QINLOCK. PPES led to dose discontinuation in 1.2% of patients, dose interruption in 2.4% of patients, and dose reduction in 1.2% of patients. Based on severity, withhold QINLOCK and then resume at same or reduced dose.

New Primary Cutaneous Malignancies: In INVICTUS, cutaneous squamous cell carcinoma (cuSCC) occurred in 4.7% of the 85 patients who received QINLOCK with a median time to event of 4.6 months (range 3.8 to 6 months). In the pooled safety population, cuSCC and keratoacanthoma occurred in 7% and 1.9% of 351 patients, respectively. In INVICTUS, melanoma occurred in 2.4% of the 85 patients who received QINLOCK. In the pooled safety population, melanoma occurred in 0.9% of 351 patients. Perform dermatologic evaluations when initiating QINLOCK and routinely during treatment. Manage suspicious skin lesions with excision and dermatopathologic evaluation. Continue QINLOCK at the same dose.

Hypertension: In INVICTUS, Grade 1-3 hypertension occurred in 14% of the 85 patients who received QINLOCK, including Grade 3 hypertension in 7% of patients. Do not initiate QINLOCK in patients with uncontrolled hypertension. Monitor blood pressure as clinically indicated. Based on severity, withhold QINLOCK and then resume at same or reduced dose or permanently discontinue.

Cardiac Dysfunction: In INVICTUS, cardiac failure occurred in 1.2% of the 85 patients who received QINLOCK. In the pooled safety population, cardiac dysfunction (including cardiac failure, acute left ventricular failure, diastolic dysfunction, and ventricular hypertrophy) occurred in 1.7% of 351 patients, including Grade 3 adverse reactions in 1.1% of patients.

In INVICTUS, Grade 3 decreased ejection fraction occurred in 2.6% of the 77 patients who received QINLOCK and who had a baseline and at least one post-baseline echocardiogram. Grade 3 decreased ejection fraction occurred in 3.4% of the 263 patients in the pooled safety population who received QINLOCK and who had a baseline and at least one post-baseline echocardiogram.

In INVICTUS, cardiac dysfunction led to dose discontinuation in 1.2% of the 85 patients who received QINLOCK. The safety of QINLOCK has not been assessed in patients with a baseline ejection fraction below 50%. Assess ejection fraction by echocardiogram or MUGA scan prior to initiating QINLOCK and during treatment, as clinically indicated. Permanently discontinue QINLOCK for Grade 3 or 4 left ventricular systolic dysfunction.

Risk of Impaired Wound Healing: QINLOCK has the potential to adversely affect wound healing. Withhold QINLOCK for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of QINLOCK after resolution of wound healing complications has not been established.

Embryo-Fetal Toxicity: QINLOCK can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least 1 week after the final dose. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment and for at least 1 week after the final dose. QINLOCK may impair fertility in males of reproductive potential.

Adverse Reactions: The most common adverse reactions (³20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, PPES, and vomiting. The most common Grade 3 or 4 laboratory abnormalities (³4%) were increased lipase and decreased phosphate.

The safety and effectiveness of QINLOCK in pediatric patients have not been established.

Administer strong CYP3A inhibitors with caution. Monitor patients who are administered strong CYP3A inhibitors more frequently for adverse reactions. Avoid concomitant use with strong CYP3A inducers.

Please click here to see the full Prescribing Information for QINLOCK.

To report SUSPECTED ADVERSE REACTIONS, contact Deciphera Pharmaceuticals, LLC, at 1-888-724-3274 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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[1], Canada[2], China[3], Hong Kong[4], Switzerland[5], Taiwan[6], and the United States[7]. For more information, visit www.deciphera.com and follow us on LinkedIn and Twitter (@Deciphera).

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

References

1. Deciphera Press Release: Deciphera Announces Australian Therapeutic Goods Administration's Approval of QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] July 14, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/deciphera-announces-australian-therapeutic-goods-administrations [Last accessed: November 2021].

2. Deciphera Press Release: Deciphera Announces Health Canada's Authorization of QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] June 22, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/deciphera-announces-health-canadas-authorization-qinlocktm [Last accessed: November 2021].
3. Zai Lab Press Release: China NMPA Approves QINLOCK® (Ripretinib) for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST) [online] March 31, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/china-nmpa-approves-qinlockr-ripretinib-treatment-advanced [Last accessed: November 2021].
4. Zai Lab Press Release: Zai Lab Announces Financial Results for Second-half and Full-year 2020 [online] March 1, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/zai-lab-announces-financial-results-second-half-and-full-year [Last accessed: November 2021].
5. Deciphera Press Release: Deciphera Announces Approval of QINLOCK® in Switzerland for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] October 12, 2021. Available from: https://investors.deciphera.com/news-releases/news-release-details/deciphera-announces-approval-qinlockr-switzerland-treatment [Last accessed: November 2021].
6. Zai Lab Press Release: QINLOCK® (Ripretinib) Approved in Taiwan for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST) [online] September 1, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/qinlockr-ripretinib-approved-taiwan-treatment-advanced [Last accessed: November 2021].
7. Deciphera Press Release: FDA Grants Full Approval of Deciphera Pharmaceuticals' QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] May 15, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/fda-grants-full-approval-deciphera-pharmaceuticals-qinlocktm [Last accessed: November 2021].

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