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): May 15, 2020

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 Number)**

200 Smith Street **Waltham, MA**	**02451**
(Address of registrant's principal executive office)	**(Zip code)**

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

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))

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.01 Par Value	**DCPH**	**The 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01 Other Events.

On May 15, 2020, Deciphera Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration approved the Company's new drug application for QINLOCK™ (ripretinib) for the treatment of adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with three or more kinase inhibitors, including imatinib. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on May 15, 2020.

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: May 15, 2020

DECIPHERA PHARMACEUTICALS, INC.

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

FDA Grants Full Approval of Deciphera Pharmaceuticals' QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor

-QINLOCK Significantly Improved Progression-Free Survival and Showed Clinically Meaningful Overall Survival in INVICTUS Phase 3 Study-

-NDA Approved 3 Months Prior to Action Date Under FDA's Real Time Oncology Review (RTOR)-

-Deciphera to Host Conference Call Today at 5:00 PM Eastern Time-

Waltham, MA – May 15, 2020 – Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced the U.S. Food and Drug Administration (FDA) has approved QINLOCK™ (ripretinib) for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. The FDA previously granted Breakthrough Therapy and Fast Track designations as well as Priority Review for QINLOCK and reviewed the New Drug Application (NDA) under the Real-Time Oncology Review (RTOR) pilot program. The QINLOCK NDA is also part of Project Orbis, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among participating international health authorities. QINLOCK targets the broad spectrum of KIT and PDGFRα mutations known to drive GIST.

"Today's approval of QINLOCK establishes a new standard of care for patients who have received three prior therapies," said Margaret von Mehren, MD, Chief of Sarcoma Oncology and Associate Director for Clinical Research, Fox Chase Cancer Center, Philadelphia, Pennsylvania. "GIST is a complex disease and the majority of patients who initially respond to traditional tyrosine kinase inhibitors eventually develop tumor progression due to secondary mutations. In the INVICTUS study, QINLOCK has demonstrated compelling clinical benefit in progression-free and overall survival. QINLOCK is well tolerated and is a crucial new therapy for these patients with a high unmet need."

"The FDA approval of QINLOCK is an exciting milestone for people with GIST who have been waiting for a new treatment option designed specifically for their disease," said Steve Hoerter, President and Chief Executive Officer of Deciphera. "I would like to thank the patients, their families and caregivers, and the healthcare professionals who made the QINLOCK clinical studies possible. With their contributions and the dedication of the team at Deciphera, we are delivering on our promise to provide important new medicines for the treatment of cancer."

The FDA approval was based on efficacy results from the pivotal Phase 3 INVICTUS study of QINLOCK in patients with advanced GIST as well as combined safety results from INVICTUS and the Phase 1 study of QINLOCK. In INVICTUS, QINLOCK demonstrated a median progression-free survival of 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, $p<0.0001$). In addition, QINLOCK demonstrated a median overall survival of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36).

The most common adverse reactions (³20%) were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodysesthesia syndrome (PPES), and vomiting. Adverse reactions resulting in permanent discontinuation occurred in 8% of patients, dosage interruptions due to an adverse reaction occurred in 24% of patients and dose reductions due to an adverse reaction occurred in 7% of patients who received QINLOCK.

Deciphera Pharmaceuticals plans to make QINLOCK commercially available in the U.S. next week.

Deciphera is committed to supporting GIST patients and removing barriers to access. As part of that commitment, Deciphera has established Deciphera AccessPoint, a patient support program that provides reimbursement and financial assistance programs for eligible patients. For more information, visit DecipheraAccessPoint.com or call 1-833-4DACCES (1-833-432-2237), Monday-Friday, 8:00 AM to 8:00 PM Eastern Time (ET).

Conference Call Information

Deciphera's management team will host a live conference call and webcast at 5:00 PM ET on Friday, May 15, 2020, to discuss the FDA approval of QINLOCK. The conference call may be accessed by dialing (866) 930-5479 (domestic) or (409) 216-0603 (international) and referring to conference ID 8696831. A webcast of the conference call will be available in the "Events and Presentations" page in the "Investors" section of the Company's website at https://investors.deciphera.com/news-events/events-presentations. The archived webcast 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 INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomized, double-blind, placebo-controlled, international, multicenter clinical study evaluating the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK or placebo once daily. The primary efficacy endpoint is progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The median PFS in the study was 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, $p<0.0001$). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p =0.0504$). QINLOCK also demonstrated a median OS of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36).

About QINLOCK (ripretinib)

Indications and Usage

QINLOCK (ripretinib) is a kinase inhibitor indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. For more information visit QINLOCK.com.

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 GIST

Gastrointestinal stromal tumor (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST is the most common sarcoma of the gastrointestinal tract, with approximately 4,000 to 6,000 new GIST cases each year in the United States and a similar incidence rate in European and other countries. Most cases of GIST are driven by a spectrum of mutations. The most common primary mutations are in KIT kinase, representing approximately 80% of cases, or in PDGFRα kinase, representing approximately 6% of cases. Current therapies are unable to inhibit the full spectrum of primary and secondary mutations, which drives resistance and disease progression. Estimates for 5-year survival range from 48% to 90%, depending on the stage of the disease at diagnosis.

About Deciphera Pharmaceuticals

Deciphera, a commercial biopharmaceutical company, is decoding cancer at the molecular level and leveraging its proprietary kinase switch control technology to develop therapies for hard-to-treat cancers. The Company has one FDA-approved product, QINLOCK, a broad-spectrum KIT and PDGFRα inhibitor, for the treatment of patients with fourth-line GIST and is using its platform to develop a diverse pipeline of drug candidates designed to improve outcomes for patients with cancer. For more information, visit www.deciphera.com.

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 as a new standard of care, the timing of commercial availability of QINLOCK in the U.S., the commercial launch of QINLOCK in the U. S., our patient access programs, review of our NDA under Project Orbis, and the potential benefit of our clinical and preclinical development programs for cancers. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “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, including, without limitation, commercial and clinical drug supply chain continuity and the commercial launch of QINLOCK, our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, the preclinical and 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, 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 and incidence and prevalence estimates, 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 make our investigational drugs and QINLOCK available to patients, and to derive revenue from product sales, and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, 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 its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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