



**Deciphera Pharmaceuticals Announces QINLOCK® Included in NCCN Guidelines® for the Treatment of Second-Line GIST Patients and FDA Grants Breakthrough Therapy Designation for QINLOCK in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18**

March 14, 2023

*– NCCN Guidelines Include QINLOCK as a Preferred Regimen for Second-Line GIST Patients Intolerant to Sunitinib –*

*– Breakthrough Therapy Designation is Based on Results from ctDNA Analysis of 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 –*

*– Company Plans to Initiate the INSIGHT Pivotal Phase 3 Study of QINLOCK Versus Sunitinib in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18 in the Second Half of 2023–*

WALTHAM, Mass.--(BUSINESS WIRE)--Mar. 14, 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 that QINLOCK® (ripretinib) has been included in the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology as a preferred regimen for second-line gastrointestinal stromal tumor (GIST) patients intolerant to sunitinib.

The Company also announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for QINLOCK for the treatment of adult patients with unresectable or metastatic GIST who received prior treatment with imatinib, and who harbor a KIT exon 11 mutation and co-occurring KIT exon 17 and/or 18 mutations (KIT exon 11+17/18 mutations). QINLOCK is Deciphera's switch-control inhibitor currently approved in 12 territories around the world, including major markets of the United States, Europe, and China for the treatment of fourth-line GIST.

"The Breakthrough Therapy Designation reflects the substantial clinical benefit of QINLOCK in second-line GIST patients harboring mutations in KIT exon 11 and 17/18 that we observed in the ctDNA analysis from the INTRIGUE Phase 3 study. If approved, we believe QINLOCK has the potential to become the standard-of-care for this group of second-line GIST patients around the world. GIST key opinion leaders and physicians have long been proponents of clinical drug development targeted at specific molecular subtypes of GIST, and we are pleased with the FDA's recognition that the ctDNA data indicates QINLOCK may demonstrate substantial improvement over the current standard-of-care in this population," said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. "Further, the inclusion of QINLOCK in the latest NCCN clinical practice guidelines underscores both the need for additional treatment options for GIST patients in the post-imatinib setting and the significance of the results from the INTRIGUE study, which demonstrated that QINLOCK is an active and well-tolerated agent."

The update to the NCCN GIST Guidelines is based on the primary analysis of the INTRIGUE Phase 3 study as published in the Journal of Clinical Oncology (Bauer S, Jones RL, Blay JY, et al. Ripretinib versus sunitinib in patients with advanced gastrointestinal stromal tumor after treatment with imatinib (INTRIGUE): A randomized, open-label, phase III trial. *J Clin Oncol* 2022; 40: 3918-3928). Key study results include:

- In the intention-to-treat (ITT) population (n=453), QINLOCK demonstrated a median PFS (mPFS) of 8.0 months compared to 8.3 months for the sunitinib arm (Hazard Ratio [HR] 1.05, nominal p value=0.72).
- Ripretinib 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%).

- Patients receiving sunitinib were three times more likely to develop Grade 3 hypertension compared to patients receiving QINLOCK (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 QINLOCK (10.0% vs. 1.3%).
- Patient reported outcome measures also showed a more favorable tolerability profile for patients receiving QINLOCK compared to patients receiving sunitinib. Patients receiving QINLOCK experienced less deterioration in their ability to engage in either work or leisure activities during treatment, and fewer patients receiving QINLOCK experienced moderate to extremely large impact on their lives due to skin toxicity across treatment cycles compared to patients receiving sunitinib.

The updated NCCN Guidelines are available online at [www.nccn.org](http://www.nccn.org).

The FDA's BTDR is intended to expedite the development and review of a medicine aiming to treat a serious or life-threatening disease with preliminary clinical evidence that indicates the drug may demonstrate substantial improvement over existing therapies. This is the second BTDR granted to QINLOCK. The BTDR is supported by an exploratory analysis from the INTRIGUE Phase 3 study in GIST patients previously treated with imatinib to evaluate anti-tumor efficacy of QINLOCK according to baseline KIT primary and secondary mutation status using circulating tumor DNA (ctDNA). Patients with mutations in KIT exon 11 and exon 17/18 only (n=52) derived substantially improved clinical benefit with QINLOCK versus sunitinib. Key results of the ctDNA analysis in the KIT exon 11 and 17/18 subgroup include:

- QINLOCK demonstrated an mPFS of 14.2 months compared to 1.5 months for the sunitinib arm (HR 0.22, nominal p value <0.0001).
- QINLOCK demonstrated a confirmed objective response rate (ORR) of 44.4% (n=12 of 27) compared to 0% for sunitinib (nominal p value 0.0001).
- OS for the QINLOCK arm has not reached a median, while patients randomized to the sunitinib arm had a median OS (mOS) of 17.5 months (HR 0.34, nominal p value 0.0061).
- The subgroup safety profiles were consistent with the primary analysis.

Based on the results of the ctDNA analysis and discussions with the FDA, 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 in the second half of 2023.

#### **About QINLOCK (ripretinib)**

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. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST. 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.

#### **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 and/or 18 and the absence of mutations in KIT exon 9, 13, and/or 14 (also referred to as patients with mutations in KIT exon 11 and 17/18). 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.

#### **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, Israel, Macau, New Zealand, Switzerland, Taiwan, the United Kingdom, and the United States. For more information, visit [www.deciphera.com](http://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 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18, the potential for QINLOCK to become the standard-of-care for second-line GIST patients with mutations in KIT exon 11 and 17/18, the ability for QINLOCK to offer substantial improvement over the current standard-of-care in this patient population, and plans to initiate the INSIGHT study in the second half of 2023; the potential benefits of QINLOCK in second-line GIST patients intolerant to sunitinib and the extent to which the NCCN Clinical Practice Guidelines are recognized and followed by the medical community. 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, 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 Annual Report on Form 10-K for the year ended December 31, 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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