



## **Deciphera Pharmaceuticals Announces Planned 2024 Corporate Milestones Supporting Evolution to a Self-Sustaining, Multi-Product Company**

January 8, 2024

- Preliminary Unaudited Fourth Quarter 2023 QINLOCK<sup>®</sup> Net Product Revenue of Approximately \$46.0 Million, an Increase of 40% Compared to the Fourth Quarter of 2022 –
- Expects to Submit Vimseltinib New Drug Application (NDA) in the Second Quarter of 2024 and Marketing Authorisation Application (MAA) in the Third Quarter of 2024 in Tenosynovial Giant Cell Tumor (TGCT); Commercial Launch Preparations Underway –
- Expects to Initiate a Phase 2 Proof-of-Concept Study of Vimseltinib for the Treatment of Chronic Graft Versus Host Disease (cGVHD) in the Fourth Quarter of 2024 –
- Preliminary Unaudited Cash, Cash Equivalents, and Marketable Securities of Approximately \$352.0 million as of December 31, 2023; Cash Runway Extended into the Second Half of 2026 –

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 8, 2024-- 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 2024 and planned 2024 corporate milestones, and announced preliminary unaudited fourth quarter and full year 2023 revenue.

"2023 was a year of important progress across our organization, in which we demonstrated our ability to drive commercial growth while advancing our clinical pipeline and strategically investing in key earlier-stage programs," said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. "Thanks to our late-stage clinical execution and global commercial excellence, we have the potential to reach \$1 billion in peak revenue with QINLOCK and vimseltinib, and we look forward to continuing this exciting evolution as we work to become a self-sustaining, multi-product company."

Planned 2024 corporate milestones and business updates include:

### **QINLOCK<sup>®</sup> (ripretinib)**

- Continue enrolling the INSIGHT pivotal 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.
- Publication in *Nature Medicine* in January 2024 of the results of a ctDNA analysis from the INTRIGUE Phase 3 study demonstrating substantial clinical benefit of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18 only.
- Continue the geographic expansion of QINLOCK in fourth-line GIST, with planned commercial launches following conclusion of pricing and reimbursement negotiations in European and international markets.
- The Company has entered into a supply and distribution agreement with GENESIS Pharma, a leading regional biopharma company, in Central and Eastern Europe under which GENESIS Pharma will be the exclusive distributor of QINLOCK in 14

countries in the European Union with a combined population of 118 million including Czech Republic, Greece, Hungary, Romania and Poland.

#### **Vimseltinib**

- Submit an NDA to the U.S. Food and Drug Administration (FDA) in the second quarter of 2024 and a MAA to the European Medicines Agency in the third quarter of 2024 for vimseltinib, an investigational, orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R, for the potential treatment of TGCT.
- Present additional results from Part 1 of the pivotal Phase 3 MOTION study of vimseltinib at a medical meeting in the second quarter of 2024.
- Present updated data from the Phase 1/2 study of vimseltinib in TGCT in the second half of 2024.
- Initiate a Phase 2 proof-of-concept study of vimseltinib for the treatment of cGVHD in the fourth quarter of 2024.

#### **Early-Stage Pipeline**

##### **DCC-3116**

- The Company expects to select a recommended Phase 2 dose for expansion cohort(s) for DCC-3116, an investigational switch-control kinase inhibitor of ULK1/2 designed to inhibit autophagy, in 2024.
- The Company has prioritized the development of DCC-3116 in combination with sotorasib and with QINLOCK and discontinued development of the encorafenib and cetuximab combination cohort prior to enrollment in any clinical studies as well as the two MEK combination cohorts.

##### **DCC-3084**

- Initiate a Phase 1 study for DCC-3084, a potential best-in-class pan-RAF inhibitor, in the first half of 2024.

##### **DCC-3009**

- Submit an investigational new drug (IND) application with the FDA for DCC-3009, a potential best-in-class pan-KIT inhibitor, in the first half of 2024 and initiate a Phase 1 study in the second half of 2024.

#### **Preliminary 2023 Financial Results**

Based on preliminary unaudited financial information, Deciphera expects total fourth quarter 2023 revenue to be approximately \$47 million and total full year 2023 revenue to be approximately \$162 million. QINLOCK net product revenue is estimated to be approximately \$46 million in the fourth quarter 2023, including approximately \$35 million in U.S. net product revenue and approximately \$11 million in international net product revenue, in addition to approximately \$1 million in collaboration revenue.

In addition, preliminary unaudited cash, cash equivalents, and marketable securities was approximately \$352 million as of December 31, 2023. 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 the second half of 2026.

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 2024.

#### **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, Iceland, Israel, Liechtenstein, Macau, New Zealand, Norway, Singapore, 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 X (@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, the ability to become a multi-product, self-sustaining company, plans to continue our geographic expansion of QINLOCK in European and international markets, plans to publish clinical data from our Phase 3 INTRIGUE study in second-line GIST patients with mutations in KIT exon 11 and 17/18, our Phase 3 INSIGHT clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18, our expectations regarding the aggregate potential revenue opportunity for QINLOCK, our ability to expand the market opportunity for QINLOCK in second-line GIST in our INSIGHT Phase 3 study; the timing of our NDA and MAA submission for vimseltinib, the potential revenue opportunity for vimseltinib, if approved, plans to present additional data from our Phase 3 MOTION study and Phase 1/2 study of vimseltinib, each in TGCT patients, plans to initiate a Phase 2 study of vimseltinib in patients with cGVHD, subject to FDA feedback; plans for our on-going phase 1/2 study of DCC-3116 and to select a recommended Phase 2 dose for at least one potential expansion cohort, subject to favorable data; initiating a Phase 1 study of DCC-3084 in the first half of 2024, submitting an IND for DCC-3009 in the first half of 2024 and initiating a Phase 1 study in the second half of 2024, each subject to FDA feedback; statements regarding the Company's preliminary unaudited fourth quarter, year-end, and net product revenue for the quarter and year-ended December 31, 2023 and preliminary unaudited cash, cash equivalents, and marketable securities for

the quarter and year-ended December 31, 2023, and cash guidance. 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 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, 2023, 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.

The Deciphera logo and the QINLOCK® word mark and logo are registered trademarks and the Deciphera word mark is a trademark of Deciphera Pharmaceuticals, LLC.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20240108730185/en/): <https://www.businesswire.com/news/home/20240108730185/en/>

**Investor Relations:**

Maghan Meyers  
Argot Partners  
[Deciphera@argotpartners.com](mailto:Deciphera@argotpartners.com)  
212-600-1902

**Media:**

David Rosen  
Argot Partners  
[David.Rosen@argotpartners.com](mailto:David.Rosen@argotpartners.com)  
212-600-1902

Source: Deciphera Pharmaceuticals, Inc.