Deciphera Pharmaceuticals Announces Fourth Quarter and Full Year 2022 Financial Results

February 7, 2023

– Fourth Quarter 2022 Total Revenue of $36.3 Million and Full Year 2022 Revenue of $134.0 Million; QINLOCK® Net Product Revenue Increased 44% to $125.5 Million in 2022 Compared to 2021 –

– Expects to Complete Enrollment in the MOTION Pivotal Phase 3 Study of Vimseltinib in the First Quarter of 2023 and Announce Top-line Results in the Fourth Quarter of 2023 –

– Plans to Initiate 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 Based on ctDNA Analysis from INTRIGUE Study –

– Generated Gross Proceeds of Approximately $143.7 Million from Public Offering in January 2023; Cash Expected to Fund Operating and Capital Expenditures into 2026 –

WALTHAM, Mass.--(BUSINESS WIRE)--Feb. 7, 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 financial results for the fourth quarter and year ended December 31, 2022 and provided a corporate update.

"We are exceptionally proud of the progress we made across our pipeline in 2022, which has set the stage for continued growth and momentum in 2023 for our commercial, clinical, and preclinical programs. We are well positioned to achieve our goals thanks to our strong balance street, which was bolstered by our recent financing that extended our cash runway into 2026," said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. "As QINLOCK ® continues to become the standard-of-care treatment for fourth-line GIST around the world, we are excited to initiate the INSIGHT pivotal Phase 3 study later this year, which seeks to build upon the substantial clinical benefit in second-line GIST patients harboring mutations in KIT exon 11 and 17/18 that we observed in the ctDNA analysis from our INTRIGUE study. We believe that with an expanded indication in the second-line setting, QINLOCK and vimseltinib in TGCT combined represent a peak global revenue opportunity of over one billion dollars. We now expect to complete enrollment in vimseltinib's MOTION pivotal Phase 3 study in the first quarter of 2023, bringing us one step closer to becoming a company with multiple approved medicines."

Fourth Quarter 2022 and Early 2023 Highlights and Upcoming Milestones

QINLOCK® (ripretinib)

- Recorded $32.9 million in QINLOCK net product revenue in the fourth quarter of 2022, including $25.6 million in U.S. net product revenue and $7.3 million in international net product revenue, an increase of 39% from net product revenue of $23.7 million in the fourth quarter of 2021.
- Included in the National Reimbursement Drug List (NRDL) by China's National Healthcare Security Administration (NHSA) for advanced gastrointestinal stromal tumor (GIST) patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting.
- Received approval in New Zealand in December 2022 and in Israel and Macau in January 2023 for the treatment of adult

patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

- Presented data from the INTRIGUE Phase 3 exploratory circulating tumor DNA (ctDNA) analysis at the American Society of Clinical Oncology (ASCO) Plenary Series Session on January 24, 2023, which followed the announcement of top-line results earlier that month.
    - Patients with mutations in KIT exon 11 and 17/18 derived substantially improved clinical benefit with QINLOCK versus sunitinib.
        - QINLOCK demonstrated a median progression free survival (mPFS) of 14.2 months compared to 1.5 months for the sunitinib arm (hazard ratio [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).
        - Overall survival (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).
- Expects 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 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 second half of 2023.

Vimseltinib

- Expects to complete enrollment for the MOTION pivotal Phase 3 study of vimseltinib, an investigational, orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R for the potential treatment of tenosynovial giant cell tumor (TGCT), in the first quarter of 2023 and announce top-line results from the study in the fourth quarter of 2023.
- Expects to present updated data from the Phase 1/2 study of vimseltinib in the second half of 2023.

DCC-3116

- Expects to initiate a new combination study evaluating DCC-3116, an investigational switch-control kinase inhibitor of ULK1/2 designed to inhibit autophagy, in combination with encorafenib and cetuximab in patients with colorectal cancer in the second half of 2023. Under the terms of the clinical trial collaboration and supply agreement with Pfizer, Inc., Deciphera will sponsor the study and Pfizer will supply encorafenib at no cost.
- Opened enrollment in three Phase 1b combination dose escalation cohorts and treated the first patient in the fourth quarter of 2022:
    - In combination with trametinib, a Food and Drug Administration (FDA)-approved MEK inhibitor, in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations.
    - In combination with binimetinib, an FDA-approved MEK inhibitor, in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations.
    - In combination with sotorasib, an FDA-approved $KRAS^{G12C}$ inhibitor, in patients with advanced or metastatic solid tumors with $KRAS^{G12C}$ mutations.
- Expects to present updated data from the single agent dose escalation phase and initial data from the combination dose escalation cohorts of the Phase 1/2 study of DCC-3116 in the second half of 2023.
- Expects to initiate one or more expansion cohorts in the ongoing Phase 1/2 study of DCC-3116 in the second half of 2023 in combination with the MEK inhibitors trametinib or binimetinib, or the $KRAS^{G12C}$ inhibitor sotorasib.
- Expects to present preclinical data on new clinical combinations with DCC-3116 in the first half of 2023.

DCC-3084

- Expects to submit an investigational new drug (IND) application with the FDA for DCC-3084, a potential best-in-class pan-RAF inhibitor, in the second half of 2023.
- Expects to present *in vitro* and *in vivo* data demonstrating its preclinical profile as a potent and selective inhibitor of BRAF/CRAF kinases, with optimized pharmaceutical properties for development in both single-agent and combination opportunities, in the first half of 2023.

Kinase Switch-Control Research Engine

- Expects to nominate a new development candidate from Deciphera's proprietary discovery engine of novel switch-control inhibitors in the first half of 2023.
- Expects to present new preclinical data from research programs at a medical meeting in the first half of 2023.

Corporate Update

- Announced the closing of its underwritten public offering of 7,986,111 shares of its common stock, including 1,041,666 shares pursuant to the option granted by Deciphera to the underwriters, which option was exercised in full. The public offering price of each share of common stock was $18.00. The aggregate gross proceeds to Deciphera from this offering

were approximately $143.7 million, before deducting underwriting discounts and commissions and other estimated offering expenses.

Fourth Quarter and Full Year 2022 Financial Results

- **Revenue:** Total revenue for the fourth quarter of 2022 was $36.3 million, which includes $32.9 million of net product revenue of QINLOCK and $3.4 million of collaboration revenue compared to $24.2 million of total revenue, including $23.7 million of net product revenue of QINLOCK and $0.5 million of collaboration revenue, for the same period in 2021. Total revenue for the year ended December 31, 2022 was $134.0 million, which includes $125.5 million of net product revenue of QINLOCK and $8.5 million of collaboration revenue compared to $96.1 million of total revenue, including $87.4 million of net product revenue of QINLOCK and $8.8 million of collaboration revenue, for the same period in 2021. International and total net product revenue for the fourth quarter includes a one-time reserve for QINLOCK product sales in Germany due to a change in German law effective as of November 2022 shortening the free pricing period retroactively to six months from twelve months.
- **Cost of Sales:** Cost of sales were $3.2 million in the fourth quarter of 2022, which includes $0.7 million in cost of product sales, compared to cost of product sales of $0.5 million for the fourth quarter of 2021. For the year ended December 31, 2022, cost of sales were $8.7 million, including $2.7 million in cost of product sales, compared to cost of sales of $2.9 million in 2021, including cost of product sales of $1.3 million. In the third quarter of 2022, the Company completed the sales of zero cost inventories of QINLOCK that had been expensed prior to FDA approval.
- **R&D Expenses:** Research and development expenses for the fourth quarter of 2022 were $48.1 million, compared to $74.9 million for the same period in 2021, and $187.8 million for the year ended December 31, 2022 compared to $257.0 million for the same period in 2021. The decrease was primarily due to lower clinical study costs related to QINLOCK, including the Phase 3 INTRIGUE study and the Phase 1 study, the discontinuation of the rebastinib program following the corporate restructuring implemented in the fourth quarter of 2021, partially offset by an increase in clinical study costs related to the Phase 3 study of vimseltinib and the Phase 1/2 study of DCC-3116. Non-cash, stock-based compensation was $22.2 million and $20.7 million for the year ended December 31, 2022 and 2021, respectively.
- **SG&A Expenses:** Selling, general, and administrative expenses for the fourth quarter of 2022 were $32.2 million, compared to $37.2 million for the same period in 2021 and $120.2 million for the year ended December 31, 2022, compared to $136.3 million for the same period in 2021. The decrease was primarily due to a decrease in personnel-related costs and professional and consultant fees. Non-cash, stock-based compensation was $29.7 million and $25.4 million for the year ended December 31, 2022 and 2021, respectively.
- **Net Loss:** For the fourth quarter of 2022, Deciphera reported a net loss of $45.9 million, or $0.60 per share, compared with a net loss of $88.4 million, or $1.51 per share, for the same period in 2021. Net loss for the year ended December 31, 2022 was $178.9 million, or $2.37 per share, compared with a net loss of $300.0 million, or $5.16 per share, for the year ended December 31, 2021.
- **Cash Position:** As of December 31, 2022, cash, cash equivalents, and marketable securities were $339.0 million, compared to $327.6 million as of December 31, 2021. Based on its current operating plans, Deciphera expects its current cash, cash equivalents, and marketable securities together with anticipated product, royalty, and supply revenues, and the net proceeds from our underwritten public offering completed in January 2023, 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 2026.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, February 7, 2023, at 8:00 AM ET. The conference call may be accessed via this link: https://register.vevent.com/register/BId831b7236a304519833842d99a13487f. A live webcast of the conference call will be available in the “Events and Presentations” page in the “Investors & News” section of the Company’s website at https://investors.deciphera.com/events-presentations. A replay 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 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 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 the potential for our preclinical and/or clinical stage pipeline assets to be first-in-class and/or best-in-class treatments, 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 vimseltinib enrollment and topline readout for the pivotal Phase 3 MOTION study and our phase 1/2 study of

vimseltinib, each in TGCT patients; plans to present updated data from the single agent dose escalation phase and initial data from the combination dose escalation cohorts of the Phase 1/2 study of DCC-3116, plans to initiate one or more combination cohorts in the Phase 1/2 study of DCC-3116, plans to initiate a new dose escalation cohort evaluating DCC-3116 in combination with encorafenib and cetuximab in patients with colorectal cancer, the benefits anticipated pursuant to our collaboration and supply agreement with Pfizer, plans to present additional preclinical data for DCC-3116; plans to submit an IND for DCC-3084 and present preclinical data for DCC-3084; plans to nominate a development candidate from our proprietary discovery engine of novel switch control inhibitors; 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, 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 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.

Deciphera Pharmaceuticals, Inc.
Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 64,741	$ 87,063
Short-term marketable securities	259,745	198,571
Accounts receivable, net	22,429	20,595
Inventory	20,561	14,125
Prepaid expenses and other current assets	25,482	18,660
Total current assets	392,958	339,014
Long-term marketable securities	14,550	41,950
Long-term investments—restricted and other long-term assets	3,277	3,110
Property and equipment, net	6,707	8,610
Operating lease assets	36,547	36,800
Total assets	$ 454,039	$ 429,484
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,612	$ 13,130
Accrued expenses and other current liabilities	64,622	80,773
Operating lease liabilities	3,235	2,870
Total current liabilities	86,469	96,773
Operating lease liabilities, net of current portion	25,879	27,991
Total liabilities	112,348	124,764
Stockholders' equity:		
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 67,637,351 shares and 58,549,644 shares issued and outstanding as of December 31, 2022 and 2021, respectively	676	585
Additional paid-in capital	1,575,361	1,358,516
Accumulated other comprehensive income	(983)	51
Accumulated deficit	(1,233,363)	(1,054,432)
Total stockholders' equity	341,691	304,720
Total liabilities and stockholders' equity	$ 454,039	$ 429,484

Deciphera Pharmaceuticals, Inc.
Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Product revenues, net	$ 32,880	$ 23,696	$ 125,504	$ 87,389
Collaboration revenues	3,465	503	8,532	8,759
Total revenues	36,345	24,199	134,036	96,148
Cost and operating expenses:				
Cost of sales	3,245	518	8,770	2,932
Research and development	48,066	74,932	187,821	257,040
Selling, general, and administrative	32,195	37,151	120,167	136,253
Total cost and operating expenses	83,506	112,600	316,758	396,225
Loss from operations	(47,160)	(88,401)	(182,722)	(300,077)
Other income (expense):				
Interest and other income, net	1,926	6	4,513	113
Total other income (expense), net	1,926	6	4,513	113
Loss before income tax expense	(45,234)	(88,395)	(178,209)	(299,964)
Income tax expense	700		722	
Net loss	$ (45,934)	$ (88,395)	$ (178,931)	$ (299,964)
Net loss per share—basic and diluted	$ (0.60)	$ (1.51)	$ (2.37)	$ (5.16)
Weighted average common shares outstanding—basic and diluted	76,440,793	58,487,041	75,500,148	58,084,325

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Investor Relations:
Maghan Meyers
Argot Partners
Deciphera@argotpartners.com
212-600-1902

Media:
David Rosen
Argot Partners
david.rosen@argotpartners.com
212-600-1902

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