Deciphera Pharmaceuticals Announces Third Quarter 2023 Financial Results

October 30, 2023

– Third Quarter 2023 Total Revenue of $43.3 Million; Net Product Revenue for QINLOCK® (ripretinib) Increased 29% to $41.8 Million Compared to Third Quarter 2022 –

– Announced Positive Top-line Results for MOTION Pivotal Phase 3 Study of Vimseltinib for TGCT and Updated Results from Phase 1/2 Study; NDA Submission Expected in Second Quarter of 2024 –

– QINLOCK Successfully Launched in Italy –

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

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 30, 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 third quarter ended September 30, 2023 and provided a corporate update.

“QINLOCK achieved another record quarter of product revenue with continued strength in commercial demand,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “With the positive results of the MOTION Phase 3 study of vimseltinib we reported earlier today, we are now one step closer to becoming a company with multiple approved products. We look forward to engaging with regulatory authorities to advance vimseltinib toward approval and deliver it to the TGCT patients in need of an effective and well tolerated treatment option."

Third Quarter 2023 Highlights and Upcoming Milestones

QINLOCK® (ripretinib)

- Recorded $41.8 million in QINLOCK net product revenue in the third quarter of 2023, including $32.7 million in U.S. net product revenue and $9.1 million in international net product revenue, an increase of 29% compared to net product revenue of $32.3 million in the third quarter of 2022. In addition, QINLOCK generated $1.5 million in collaboration revenue including royalties and supply revenue with Zai Lab, the Company’s partner in Greater China.
- Successfully launched QINLOCK in Italy for the treatment of fourth-line gastrointestinal stromal tumor (GIST).
- Initiated the INSIGHT Phase 3 study by opening the first sites for enrollment comparing QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18.

Vimseltinib

- Announced positive top-line results from 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). The study met its primary endpoint in the intent-to-treat (ITT) population demonstrating statistically significant and clinically meaningful improvements in objective response rate (ORR) at Week 25

compared to placebo. In the ITT population, the ORR at Week 25 was 40% for the vimseltinib arm and 0% for the placebo arm (p-value <0.0001). In addition, the study met all key secondary endpoints demonstrating statistically significant and clinically meaningful improvements in tumor volume score (TVS), range of motion (ROM), physical function, stiffness, quality of life, and pain compared to placebo. In the ITT population, the ORR by TVS at Week 25 was 67% for the vimseltinib arm and 0% for the placebo arm (p<0.0001). Treatment with vimseltinib also demonstrated an improvement in ROM at Week 25 of 18.4% vs. a 3.8% improvement for placebo (p=0.0077). Treatment with vimseltinib was well-tolerated in patients with TGCT and the safety profile was consistent with previously disclosed data. There was no evidence of cholestatic hepatotoxicity.

- Announced updated results from the Phase 1/2 study of vimseltinib as of a June 27, 2023 cutoff date demonstrating strong clinical benefit with best overall response rates of 72% (Phase 1) and 64% (Phase 2 Cohort A), a favorable long-term safety profile with no evidence of cholestatic hepatotoxicity and increasing median treatment duration of 25.1 months (Phase 1) and 21.0 months (Phase 2 Cohort A). Results from the Phase 1 portion of the study are being presented in an oral presentation and results from Cohorts A and B of the Phase 2 portion of the study are being presented in two poster presentations at the Connective Tissue Oncology Society 2023 Annual Meeting in Dublin, Ireland on November 1-4, 2023.
- Expects to submit a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2024 and a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) in the third quarter of 2024.

DCC-3116

- Enrollment is ongoing in combination escalation cohorts evaluating the potential first-in-class ULK inhibitor, DCC-3116, in combination with binimetinib, trametinib, sotorasib, encorafenib/cetuximab, and QINLOCK, designed to select recommended Phase 2 combination dosing for potential expansion cohorts.

DCC-3084

- Expects to submit an Investigational New Drug (IND) application to the FDA for its pan-RAF inhibitor, DCC-3084, by year end 2023.

DCC-3009

- Expects to submit an IND application to the FDA for its pan-KIT inhibitor, DCC-3009, in the first half of 2024.

Third Quarter 2023 Financial Results

- **Revenue:** Total revenue for the third quarter of 2023 was $43.3 million, which includes $41.8 million of net product revenue of QINLOCK and $1.5 million of collaboration revenue compared to $36.0 million of total revenue, including $32.3 million of net product revenue of QINLOCK and $3.7 million of collaboration revenue, for the same period in 2022.
- **Cost of Sales:** Cost of sales were $1.3 million in the third quarter of 2023 compared to cost of sales of $3.3 million for the third quarter of 2022. In the third quarter of 2022, Deciphera completed the sale of zero cost inventories of QINLOCK that had been expensed prior to FDA approval.
- **R&D Expenses:** Research and development expenses for the third quarter of 2023 were $62.5 million, compared to $47.5 million for the same period in 2022. The increase was primarily due to an increase in clinical study costs for QINLOCK and clinical study costs related to the Phase 1/2 study of DCC-3116. Non-cash, stock-based compensation was $5.0 million and $5.3 million for the third quarters of 2023 and 2022, respectively.
- **SG&A Expenses**: Selling, general, and administrative expenses for the third quarter of 2023 were $33.3 million, compared to $30.0 million for the same period in 2022. The increase was primarily due to an increase in professional, consulting, and other expenses as well as personnel-related costs. Non-cash, stock-based compensation was $6.1 million and $7.1 million for the third quarters of 2023 and 2022, respectively.
- **Net Loss:** For the third quarter of 2023, Deciphera reported a net loss of $49.6 million, or $0.58 per share, compared with a net loss of $43.0 million, or $0.55 per share, for the same period in 2022.
- **Cash Position:** As of September 30, 2023, cash, cash equivalents, and marketable securities were $376.9 million, compared to $389.4 million as of June 30, 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 milestones received 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, October 30, 2023, at 8:00 AM ET. The conference call may be accessed via this link: https://register.vevent.com/register/BIc2885b197da74145bfc30deb5fb11858. 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, Singapore, 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 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 vimseltinib to become our second approved medicine, plans to submit an NDA for vimseltinib in the second quarter of 2024 and an MAA in the third quarter of 2024, and plans to present additional data at upcoming medical congresses; plans for our ongoing Phase 1/2 studies of DCC-3116; plans to submit an IND application to the FDA for DCC-3084 by the end of 2023; plans to submit an IND application to the FDA for DCC-3009 in the first half of 2024; 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 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.

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$108,087	$64,741
Short-term marketable securities	230,988	259,745
Accounts receivable, net	27,549	22,429
Inventory	27,105	20,561
Prepaid expenses and other current assets	23,847	25,482
Total current assets	417,576	392,958
Long-term marketable securities	37,850	14,550
Long-term investments—restricted and other long-term assets	3,337	3,277
Property and equipment, net	5,864	6,707
Operating lease assets	33,209	36,547
Total assets	$497,836	$454,039
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$21,453	$18,612
Accrued expenses and other current liabilities	68,005	64,622
Operating lease liabilities	3,436	3,235
Total current liabilities	92,894	86,469
Operating lease liabilities, net of current portion	23,272	25,879
Total liabilities	116,166	112,348
Commitments and contingencies		
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; 79,975,625 shares and 67,637,351 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	799	676
Additional paid-in capital	1,762,882	1,575,361
Accumulated other comprehensive income (loss)	(896)	(983)
Accumulated deficit	(1,381,115)	(1,233,363)
Total stockholders' equity	381,670	341,691
Total liabilities and stockholders' equity	$497,836	$454,039

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product revenues, net	$41,820	$32,318	$112,362	$92,624
Collaboration revenues	1,493	3,656	2,700	5,067
Total revenues	43,313	35,974	115,062	97,691
Cost and operating expenses:				
Cost of sales	1,286	3,344	1,947	5,525
Research and development	62,463	47,485	175,524	139,755
Selling, general, and administrative	33,252	30,026	97,311	87,972
Total cost and operating expenses	97,001	80,855	274,782	233,252
Loss from operations	(53,688)	(44,881)	(159,720)	(135,561)
Other income (expense):				
Interest and other income, net	4,107	1,838	11,968	2,565
Total other income (expense), net	4,107	1,838	11,968	2,565
Net loss	$(49,581)	$(43,043)	$(147,752)	$(132,996)
Net loss per share—basic and diluted	$(0.58)	$(0.55)	$(1.75)	$(1.82)
Weighted average common shares outstanding—basic and diluted	85,788,613	78,206,647	84,506,593	73,129,804

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