Deciphera Pharmaceuticals, Inc. Announces Fourth Quarter and Full Year 2021 Financial Results

February 8, 2022

– Fourth Quarter 2021 Revenue of $24.2 Million and Full Year 2021 Revenue of $96.1 Million –

– Launch of QINLOCK® in Europe Underway –

– Pivotal Phase 3 MOTION Study of Vimseltinib in TGCT Patients Underway; Updated Phase 1/2 Data Expected in 2H 2022 –

– Phase 1 Single Agent Dose Escalation Data for DCC-3116 Expected in 2H 2022; Initiation of Phase 1 Combination Dose Escalation Cohorts Expected in 2H 2022 –

– New Development Candidate from Pan-RAF Research Program Expected in 2022 –

WALTHAM, Mass.--(BUSINESS WIRE)--Feb. 8, 2022-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results for the fourth quarter and year ended December 31, 2021, and provided a corporate update.

“I am immensely proud of our organization’s achievements in 2021 and believe that we are well positioned for long-term success as we work towards our expected milestones in 2022,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “While the unexpected results of the INTRIGUE study and subsequent restructuring at the end of last year were very difficult, we are fortunate to have a robust pipeline and look to build on the progress we made across our pipeline last year, as we continue to execute on our mission of delivering important new medicines to improve the lives of people with cancer.”

Mr. Hoerter continued, “We have rapidly progressed vimseltinib, our potential best-in-class inhibitor of CSF1R, to Phase 3 development for the treatment of tenosynovial giant cell tumor, or TGCT, and we expect to present updated data from the Phase 1/2 study in patients with TGCT in the second half of this year. In addition, we remain very excited by our first-in-class autophagy pathway inhibitor, DCC-3116, and plan to present initial data from the single agent dose escalation portion of the Phase 1 study in the second half of 2022. We also continue to focus on our next wave of therapeutic candidates, including our pan-RAF research program, and expect to nominate a clinical development candidate later this year.”

Fourth Quarter 2021 Highlights and Upcoming 2022 Milestones

QINLOCK® (ripretinib)

- Recorded $23.7 million in QINLOCK net product revenue in the fourth quarter of 2021, including $21.5 million in U.S. net product revenue.
- Received approval of QINLOCK in the European Union, the United Kingdom, and Switzerland for the treatment of adult patients with fourth-line gastrointestinal stromal tumor (GIST).
- Launched in Germany in January 2022, and the transition to a post-approval paid access program in France is expected in the first half of 2022.
- Presented results of the Phase 3 INTRIGUE study in second-line GIST at the American Society of Clinical Oncology (ASCO) Plenary Series Session on January 25, 2022, which followed the announcement in November 2021 of the top-line results.
    - The results showed that the efficacy of QINLOCK and sunitinib were comparable, although the study did not meet the primary endpoint of an improvement in progression free survival compared to sunitinib.
    - QINLOCK was generally well tolerated and fewer patients in the QINLOCK arm experienced Grade 3-4 treatment-emergent adverse events compared to sunitinib (41.3% vs 65.6%). Patient reported outcome data also showed a more favorable tolerability profile for patients on QINLOCK compared to patients on sunitinib.
- Updated National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for GIST in January 2022 now include the use of QINLOCK 150 mg twice daily (BID) after disease progression if previously treated with QINLOCK 150 mg once daily in fourth-line GIST patients.

Vimseltinib

- Initiated the pivotal Phase 3 MOTION study of vimseltinib. MOTION is a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with TGCT who are not amenable to surgery. The primary endpoint of the study is objective response rate at week 25 as measured by RECIST v1.1 by blinded independent central review.
- Announced that vimseltinib was granted fast track designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with TGCT who are not amenable to surgery. This designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and demonstrate the potential to address an

unmet medical need.
- Expects to present updated data from the Phase 1/2 study in TGCT patients in the second half of 2022.

DCC-3116

- Presented preclinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics demonstrating that DCC-3116 inhibits EGFR inhibitor-induced autophagy in multiple EGFR-mutant non-small cell lung cancer cell lines and decreases tumor burden in combination with osimertinib and afatinib in an EGFR mutant xenograft model.
- Expects to present data in the second half of 2022 from the single agent dose escalation portion of the Phase 1 study of DCC-3116 in patients with advanced or metastatic tumors with a mutant RAS or RAF gene.
- Expects to initiate Phase 1 study dose escalation cohorts in the second half of 2022 in combination with trametinib, an FDA-approved MEK inhibitor, in patients with selected mutations in advanced or metastatic pancreatic ductal adenocarcinoma, non-small-cell lung cancer (NSCLC), colorectal cancer, and melanoma.
- Planning underway to add a combination with a KRAS G12C inhibitor in NSCLC to the ongoing Phase 1 study, subject to feedback from regulatory authorities, based on positive preclinical data.
- Expects to present additional preclinical data for DCC-3116 in 2022 and continue to explore preclinical combinations with multiple additional anti-cancer agents with diverse mechanisms of action.

Proprietary Drug Discovery Platform

- Expects to nominate a development candidate in 2022 from the pan-RAF inhibitor research program, using the Company's novel switch-control inhibitor platform.

Fourth Quarter and Full Year 2021 Financial Results

- **Revenue**: Total revenue for the fourth quarter was $24.2 million, which includes $23.7 million of net product revenue of QINLOCK and $0.5 million of collaboration revenue compared to $19.5 million of total and net product revenue of QINLOCK for the same period in 2020. Total revenue for the year ended December 31, 2021 was $96.1 million, which includes net sales of QINLOCK of $87.4 million and $8.8 million in collaboration revenue compared to $42.1 million, which includes net sales of QINLOCK of $39.5 million and $2.6 million in collaboration revenue, for the same period in 2020.

- **Cost of Sales:** Cost of sales were $0.5 million in the fourth quarter of 2021 and $2.9 million for the year ended December 31, 2021 compared to $0.1 million and $0.2 million in the same periods, respectively, in 2020. Cost of sales for newly launched products will not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. Deciphera does not expect the cost of sales as a percentage of net sales of QINLOCK to increase significantly after the Company has sold all zero cost inventories and commenced the sales of inventories which will reflect the full cost of manufacturing. The Company expects to continue to sell the zero cost inventories of QINLOCK in the U.S. during 2022.

- **R&D Expenses:** Research and development expenses for the fourth quarter of 2021 were $74.9 million, compared to $52.3 million for the same period in 2020, and $257.0 million for the year ended December 31, 2021, compared to $199.0 million for the same period in 2020. The increase was primarily due to the one-time restructuring charge of $22.2 million of research and development costs related to employee termination costs and discontinuation costs. In addition, there was an increase in 2021 in research and development expenses related to personnel costs, preclinical costs, and clinical trial costs related to start-up activities for the Phase 3 MOTION study of vimseltinib. Non-cash, stock-based compensation was $20.7 million and $17.4 million for the year ended December 31, 2021 and 2020, respectively.

- **SG&A Expenses:** Selling, general, and administrative expenses for the fourth quarter of 2021 were $37.2 million, compared to $30.1 million for the same period in 2020 and $136.3 million for the year ended December 31, 2021, compared to $114.1 million for the same period in 2020. The increase was primarily due to the one-time restructuring charge of $4.0 million of selling, general, and administrative expenses related to employee termination costs. In addition, personnel costs as well as external spend related to professional fees, including those associated with establishing a direct commercial infrastructure and commercial preparedness in Germany and France to support a launch of QINLOCK in Europe. Non-cash, stock-based compensation was $25.4 million and $19.7 million for the year ended December 31, 2021 and 2020, respectively.

- **Net Loss:** For the fourth quarter of 2021, Deciphera reported a net loss of $88.4 million, or $1.51 per share, compared with a net loss of $62.7 million, or $1.10 per share, for the same period in 2020. Net loss for the year ended December 31, 2021 was $300.0 million, or $5.16 per share, compared with a net loss of $266.5 million, or $4.78 per share, for the year ended December 31, 2020.

- **Cash Position:** As of December 31, 2021, cash, cash equivalents, and marketable securities were $327.6 million,

compared to $561.3 million as of December 31, 2020. 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 2024.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, February 8, 2022 at 4:30 PM ET. To access the live call by phone please dial (866) 930-5479 (domestic) or (409) 216-0603 (international); the conference ID is 8293127. A live audio webcast of the event may also be accessed through the "Investors" section of Deciphera's website at www.deciphera.com. A replay of the webcast will be available for 30 days following the event.

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, 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 vimseltinib for the pivotal Phase 3 MOTION study in TGCT patients, the potential for vimseltinib to be a best-in-class treatment for TGCT, presenting updated vimseltinib data from our Phase 1/2 study in TGCT patients, initial data from the dose escalation phase of the Phase 1 study of DCC-3116, plans to initiate the trametinib combination dose escalation portion of the Phase 1 study of DCC-3116, plans to expand the ongoing Phase 1 study of DCC-3116 to add a combination with a mutant KRAS G12C inhibitor in NSCLC patients subject to feedback from regulatory authorities, plans to present additional pre-clinical data for DCC-3116, exploration of additional preclinical combinations of DCC-3116, nominating a development candidate for our pan-RAF research program, ex-U.S. strategies including executing on our commercial launch of QINLOCK in fourth-line GIST in Germany and our plans to transition to a post-approval paid access program in France, 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 provide access to QINLOCK in European countries other than Germany and France through other channels, the severity and duration of the impact of COVID-19 on our business and operations, 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, 2021, 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
(In thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 87,063	$ 135,897
Short-term marketable securities	198,571	416,033
Accounts receivable, net	20,595	13,896
Inventory	14,125	5,716
Prepaid expenses and other current assets	18,660	12,489
Total current assets	339,014	584,031
Long-term marketable securities	41,950	9,375
Long-term investments—restricted	3,110	3,102
Property and equipment, net	8,610	9,583
Operating lease assets	36,800	36,341
Total assets	$ 429,484	$ 642,432
Liabilities and Stockholders' Equity		

Current liabilities:		
Accounts payable	$ 13,130	$ 12,308
Accrued expenses and other current liabilities	80,773	55,227
Operating lease liabilities	2,870	2,457
Total current liabilities	96,773	69,992
Operating lease liabilities, net of current portion	27,991	28,764
Total liabilities	124,764	98,756
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; 58,549,644 shares and 57,596,144 shares issued and outstanding as of December 31, 2021 and 2020, respectively	585	576
Additional paid-in capital	1,358,516	1,297,557
Accumulated other comprehensive income (loss)	51	11
Accumulated deficit	(1,054,432)	(754,468)
Total stockholders' equity	304,720	543,676
Total liabilities and stockholders' equity	$ 429,484	$ 642,432

DECIPHERA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Product revenues, net	$ 23,696	$ 19,472	$ 87,389	$ 39,461
Collaboration revenues	503	14	8,759	2,626
Total revenues	24,199	19,486	96,148	42,087
Cost and operating expenses:				
Cost of sales	518	127	2,932	225
Research and development	74,932	52,288	257,040	198,970
Selling, general, and administrative	37,151	30,070	136,253	114,082
Total cost and operating expenses	112,600	82,485	396,225	313,277
Loss from operations	(88,401)	(62,999)	(300,077)	(271,190)
Other income (expense):				
Interest and other income, net	6	259	113	4,701
Total other income (expense), net	6	259	113	4,701
Net loss	$ (88,395)	$ (62,740)	$ (299,964)	$ (266,489)
Net loss per share—basic and diluted	$ (1.51)	$ (1.10)	$ (5.16)	$ (4.78)
Weighted average common shares outstanding—basic and diluted	58,487,041	57,223,076	58,084,325	55,780,982

View source version on businesswire.com: https://www.businesswire.com/news/home/20220208005939/en/

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

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

Source: Deciphera Pharmaceuticals, Inc.