Deciphera Pharmaceuticals, Inc. Announces Fourth Quarter and Full Year 2020 Financial Results

February 9, 2021

- Fourth Quarter 2020 QINLOCK® Net Revenue of $19.5 Million and Full Year 2020 QINLOCK Net Revenue of $39.5 Million -

- Top-line Results in INTRIGUE Phase 3 Study of QINLOCK in Patients with Second-line GIST Expected in the Second Half of 2021 -

- Pipeline Candidates, Vimseltinib (DCC-3014), Rebastinib and DCC-3116, Continue to Advance with Significant Clinical Milestones Expected in 2021 -

WALTHAM, Mass.--(BUSINESS WIRE)--Feb. 9, 2021-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results for the fourth quarter and year ended December 31, 2020, and provided a business update.

“We made significant progress in 2020 with the successful launch of QINLOCK, completing enrollment in the Phase 3 INTRIGUE study in second-line GIST patients, and generating promising new data for both vimseltinib and rebastinib,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “We’re incredibly excited by the opportunities ahead for the Company in 2021. Specifically, we look forward to top-line results from the INTRIGUE study and are actively preparing for a potential EMA approval for QINLOCK in fourth-line GIST in the second half of this year.”

Mr. Hoerter continued, “In addition, we remain very excited by the prospects of our maturing pipeline. We are on track to report additional data from and finalize pivotal development plans for both vimseltinib and rebastinib in the second half of this year, and also plan to initiate the Phase 1 study of DCC-3116, our ULK kinase inhibitor for the potential treatment of patients with cancers driven by mutations in RAS or RAF genes, in the second quarter of 2021.”

Fourth Quarter 2020 Highlights and Upcoming Milestones

- **QINLOCK (ripretinib)**
  - Recorded $19.5 million in QINLOCK net product revenue in the fourth quarter of 2020, including $18.5 million in U.S. net product revenue.
  - Completed enrollment in the INTRIGUE Phase 3 clinical study evaluating the efficacy and safety of QINLOCK compared to sunitinib in patients with second-line GIST. Top-line results for this study are expected in the second half of 2021.
  - Received validation from the European Medicines Agency (EMA) for the Marketing Authorisation Application for QINLOCK in fourth-line GIST. Potential EMA approval is expected in the second half of 2021.
  - Presented new data at the Connective Tissue Oncology Society (CTOS) 2020 Virtual Annual Meeting with results from an exploratory analysis from the Phase 3 INVICTUS study that highlighted the broad spectrum of mutations that drive GIST and clinical data demonstrating QINLOCK’s clinically meaningful activity in patients with a broad spectrum of KIT and PDGFRA mutations.
  - Expects potential approval from the China National Medical Products Administration (NMPA) in the first half of 2021.

- **Vimseltinib (DCC-3014)**
  - Presented preliminary results from the ongoing Phase 1/2 study of vimseltinib, a CSF1R inhibitor, in patients with tenosynovial giant cell tumor (TGCT) at the CTOS 2020 Virtual Annual Meeting. The results showed a 41% objective response rate, confirmed and unconfirmed, including one confirmed complete response, and treatment was generally well-tolerated with treatment-emergent adverse events mostly grade 1 or 2. Based on these preliminary results, the expansion cohorts for vimseltinib in TGCT patients opened at the recommended Phase 2 dose of 30 mg twice weekly.
  - Expects to present updated data from the ongoing Phase 1/2 study in patients with TGCT in the second half of 2021.
  - Plans to finalize the pivotal development plan for vimseltinib in TGCT in the second half of 2021.

- **Rebastinib**
  - Completed enrollment in the endometrial cancer cohort and the platinum-resistant ovarian cancer cohort of the ongoing Phase 1b/2 study of rebastinib, an inhibitor of TIE2, in combination with paclitaxel.
  - Expects to present updated data from the ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in the endometrial cancer cohort in the second quarter of 2021, and the platinum-resistant ovarian cancer cohort in the second half of 2021.

- Plans to finalize the pivotal development plan for rebastinib in combination with paclitaxel in the second half of 2021.

- **DCC-3116**
  - Submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA).
  - Plans to initiate the Phase 1, multicenter, open-label, first-in-human study of DCC-3116 as a single agent and then in combination with trametinib in patients with advanced or metastatic tumors with a mutant RAS or RAF gene in the second quarter of 2021.

- **Corporate Update**
  - Today announced the appointment of Margarida Duarte as Senior Vice President, Head of International. Ms. Duarte was most recently Vice President, Head of Commercial for Canada, Europe, Middle East and Africa at Alnylam Pharmaceuticals, where she was instrumental in the launch of multiple new products. She brings to Deciphera over 15 years of experience in the global pharmaceutical industry and previous leadership roles in commercial, marketing, and strategy, along with experience leading cross functional teams in medical, regulatory, supply chain, and global product development.

Fourth Quarter and Full Year 2020 Financial Results

- **Revenue:** Total net revenue for fourth quarter was $19.5 million, which includes U.S. sales of QINLOCK of $18.5 million and ex-U.S. sales of QINLOCK of $1.0 million. In the fourth quarter of 2019, the Company did not generate revenue. Total revenue for the year ended December 31, 2020 was $42.1 million, which includes $39.5 million in sales of QINLOCK and $2.6 million in collaboration revenue. Net product revenues for the year ended December 31, 2020 includes U.S. sales of QINLOCK of $38.0 million and ex-U.S. sales of QINLOCK of $1.5 million. This compares to total revenue of $25.0 million for the year ended December 31, 2019, which was related to the Company's exclusive license agreement with Zai Lab to advance the development and commercialization of ripretinib in Greater China.

- **Cost of Sales**: Cost of sales were $0.1 million in the fourth quarter of 2020 and $0.2 million for the year ended December 31, 2020. There were no cost of sales in 2019 as no product sales were generated during that period. Cost of sales will not be significant until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold.

- **R&D Expenses:** Research and development expenses for the fourth quarter of 2020 were $52.3 million, compared to $46.6 million for the same period in 2019, and $199.0 million for the year ended December 31, 2020, compared to $157.6 million for the same period in 2019. The increase was primarily due to personnel costs, preclinical costs, and clinical trial costs related to vimseltinib, rebastinib, DCC-3116, and the Phase 3 INTRIGUE study in second-line GIST. The increase was partially offset by a decrease in clinical trial expenses related to the Phase 3 INVICTUS study in fourth-line and fourth-line plus GIST. Non-cash, stock-based compensation was $17.4 million and $7.9 million for the year ended December 31, 2020 and 2019, respectively.

- **SG&A Expenses:** Selling, general and administrative expenses for the fourth quarter of 2020 were $30.1 million, compared to $23.7 million for the same period in 2019 and $114.1 million for the year ended December 31, 2020, compared to $68.1 million for the same period in 2019. The increase was primarily due to personnel costs as well as external spend associated with commercial preparedness and launch of QINLOCK, increased expenses incurred in connection with Deciphera's new headquarters that commenced in October 2019, and technology-related costs to support the growth of the business. Non-cash, stock-based compensation was $19.7 million and $12.5 million for the year ended December 31, 2020 and 2019, respectively.

- **Net Loss:** For the fourth quarter of 2020, Deciphera reported a net loss of $62.7 million, or $1.10 per share, compared with a net loss of $67.2 million, or $1.31 per share, for the same period in 2019. Net loss for the year ended December 31, 2020 was $266.5 million, or $4.78 per share, compared with a net loss of $192.3 million, or $4.48 per share, for the year ended December 31, 2019.

- **Cash Position:** As of December 31, 2020, cash, cash equivalents and marketable securities were $561.3 million, compared to $579.6 million as of December 31, 2019. Based on its current operating plans, Deciphera expects its current cash, cash equivalents, and marketable securities together with anticipated product revenues, but excluding any potential future milestone payments or other payments under its collaboration or license agreements, will enable the Company to fund its operating and capital expenditures into the second half of 2022.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, February 9, 2021 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 5826559. 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 FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is also approved for fourth-line GIST in Canada and Australia. 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 regarding 2021 corporate milestones and timing for these goals, including, without limitation, top-line data from our Phase 3 INTRIGUE study in second-line GIST, potential EMA and NMPA approval of QINLOCK for the treatment of fourth-line GIST, finalizing pivotal study plans for vimseltinib (DCC-3014) in TGCT patients and for the rebastinib/paclitaxel combination, presenting updated data from the Phase 1/2 study of vimseltinib (DCC-3014) in TGCT patients, presenting updated data from the Phase 1b/2 study of rebastinib in combination with paclitaxel for patients with endometrial cancer and also from patients with platinum-resistant ovarian cancer, initiating a phase 1 study of DCC-3116; and expanding the geographic reach of QINLOCK. 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 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 candidates and in additional indications for our existing drug, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, 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, our ability to build and scale our operations to support growth in additional geographies, 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, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, 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, 2020, 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. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 135,897	$ 120,320
Short-term marketable securities	416,033	459,256
Accounts receivable, net	13,896	—
Inventory	5,716	—
Prepaid expenses and other current assets	12,489	13,832
Total current assets	584,031	593,408
Long-term marketable securities	9,375	—
Long-term investments—restricted	3,102	1,510
Property and equipment, net	9,583	6,333
Operating lease assets	36,341	21,158
Total assets	$ 642,432	$ 622,409
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,308	$ 19,575
Accrued expenses and other current liabilities	55,227	38,716
Operating lease liabilities	2,457	1,747
Total current liabilities	69,992	60,038
Operating lease liabilities, net of current portion	28,764	15,904

Total liabilities	98,756	75,942
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 57,596,144 shares and 51,617,639 shares issued and outstanding as of December 31, 2020 and 2019, respectively	576	516
Additional paid-in capital	1,297,557	1,033,819
Accumulated other comprehensive income (loss)	11	111
Accumulated deficit	(754,468)	(487,979)
Total stockholders' equity	543,676	546,467
Total liabilities and stockholders' equity	$ 642,432	$ 622,409

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

	Year Ended December 31,		
	2020	**2019**	**2018**
Revenues:			
Product revenues, net	$ 39,461	$ —	$ —
Collaboration revenues	2,626	25,000	—
Total revenues	42,087	25,000	—
Cost and operating expenses:			
Cost of sales	225	—	—
Research and development	198,970	157,610	82,887
Selling, general, and administrative	114,082	68,116	21,212
Total cost and operating expenses	313,277	225,726	104,099
Loss from operations	(271,190)	(200,726)	(104,099)
Other income (expense):			
Interest and other income, net	4,701	8,537	4,329
Interest expense	—	(67)	(84)
Total other income (expense), net	4,701	8,470	4,245
Net loss	$ (266,489)	$ (192,256)	$ (99,854)
Net loss per share—basic and diluted	$ (4.78)	$ (4.48)	$ (2.82)
Weighted average common shares outstanding—basic and diluted	55,780,982	42,869,058	35,390,480

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

	Three Months Ended December 31,	
	2020	**2019**
Revenues:		
Product revenues, net	$ 19,472	$ —
Collaboration revenues	14	—
Total revenues	19,486	—
Cost and operating expenses:		
Cost of sales	127	—
Research and development	52,288	46,636
Selling, general, and administrative	30,070	23,737
Total cost and operating expenses	82,485	70,373
Loss from operations	(62,999)	(70,373)
Other income (expense):		
Interest and other income, net	259	3,169
Interest expense	—	(12)
Total other income (expense), net	259	3,157
Net loss	$ (62,740)	$ (67,216)
Net loss per share—basic and diluted	$ (1.10)	$ (1.31)
Weighted average common shares outstanding—basic and diluted	57,223,076	51,260,062

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