Deciphera Pharmaceuticals, Inc. Announces Third Quarter 2020 Financial Results

November 5, 2020

– U.S. QINLOCK® Net Revenue of $14.7 Million in the First Full Quarter of Launch –

– Marketing Authorisation Application for QINLOCK in Fourth-line GIST Validated by the European Medicines Agency; Commercial Planning for Europe Underway –

– Enrollment for QINLOCK Phase 3 INTRIGUE Study Expected to be Completed in Fourth Quarter 2020 –

– DCC-3014 Phase 1 Study Results in Additional TGCT Patients to be Featured in an Oral Presentation at the CTOS 2020 Virtual Annual Meeting –

– Company to Host Conference Call Today at 4:30 PM ET –

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 5, 2020-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results and provided a business update for the third quarter ended September 30, 2020.

“The strong U.S. commercial launch of QINLOCK, which is reflected in our first full quarter of results since the approval in May, is a testament to the potential for this new medicine to be a best-in-class treatment for people with GIST,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “During the third quarter, we also made substantial progress in preparing to bring QINLOCK to eligible patients around the world, including the submission and validation of the MAA by the EMA and the establishment of distribution agreements in Canada and Australia.”

Mr. Hoerter continued, “In addition to executing on the successful launch of QINLOCK, we continue to advance our pipeline of promising product candidates. Notably, we look forward to presenting new data from our Phase 1/2 study of DCC-3014 in TGCT patients at the CTOS 2020 Virtual Meeting later this month.”

Third Quarter 2020 Highlights and Recent Business Updates

- **QINLOCK (ripretinib) Commercialization**
  - Recorded $15.2 million in net product revenue in the third quarter of 2020, including $14.7 million in U.S. net product revenue in the first full quarter of commercial launch following FDA approval in May 2020.
  - Submitted and received validation of a Marketing Authorisation Application (MAA) for QINLOCK in fourth-line gastrointestinal stromal tumor (GIST) by the European Medicines Agency (EMA). Validation of the MAA confirms that the application is sufficiently complete for the EMA to begin its formal review process.
  - Announced plans to establish a targeted commercial infrastructure in key European markets to support the potential launch of QINLOCK, as well as to support additional future product launches.
  - Entered into exclusive distribution agreements with the following partners to distribute QINLOCK in other territories:
    - Medison to distribute QINLOCK in Canada and Israel. Health Canada approved QINLOCK for fourth-line GIST in June 2020 under the U.S. FDA’s Project Orbis, an initiative that enables concurrent review of oncology products by international regulatory agencies.
    - Specialised Therapeutics Asia (STA) to distribute QINLOCK in Australia, New Zealand, Singapore, Malaysia, and Brunei. The Australian Therapeutic Goods Administration (TGA) approved QINLOCK in July 2020 under the U.S. FDA’s Project Orbis.
  - Presented two mini oral presentations on QINLOCK at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 in September. The first mini oral presentation was on the nine-month follow-up data from the Phase 3 INVICTUS study in patients with fourth-line and fourth-line plus GIST. The second mini oral presentation was on the ongoing Phase 1 study of QINLOCK in patients with second-line through fourth-line plus GIST. The presentation highlighted that the patients receiving QINLOCK who, upon disease progression, dose escalated to QINLOCK 150 mg twice daily (BID) experienced additional, clinically meaningful, progression-free survival benefit across all lines of therapy.
- **Rebastinib**
  - Presented results from Part 2 (Stage 1) of the platinum-resistant ovarian cancer cohort in the ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in an E-poster presentation at the ESMO Virtual Congress 2020. Data presented demonstrated encouraging efficacy with an objective response rate of 38%, confirmed and unconfirmed, and a clinical benefit rate of 88% at eight weeks. Treatment with rebastinib 50 mg BID in combination with paclitaxel was generally well-tolerated. Enrollment in Stage 2 of the platinum-resistant ovarian cancer cohort at the rebastinib 50 mg BID dose is completed and further efficacy and safety evaluation is ongoing.
  - Presented results from Part 1 of the Phase 1b/2 study of rebastinib in combination with carboplatin in an E-poster presentation at the ESMO Virtual Congress 2020. The clinical benefit rate was 50% at six weeks and 36% at

twelve weeks, and the median duration of treatment was 7.8 weeks. Rebastinib in combination with carboplatin was generally well-tolerated. The Part 2 portion of the ongoing Phase 1/2 study is currently enrolling patients and will evaluate the safety and efficacy of rebastinib at the recommended Phase 2 dose of 50 mg BID in combination with carboplatin.

Upcoming Scientific Congress Presentations

- **Connective Tissue Oncology Society (CTOS) 2020 Virtual Annual Meeting, November 18-21**
  - **DCC-3014**
    - **Oral Presentation:** “Phase 1 dose-escalation study of the safety, tolerability, pharmacokinetics, and pharmacodynamics of DCC-3014 in advanced solid tumors and tenosynovial giant cell tumor”
  - **QINLOCK (ripretinib)**
    - **Oral Presentation:** “Characterization of the extensive heterogeneity of KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: genomic analysis of the phase 3 INVICTUS study”
    - **Poster Presentation:** “Ripretinib demonstrated activity across all KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: analysis from the phase 3 INVICTUS study”
    - **Oral Presentation:** “Ripretinib intra-patient dose escalation following disease progression provides clinically meaningful progression-free survival in gastrointestinal stromal tumor in phase 1 study”
    - **Poster Presentation**: “Clinical benefit with ripretinib as ≥4th line treatment in patients with advanced gastrointestinal stromal tumor: update from the phase 3 INVICTUS study”

Third Quarter 2020 Financial Results

- **Revenue:** Total revenue for the third quarter of 2020 was $15.5 million, which includes $15.2 million of net product revenue from sales of QINLOCK and $0.3 million of collaboration revenue. Net product revenues for the third quarter of 2020 includes U.S. sales of QINLOCK of $14.7 million and ex-U.S. sales of QINLOCK of $0.5 million. In the third quarter of 2019, the Company did not generate revenue.

- **Cost of Sales**: Cost of sales for the third quarter of 2020 was $0.1 million as the majority of the manufacturing costs related to third quarter QINLOCK sales were incurred prior to FDA approval, and thus, were recorded as R&D expense. Cost of sales will not be significant until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. In the third quarter of 2019, there were no cost of sales as no product sales were generated during that period.

- **R&D Expenses:** Research and development expenses for the third quarter of 2020 were $49.2 million, compared to $40.4 million for the same period in 2019. The increase was primarily due to personnel costs, preclinical costs, and clinical trial costs related to DCC-3014, rebastinib, and the Phase 3 INTRIGUE trial in second-line GIST. The increase was partially offset by a decrease in clinical trial expenses related to the Phase 3 INVICTUS trial in fourth-line and fourth-line plus GIST. Non-cash, stock-based compensation was $4.5 million and $2.0 million for the third quarters of 2020 and 2019, respectively.

- **SG&A Expenses:** Selling, general and administrative expenses for the third quarter of 2020 were $30.1 million, compared to $18.0 million for the same period in 2019. The increase was primarily a result of 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 $5.3 million and $2.7 million for the third quarters of 2020 and 2019, respectively.

- **Net Loss:** For the third quarter of 2020, Deciphera reported a net loss of $63.7 million, or $1.13 per share, compared with a net loss of $56.2 million, or $1.28 per share, for the same period in 2019. The increase in net loss was primarily related to increases in R&D and SG&A expenses, partially offset by the recognition of revenues in the third quarter of 2020, as discussed above.

- **Cash Position:** As of September 30, 2020, cash, cash equivalents and marketable securities were $584.3 million, compared to $579.6 million as of December 31, 2019. The increase was primarily due to the Company’s follow-on public offering in February 2020 that provided net proceeds of $188.4 million, partially offset by cash used in operations. 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, November 5, 2020 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 6048987. 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 GIST. QINLOCK is also approved in Canada and Australia for fourth-line GIST. For more information, visit www.Deciphera.com and follow us on Twitter (@Deciphera) and LinkedIn.

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 corporate milestone timing, including INTRIGUE enrollment, clinical and other data to be presented at future medical congresses, such as CTOS, and the review of our MAA filing with the EMA, commercial planning for Europe, the potential of QINLOCK to be a best-in-class treatment for GIST, and our cash runway. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "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, 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, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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
(Unaudited, in thousands, except share and per share amounts)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 111,154	$ 120,320
Short-term marketable securities	434,171	459,256
Accounts receivable, net	11,814	—
Inventory	4,596	—
Prepaid expenses and other current assets	9,723	13,832
Total current assets	571,458	593,408
Long-term marketable securities	38,989	—
Long-term investments—restricted	2,125	1,510
Property and equipment, net	9,925	6,333
Operating lease assets	37,171	21,158
Total assets	$ 659,668	$ 622,409
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,237	$ 19,575
Accrued expenses and other current liabilities	48,941	38,716
Operating lease liabilities	2,010	1,747
Total current liabilities	61,188	60,038

Operating lease liabilities, net of current portion	29,394	15,904
Total liabilities	90,582	75,942
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; 56,641,065 shares and 51,617,639 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	566	516
Additional paid-in capital	1,260,209	1,033,819
Accumulated other comprehensive income (loss)	39	111
Accumulated deficit	(691,728)	(487,979)
Total stockholders' equity	569,086	546,467
Total liabilities and stockholders' equity	$ 659,668	$ 622,409

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,	
	2020	2019	2020	2019
Revenues:				
Product revenues, net	$ 15,164	$ —	$ 19,989	$ —
Collaboration revenues	285	—	2,612	25,000
Total revenues	15,449	—	22,601	25,000
Cost and operating expenses:				
Cost of sales	90	—	98	—
Research and development	49,213	40,374	146,682	110,974
Selling, general, and administrative	30,143	17,979	84,012	44,379
Total cost and operating expenses	79,446	58,353	230,792	155,353
Loss from operations	(63,997)	(58,353)	(208,191)	(130,353)
Other income (expense):				
Interest and other income, net	296	2,174	4,442	5,368
Interest expense	—	(17)	—	(55)
Total other income (expense), net	296	2,157	4,442	5,313
Net loss	$ (63,701)	$ (56,196)	$ (203,749)	$ (125,040)
Net loss per share—basic and diluted	$ (1.13)	$ (1.28)	$ (3.68)	$ (3.12)
Weighted average common shares outstanding—basic and diluted	56,390,748	43,803,508	55,296,775	40,041,321

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