# Deciphera Pharmaceuticals, Inc. Announces Fourth Quarter and Full Year 2019 Financial Results

March 9, 2020

*- NDA for Ripretinib for the Treatment of Advanced GIST Accepted for Priority Review by U.S. FDA with PDUFA Date of August 13, 2020; Commercial Preparations Underway to Support Potential Approval and Launch -*

*- INTRIGUE Pivotal Phase 3 Study of Ripretinib in Second-line GIST Expected to Complete Enrollment in the Second Half of 2020 -*

*- Ended 2019 with Cash, Cash Equivalents and Marketable Securities of $579.6 Million -*

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

WALTHAM, Mass.--(BUSINESS WIRE)-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results for the fourth quarter and year ended December 31, 2019 and provided an update on clinical and corporate developments.

“2019 was a year of outstanding execution for Deciphera,” said Steve Hoerter, President and Chief Executive Officer. “In 2020, our top priority is preparing for the potential approval and launch of ripretinib now that the NDA has been accepted by the FDA for Priority Review. Patients with GIST are in need of a new treatment option, and we believe ripretinib has the potential to transform the treatment of this disease.”

Mr. Hoerter continued, “Our broad development program for ripretinib is on track, and we look forward to the completion of enrollment in INTRIGUE, our pivotal Phase 3 study of ripretinib in second-line GIST, in the second half of this year. Beyond ripretinib, we remain focused on the balance of our wholly-owned, clinical-stage pipeline, with updated clinical data for both DCC-3014 and rebastinib, as well as an IND submission for DCC-3116, expected later this year.”

**Recent Program Highlights**

- **Ripretinib**
  - Announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the New Drug Application (NDA) seeking approval for ripretinib for the treatment of patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib, sunitinib, and regorafenib, and assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 13, 2020.

    The NDA is being reviewed by the FDA under the Oncology Center of Excellence Real-Time Oncology Review (RTOR) pilot program. This pilot program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Additional information about RTOR can be found at: https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program.

  - Received Priority Review, under the Project Orbis initiative, for the marketing authorization applications in Canada and Australia. Project Orbis, an initiative of the FDA Oncology Center of Excellence, is designed to provide a framework for concurrent submission and review of oncology products among international partners. Additional information about the Project Orbis initiative can be found at: https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis.

- **DCC-3014**
  - Presented preliminary data from the ongoing Phase 1 study of DCC-3014, including anti-tumor activity in three initial patients with diffuse-type tenosynovial giant cell tumor (TGCT). These data, which provide clinical proof-of-concept for DCC-3014’s potential in diffuse-type TGCT, were presented at the Connective Tissue Oncology Society (CTOS) 2019 Annual Meeting. DCC-3014 was also shown to be generally well tolerated with no reported grade 3 or higher treatment-emergent adverse events in initial diffuse-type TGCT patients.

- **Rebastinib**
  - Announced the selection of the Phase 2 dose for rebastinib in the Phase 1b/2 study in combination with carboplatin and activation of Part 2 of the study in patients with breast cancer, ovarian cancer, and mesothelioma.

**Recent Corporate Updates**

- Announced the closing of an underwritten public offering of 3,659,090 shares of common stock at a public offering price of $55.00 per share in February 2020. Total net proceeds to Deciphera were approximately $188.4 million, after deducting underwriting discounts and commissions and other offering expenses.
- Announced the appointment of Ron Squarer to its Board of Directors. Mr. Squarer served as Chief Executive Officer and a member of the Board of Directors of Array BioPharma, Inc. from 2012 until its acquisition by Pfizer Inc. in August 2019 following the successful commercial launches of both Braftovi® and Mektovi® and brings over two decades of experience in the biopharmaceutical industry.
- Announced the appointment of Frank S. Friedman to its Board of Directors. Mr. Friedman recently served as the global Chief Operating Officer of Deloitte Touche Tohmatsu Limited, culminating a 40-year career at the organization.

**Fourth Quarter 2019 Financial Results**

- **Cash Position:** As of December 31, 2019, cash, cash equivalents, and marketable securities were $579.6 million, compared to cash and cash equivalents of $293.8 million as of December 31, 2018. The increase was primarily due to the follow-on public offering in the third quarter of 2019 and did not include the proceeds from the Company's follow-on public offering completed in February 2020. We expect our current cash, cash equivalents, and marketable securities, together with the proceeds from our recent follow-on public offering in February 2020, will enable us to fund our operating and capital expenditures into the second half of 2022.
- **R&D Expenses:** Research and development expenses for the fourth quarter of 2019 were $46.6 million, compared to $27.4 million for the same period in 2018. The increase was primarily due to personnel costs as well as clinical trial costs related to ripretinib, DCC-3014, and rebastinib. Non-cash stock-based compensation was $2.5 million and $1.0 million for the fourth quarters of 2019 and 2018, respectively.
- **SG&A Expenses:** Selling, general, and administrative expenses for the fourth quarter of 2019 were $23.7 million, compared to $6.5 million for the same period in 2018. The increase was primarily due to personnel costs as well as external spend associated with commercial readiness and moving to our new headquarters. Non-cash stock-based compensation was $2.9 million and $1.8 million for the fourth quarters of 2019 and 2018, respectively.
- **Net Loss:** For the fourth quarter of 2019, Deciphera reported a net loss of $67.2 million, or $1.31 per share, compared with a net loss of $32.3 million, or $0.86 per share, for the same period in 2018. The increase in the net loss is primarily due to the increase in R&D expenses and G&A expenses discussed above.

**Conference Call and Webcast**

Deciphera will host a conference call and webcast to discuss this announcement today, March 9, 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 1669368. 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 Pharmaceuticals is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance -causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate and/or durability of their responses to treatment.

**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 our goal of bringing ripretinib to patients with advanced GIST, the potential for ripretinib to transform treatment of advanced GIST, working with the FDA through its review of our NDA application via the FDA's Real-Time Oncology Review (RTOR) pilot program, working with the FDA, Health Canada and the Therapeutic Goods Administration (TGA) on our Canadian and Australian regulatory approval filings under the Project Orbis initiative, and the possible benefits of those programs and breakthrough therapy designation, receipt of priority review, preparing for the potential commercial launch of ripretinib in the United States, if approved, the progress and potential of our clinical and preclinical development programs for DCC-3014, rebastinib, and DCC-3116, and corporate guidance for 2020, including timing of completion of enrollment in the INTRIGUE Phase 3 study, progress on the pipeline and cash guidance. 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 delay of any current or planned clinical studies or the development of our product candidates, including ripretinib, our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, the preclinical and clinical results for our product candidates, which may not support further development of such product candidates, the possibility that results experienced in early, preliminary, top-line or initial data may not be indicative of the results experienced in final

data, our ability to work with the FDA under its RTOR pilot program and our ability to work with the FDA, Health Canada and the TGA under the Project Orbis initiative and timely respond to information requests or requirements in connection with our recently-filed NDAs and marketing approval applications in Canada and Australia for ripretinib in fourth-line GIST, that acceptance into the RTOR and Project Orbis programs does not guarantee or influence approvability of our NDAs for ripretinib in fourth-line GIST, which are subject to the standard benefit-risk evaluation by the FDA, Health Canada and the TGA, and that we may not derive any benefit from inclusion in the RTOR or Project Orbis programs, including, but not limited to, a more efficient review process compared to investigational drugs evaluated without these programs or under standard FDA, Health Canada or TGA procedures, the fact that these programs are being tested by the FDA, are not formal regulatory pathways with regulatory process, regulations or procedures, and may be suspended or halted at any time, including, without limitation, because the FDA decides not to continue these programs, or because the FDA determines that our application no longer meets its criteria for inclusion in one or both of these programs, the fact that receipt of a breakthrough therapy designation for a product candidate, such as ripretinib, may not result in us receiving any of the benefits of such designation such as a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, the fact such designation does not assure ultimate approval by the FDA and is subject to the risk the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened, the fact that priority review may not result in any more efficient review or other benefits, our ability to manage and 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 plan for potential commercialization of our product candidates, such as ripretinib, and if approved, execute on our marketing plans, the inherent uncertainty in estimates of patient populations and incidence and prevalence estimates, 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 regulatory approval, if at all, and make our investigational drugs, including ripretinib, available to patients, and, once commercial, to derive revenue from product sales, and other risks identified in our SEC filings, including our Annual Report on Form 10-K for the quarter and year ended December 31, 2019, 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 its 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, | |
|---|---|---|
| | **2019** | **2018** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 120,320 | $293,764 |
| Marketable securities | 459,256 | — |
| Prepaid expenses and other current assets | 13,832 | 7,273 |
| Total current assets | 593,408 | 301,037 |
| Long-term investment—restricted | 1,510 | 1,069 |
| Property and equipment, net | 6,333 | 13,453 |
| Operating lease assets | 21,158 | — |
| Total assets | $ 622,409 | $315,559 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 19,575 | $ 8,308 |
| Accrued expenses and other current liabilities | 38,716 | 13,709 |
| Operating lease liabilities | 1,747 | 539 |
| Notes payable to related party | — | 187 |
| Total current liabilities | 60,038 | 22,743 |
| Notes payable to related party, net of current portion | — | 1,107 |
| Operating lease liabilities, net of current portion | 15,904 | 11,347 |
| Other long-term liabilities | — | 381 |
| Total liabilities | 75,942 | 35,578 |
| 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; 51,617,639 shares and 37,676,760 shares issued and outstanding as of December 31, 2019 and 2018, respectively | 516 | 377 |
| Additional paid-in capital | 1,033,819 | 575,327 |
| Accumulated other comprehensive income (loss) | 111 | — |
| Accumulated deficit | (487,979) | (295,723) |
| Total stockholders' equity | 546,467 | 279,981 |
| Total liabilities and stockholders' equity | $ 622,409 | $315,559 |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| Revenues | $ 25,000 | $ — | $ — |
| Operating expenses: | | | |
| Research and development | 157,610 | 82,887 | 39,514 |
| Selling, general, and administrative | 68,116 | 21,212 | 11,421 |
| Total operating expenses | 225,726 | 104,099 | 50,935 |
| Loss from operations | (200,726) | (104,099) | (50,935) |
| Other income (expense): | | | |
| Interest and other income, net | 8,537 | 4,329 | 746 |
| Interest expense | (67) | (84) | (95) |
| Total other income (expense), net | 8,470 | 4,245 | 651 |
| Net loss | $ (192,256) | $ (99,854) | $ (50,284) |
| | | | |
| Net loss per share—basic and diluted | $ (4.48) | $ (2.82) | $ (2.99) |
| Weighted average common shares outstanding—basic and diluted | 42,869,058 | 35,390,480 | 16,792,179 |

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

| | Three Months Ended December 31, | |
|---|---|---|
| | **2019** | **2018** |
| Revenues | $ — | $ — |
| Operating expenses: | | |
| Research and development | 46,636 | 27,356 |
| Selling, general, and administrative | 23,737 | 6,474 |
| Total operating expenses | 70,373 | 33,830 |
| Loss from operations | (70,373) | (33,830) |
| Other income (expense): | | |
| Interest and other income, net | 3,169 | 1,551 |
| Interest expense | (12) | (20) |
| Total other income (expense), net | 3,157 | 1,531 |
| Net loss | $ (67,216) | $ (32,299) |
| | | |
| Net loss per share—basic and diluted | $ (1.31) | $ (0.86) |
| Weighted average common shares outstanding—basic and diluted | 51,260,062 | 37,665,599 |

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