Deciphera Pharmaceuticals Reports Updated Preliminary Phase 1 Clinical Study Results with DCC-2618 at the European Society of Medical Oncology (ESMO) 2018 Congress

October 19, 2018

- Preliminary Median Progression Free Survival and Disease Control Rates from the Phase 1 Study of DCC-2618 in Second- and Third-Line GIST Patients Demonstrate the Potential for Improved and Durable Clinical Outcomes in Patients with Less Advanced Disease -

- Updated Objective Response Rates and Disease Control Rates Observed in these Preliminary Results with DCC-2618 Continue to Exceed Previously Published Results of Registrational Trials for Currently Approved Therapies in Second- and Third-Line GIST Patients -

- Median Progression Free Survival in Fourth-Line and Fourth-Line-Plus GIST Patients Demonstrate the Potential for Durable Clinical Outcomes with DCC-2618 in Patients with Advanced Disease -

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 19, 2018-- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, announced the presentation today of updated preliminary results from its ongoing Phase 1 clinical study of DCC-2618, the company’s broad-spectrum KIT and PDGFRα inhibitor, in patients with

gastrointestinal stromal tumors (GIST) as a proffered paper presentation at the European Society of Medical Oncology (ESMO) 2018 Congress in Munich, Germany.

“We are extremely pleased with the preliminary results presented today that we believe demonstrate the potential of DCC-2618 to provide improved, durable clinical benefit for GIST patients from second-line through fourth-line-plus,” said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. “While the data set is still maturing, we believe the median progression free survival value of 42 weeks observed in second-line GIST patients strongly supports our planned randomized Phase 3 study, INTRIGUE, in second-line GIST patients, which we expect to initiate before the end of the year. In addition, the disease control rate and objective response rate observed with DCC-2618 in second-line GIST patients continues to exceed the values reported in previously published, centrally-read, registrational trials for sunitinib.”

The presentation reported preliminary results with a cutoff date of August 31, 2018 that include investigator-assessed median progression free survival (mPFS), objective response rates by best response (ORR) and disease control rates at 3 months (DCR) as determined by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 across 178 patients receiving DCC-2618 at doses of ≥100mg daily:

Line of Therapy	GIST Patients (n)	DCR at 3 Months	ORR[1]	Median Progression[5] Free Survival
2nd Line[4]	38	79%	18%[2]	42 weeks
3rd Line[4]	29	83%	24%	40 weeks
≥4th Line	111	66%	9%[3]	24 weeks
2nd & 3rd Line[4]	67	81%	21% [2 & 3]	40 weeks

Notes: (1) Includes nine unconfirmed responses: 2nd line (n=1), 3rd line (n=3) and ≥4th line (n=5); (2) Does not reflect one PR reported after cutoff date, which would result in an ORR in 2nd line of 21% and an ORR in 2nd line and 3rd line combined of 22%; (3)

Excludes five patients due to missing data at the time of data cutoff (n=2), lack of first tumor assessment (n=1), withdrawal of consent prior to first assessment (n=1) and unrelated death at C1D4 prior to first assessment (n=1); (4) 59 of 67 combined 2nd line and 3rd line patients received 150mg once daily; and (5) Censored patients for mPFS were 2nd line (58%), 3rd line (52%), 4th line and 4th line plus (35%) and 2nd and 3rd line (55%).

"The preliminary progression free survival data and objective response rates observed with DCC-2618 are very encouraging across all lines of therapy presented: second-, third-, and fourth-line and beyond," said Suzanne George, M.D., Director of Clinical Research, Center for Sarcoma and Bone Oncology and Senior Physician at the Dana Farber Cancer Institute and Associate Professor of Medicine at Harvard Medical School. "There is a clear unmet need for effective and well tolerated options for patients with metastatic GIST beyond the first-line."

Highlights from the proffered paper include:

Preliminary Clinical Activity in Second-, Third-, Fourth- and Fourth-Line-Plus GIST Patients Demonstrates the Potential for Durable Clinical Outcomes with DCC-2618

- Progression Free Survival (mPFS): The mPFS values observed with DCC-2618 were 42 weeks in second-line patients and 40 weeks in third-line patients. Previously published results for approved therapies from centrally-read registrational trials reported a mPFS for sunitinib of 24 weeks in second-line patients and a mPFS for regorafenib of 21 weeks in third-line patients. In fourth- and fourth-line-plus patients, where there are currently no approved therapies, the observed mPFS with DCC-2618 was 24 weeks. Published studies have reported a mPFS of 4-6 weeks for similarly heavily pre-treated patients who did not receive an active therapy.
- Disease Control Rate (DCR): The observed DCRs at three months of 79% in second-line patients and 83% in third-line patients exceed the previously published results for approved therapies from centrally-read registrational trials of 60% for sunitinib in second-line patients and 53% for regorafenib in third-line patients. The DCR observed for DCC-2618 in fourth-line and fourth-line-plus patients was 66%.

- Objective Response Rate (ORR): The observed ORRs of 18% in second-line patients and 24% in third-line patients continue to exceed the previously published results for approved therapies from centrally-read registrational trials of 7% for sunitinib in second-line patients and 5% for regorafenib in third-line patients. These values do not include a partial response in one second-line patient that was observed after the cutoff date, which would result in an ORR in second-line patients of 21%. The ORR observed for DCC-2618 in fourth-line and fourth-line-plus patients was 9%.

Prolonged Treatment Duration in GIST Patients Receiving DCC-2618 – Cutoff Date of August 31, 2018

- In the second-line cohort, as of the cutoff date, 17 patients received DCC-2618 at doses of ≥100mg daily for >6 months with 65% (11 of 17) of these patients remaining on study.
- In the third-line cohort, as of the cutoff date, 20 patients received DCC-2618 at doses of ≥100mg daily for >6 months with 75% (15 of 20) of these patients remaining on study.
- In the fourth-line and fourth-line-plus patients, as of the cutoff date, 46 patients received DCC-2618 at doses of ≥100mg daily for >6 months with 74% (34 of 46) of these patients remaining on study.

Updated Safety Data Continue to Demonstrate a Favorable Tolerability Profile for DCC-2618

- For 178 GIST patients treated at doses above ≥100mg daily, DCC-2618 was generally well tolerated.
- Among the treatment-emergent adverse events (TEAEs) reported by investigators (>10%), regardless of relationship to DCC-2618, the most common were: alopecia (50%), myalgia (44%), fatigue (43%), constipation (34%), hand-foot skin reaction (32%), nausea (30%), decreased appetite (28%), weight decreased (24%), abdominal pain (23%), diarrhea (23%) and lipase increase (23%).
- Among the 178 GIST patients treated at doses above ≥100mg daily:

- 14% (24) patients experienced dose reductions due to TEAE.

- 11% (19) experienced treatment discontinuations due to TEAE.

A copy of the proffered paper will be available on the Deciphera Pharmaceuticals website in the Science section under “Presentations and Publications” located at www.deciphera.com. A copy of the updated Corporate Presentation will be available on the Deciphera Pharmaceuticals website in the Investor section under “Events and Presentations” located at www.deciphera.com.

About DCC-2618

DCC-2618 is a KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including gastrointestinal stromal tumors, or GIST, systemic mastocytosis, or SM, and glioblastoma multiforme. DCC-2618 was specifically designed to improve the treatment of GIST patients by inhibiting a broad spectrum of mutations in KIT and PDGFRα. DCC-2618 is a KIT and PDGFRα inhibitor that blocks initiating and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, involved in GIST as well as the primary D816V exon 17 mutation involved in SM. DCC-2618 also inhibits primary PDGFRα mutations in exons 12, 14 and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

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.

Availability of Other Information About Deciphera Pharmaceuticals

Investors and others should note that Deciphera Pharmaceuticals communicates with its investors and the public using its company website (www.deciphera.com), including but not limited to investor presentations and scientific presentations, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Deciphera Pharmaceuticals posts on these channels and websites could be deemed to be material information. As a result, Deciphera Pharmaceuticals encourages investors, the media and others interested in Deciphera Pharmaceuticals to review the information that it posts on these channels, including Deciphera Pharmaceuticals' investor relations website, on a regular basis. This list of channels may be updated from time to time on Deciphera Pharmaceuticals' investor relations website and may include other social media channels than the ones described above. The contents of Deciphera Pharmaceuticals' website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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, statements regarding the planned initiation later this year of our Phase 3 trial, INTRIGUE, in second line GIST patients; the need for a broad-spectrum KIT inhibitor in all post-imatinib lines of therapy; potential for DCC-2618 as an effective and well tolerated therapy to treat a wide range of patients with GIST; statements regarding the potential benefits to patients of DCC-2618; statements regarding plans and timelines for the clinical development of DCC-2618; and Deciphera Pharmaceuticals' strategy, business plans and focus. The words "designed to," "may," "will," "could," "would," "should," "expect," "plan," "approximate," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and variations of these words or 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 trials or the development of our drug candidates, including DCC-2618, our ability to successfully demonstrate the efficacy and safety of our drug candidates, the preclinical and clinical results for our drug candidates, which may not support further development of such drug candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and other risks identified in our SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20181019005019/en/

Source: Deciphera Pharmaceuticals, Inc.

Media:
The Yates Network
Gina Nugent, 617-460-3579
gina@theyatesnetwork.com
or
Investor Relations:
Argot Partners
Laura Perry or Sam Martin, 212-600-1902

Laura@argotpartners.com or Sam@argotpartners.com

or

Company:

Deciphera Pharmaceuticals, LLC

Christopher J. Morl, 781-209-6418

Chief Business Officer

cmorl@deciphera.com