Deciphera Pharmaceuticals, Inc. Announces Orphan Drug Designation from the EMA for DCC-2618 for the Treatment of Gastrointestinal Stromal Tumors

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WALTHAM, Mass., Nov. 28, 2017 (GLOBE NEWSWIRE) -- Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today announced that the European Medicines Agency (EMA) has granted orphan drug designation (ODD) to DCC-2618, the Company's pan-KIT and PDGFRα inhibitor, for the treatment of gastrointestinal stromal tumors (GIST). According to the American Cancer Society, in 2015 approximately 5,000 patients were newly diagnosed with GIST in the United States and estimates for 5-year survival range from 48% to 90% depending upon the stage of the disease at diagnosis.

"The EMA orphan drug designation is a key regulatory milestone that will further facilitate and accelerate our clinical development of DCC-2618 for the treatment of GIST," said Michael D. Taylor, Ph.D., Deciphera's President and Chief Executive Officer. "We believe that DCC-2618, which previously received orphan drug designation for the treatment of gastrointestinal stromal tumors from the U.S. Food and Drug Administration, has the potential to serve as a much-needed therapeutic option for these patients."

An orphan drug designation from the EMA allows a pharmaceutical company to benefit

from incentives from the EU to develop a medicine for a rare disease. Applications for ODD are examined by the Committee for Orphan Medicinal Products (COMP), which adopts an opinion that is forwarded to the European Commission (EC). The EC then decides whether to grant an orphan designation for the medicine in question within 30 days of receipt of the COMP opinion. Pharmaceutical companies that obtain ODD benefit from a number of incentives, including protocol assistance, a type of scientific advice specific for designated orphan medicines, and market exclusivity once the medicine is on the market. Fee reductions are also available, depending on the status of the sponsor and the type of service required.

About DCC-2618

DCC-2618 is currently in a first-in-human Phase 1 clinical trial. DCC-2618 is a pan-KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including gastrointestinal stromal tumors, glioblastoma multiforme and systemic mastocytosis.

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 potential for DCC-2618 to treat 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 "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 trials or the development of Deciphera Pharmaceuticals' drug candidates, including DCC-2618; Deciphera Pharmaceuticals' advancement of multiple early-stage efforts; Deciphera

Pharmaceuticals' ability to utilize the EMA orphan drug designation to accelerate the clinical development of DCC-2618 for the treatment of GIST; Deciphera Pharmaceuticals' ability to successfully demonstrate the efficacy and safety of its drug candidates; the preclinical and clinical results for Deciphera Pharmaceuticals' drug candidates, which may not support further development of such drug candidates; and actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; Deciphera Pharmaceuticals' ability to develop and commercialize companion diagnostic tests for its current and future drug candidates. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Deciphera Pharmaceuticals' most recent quarterly report on Form 10-Q, and other filings that Deciphera Pharmaceuticals may make with the SEC in the future. Any forward-looking statements contained in this press release represent Deciphera Pharmaceuticals' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Deciphera Pharmaceuticals explicitly disclaims any obligation to update any forward-looking statements.

Contacts:
Media:
Gina Nugent, The Yates Network
gina@theyatesnetwork.com
617-460-3579

Investor Relations:
Laura Perry or Sam Martin, Argot Partners
Laura@argotpartners.com or Sam@argotpartners.com
212-600-1902

Company:
Christopher J. Morl, Chief Business Officer
Deciphera Pharmaceuticals, Inc.
cmorl@deciphera.com
781-209-6418

Primary Logo

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