Deciphera Pharmaceuticals Announces FDA Orphan Drug Designation for DCC-2618 for the Treatment of Glioblastoma Multiforme and Anaplastic Astrocytoma

September 5, 2017

Waltham, MA – September 5, 2017 – Deciphera Pharmaceuticals, a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today announced that the U.S. Food and Drug Administration ("FDA") has granted orphan drug designation to DCC-2618, the Company's pan-KIT and PDGFRα inhibitor, for the treatment of glioblastoma multiforme and anaplastic astrocytoma. Glioblastoma multiforme and anaplastic astrocytoma are the most common and most severe forms of non-metastatic brain cancer. According to the Central Brain Tumor Registry of the United States, each year approximately 12,000 patients will be diagnosed with these cancers which have an expected 2-year survival of 15% to 20%.

"Receipt of orphan drug designation for glioblastoma multiforme and anaplastic astrocytoma marks an important milestone for the DCC-2618 development program and highlights the need for novel therapies for the treatment of these devastating brain tumors," 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, has the potential to serve as a much needed therapeutic option for these patients."

Orphan drug designation is granted by the FDA to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides certain incentives which may include tax credits towards the cost of clinical trials and prescription drug user fee waivers. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity.

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.

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