For Immediate Release

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FLAG Therapeutics Receives Rare Pediatric Disease (RPD) Designation for FLAG-003 for the Treatment of Children with Diffuse Intrinsic Pontine Glioma (DIPG)

Raleigh, NC, **January 31, 2023—** FLAG Therapeutics, Inc., announced today that FLAG-003, an investigational small molecule therapy for the treatment of Diffuse Intrinsic Pontine Glioma (DIPG), a rare, highly aggressive and difficult to treat brain tumor found in children, has been granted Rare Pediatric Disease (RPD) designation from the U.S. Food and Drug Administration (FDA). FLAG-003, the company's lead program for the treatment of all gliomas, is engineered to cross the blood brain barrier and specifically target and kill cancer cells by simultaneously blocking the formation of a tumor vascular system and disrupting cancer cell replication by inhibiting tubulin. The FDA grants RPD designation to drugs intended for the prevention or treatment of rare pediatric diseases.

Key Points

- Rare Pediatric Disease (RPD) designation is granted to drugs in development for the treatment of rare childhood diseases (diseases affecting children 18 years of age and younger and fewer than 200,000 people in the United States).
- Under the RPD program, the sponsor may qualify for a priority review voucher (PRV) if the drug is initially approved for the disease for which the RPD designation was granted. Holders of a PRV can redeem the voucher to obtain priority review for any subsequent marketing application, or they can sell or transfer it to other developers.
- FLAG-003 was previously granted Orphan Drug Designation (ODD) for the treatment of all gliomas, including glioblastoma multiforme (GBM) and DIPG, by the FDA.

"Receiving Rare Pediatric Disease designation for FLAG-003 for children with DIPG underscores the dire need for a treatment option for this devastating, fatal form of brain cancer," stated Frank Sorgi, Ph.D., President and Chief Executive Officer of FLAG Therapeutics. Dr. Sorgi continued, "Data from our preclinical studies have shown that FLAG-003 crosses the blood brain barrier, a major hurdle in the treatment of all forms of brain cancer, and selectively targets and kills tumor cells. We look forward to advancing FLAG-003 into the clinic and remain steadfast in our commitment to developing solutions to address difficult-to-treat cancers."

About FLAG-003

FLAG-003 is a novel multi-specific small molecule therapeutic designed to target, bind and kill cancer cells through two well-established mechanisms of action (MoA): anti-angiogenesis and tubulin inhibition. By simultaneously constricting the tumor vascular system and inhibiting tubulin formation needed for cellular division, FLAG-003 holds the potential to kill cancer cells while leaving normal healthy cells

unharmed. Importantly, due to its remarkably low molecular weight, preclinical data have demonstrated the ability of FLAG-003 to cross the blood brain barrier (BBB) as well as evade detection by the Pgp-efflux pump, two characteristics that make it a promising investigational product candidate for the treatment of gliomas, including Glioblastoma Multiforme (GBM) and Diffuse Intrinsic Pontine Glioma (DIPG).

About RPD Designation

The Rare Pediatric Disease (RPD) designation program is offered by the FDA to encourage the development of new drugs for rare pediatric diseases (diseases affecting children 18 years of age and younger and fewer than 200,000 people in the United States). Under the RPD program, a sponsor who receives approval for a drug or biologic for a rare pediatric disease for which the RPD designation has been granted, may qualify for a priority review voucher (PRV) at the time of market approval. Holders of a PRV can redeem the voucher to obtain priority review, which shortens review from 10-months to 6-months, for any subsequent marketing application, or they can sell or transfer it to other developers. Recently, PRVs have commanded prices between $95 million to $125 million.

About Childhood DIPG

Diffuse Intrinsic Pontine Glioma (DIPG) is a highly aggressive, difficult to treat malignant brain tumor that is usually diagnosed in children between the ages of five and nine. It accounts for nearly 10 percent of all childhood central nervous system tumors. In the United States, approximately 300 children are diagnosed with DIPG each year. Due to its location in the brain stem, surgery is not an option; results of first line treatment with radiation are typically short lived, lasting on average approximately six to nine months.[1] At present, there are no approved drug therapies for the treatment of DIPG.

About FLAG Therapeutics, Inc.

FLAG Therapeutics is a near-term clinical stage biopharmaceutical company focused on the development of new small molecule therapeutics for difficult-to-treat cancers. The company leverages its three proprietary drug platforms to develop novel multi-specific small molecule therapeutics designed to specifically target, bind, and kill cancer cells through well-established mechanisms of action. FLAG Therapeutics has a robust intellectual property (IP) portfolio surrounding all of its drug discovery platforms as well as the potential for extended market exclusivity offered through the U.S Food and Drug Administration's Orphan Drug Designation and Pediatric Drug Designation programs for qualifying indications. To date, FLAG's IP portfolio includes over 100 issued patents and over 30 pending applications covering both composition of matter and method of use. For more information, please visit the company's website at www.flagtherapeutics.com.

[1] Source https://www.dana-farber.org/childhood-diffuse-intrinsic-pontine-glioma

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