For Immediate Release

FLAG Therapeutics Granted Orphan Drug Designation for FLAG-003 for the Treatment of Glioma

RALEIGH, N.C., February 29, 2016 – FLAG Therapeutics Inc. announced today that the U.S. Food and Drug Administration's Office of Orphan Products Development and the European Medicines Agency (EMA) have both granted Orphan Drug Designation to FLAG-003 for the treatment of glioma. Gliomas (including Glioblastoma Multiforme (GBM)) are the most aggressive and deadliest forms of brain cancer and have a very poor prognosis for survival. The 2-year and 5-year survival rates are 27% and 10% respectively, with the median progression-free survival (PFS) being only 6.9 months.

"The decision to grant FLAG-003 orphan drug designation in both the US and EU is an important milestone for our clinical program and underscores the urgency for a safe and effective treatment for these rare and deadly forms of brain cancer. We look forward to continuing to work cooperatively with both the FDA and the EMA to advance this potentially important new therapy through the clinical testing and regulatory process." FLAG expects to initiate its Phase I study in Q4 of 2016, according to Frank Sorgi, FLAG's President & CEO.

The Orphan Drug Designation is granted to drugs which are defined as those intended for the safe and effective treatment, prevention or diagnosis of rare diseases/disorders that affect fewer than 200,000 Americans annually (5 in 10,000 people in EU). Orphan drug designation entitles FLAG Therapeutics to 7 years marketing exclusivity following product launch in the United States (10 years marketing exclusivity in the EU) and enables the company to apply for research funding, tax credits, waiver or partial payment of application fees, protocol assistance and access to the central authorization procedure within the EU.

FLAG-003 for the treatment of Glioma

FLAG-003 is a small molecule which exerts both cytotoxic and cytostatic activity due to two distinct and well characterized mechanisms of action. It possesses cytotoxic anti-tubulin activity by binding to the colchicine site of tubulin causing microtubule depolymerization. It also possesses anti-angiogenic activity through binding and inhibition of receptor tyrosine kinase (RTK) activity. The antitubulin and anti-angiogenic activities of FLAG-003 have translated into potent antitumor and anti-vascular effects *in vivo* with significantly better inhibitory activity on GBM tumor growth and vascularization than the currently approved chemotherapy, temozolomide (TMZ).

About FLAG Therapeutics

FLAG Therapeutics is a NC-based company founded on breakthrough research that has yielded two novel classes of small, water-soluble oncology drugs. These compounds have well elucidated mechanisms of action against clinically validated targets. In preclinical models, FLAG's compounds have demonstrated statistically significant superiority in the appropriate disease models vs. approved comparator drugs. Each program has a late-stage preclinical lead within one year from IND filing. To learn more, please visit us at www.flagtherapeutics.com.

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