



## Triphase Accelerator Corporation Announces FDA Orphan Drug Designation for Marizomib in Malignant Glioma

Toronto and San Diego, November 19, 2015 -- Triphase Accelerator Corporation, a private drug development company dedicated to advancing novel compounds through Phase 2 proof-of-concept, today announced that the US Food and Drug Administration (FDA) granted orphan drug designation for marizomib for the treatment of patients with malignant glioma, an aggressive form of brain cancer with a significant unmet need due to its poor prognosis. Triphase is evaluating marizomib, a novel and highly potent proteasome inhibitor, in combination with bevacizumab in patients with recurrent glioblastoma.

“The orphan drug designation granted by the FDA recognizes the unique potential of marizomib to benefit patients with malignant glioma, for whom current therapies provide minimal benefit,” said Mohit Trikha, Ph.D., Chief Scientific Officer and Head of R&D at Triphase Accelerator. “Our Triphase Accelerator model enables faster and more efficient drug development than traditional approaches, due to our extensive clinical and regulatory experience in developing marizomib, and our relationships with key investigators and leading institutions. Building on our experience and working with urgency and dedication, Triphase Accelerator rapidly advances novel compounds through Phase 2 proof-of-concept in key areas of high patient need, such as malignant glioma.”

Orphan drug designation is granted by the FDA Office of Orphan Products Development (OOPD) to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the United States. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity, as well as tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance, and waiver of Prescription Drug User Fee Act (PDUFA) filing fees. The OOPD also works on rare disease issues with the medical and research communities, professional organizations, academia, governmental agencies, industry, and rare disease patient groups

### **About Marizomib**

Marizomib is a novel, irreversible, potent and brain-penetrant proteasome inhibitor which inhibits all three proteasome subunits, thus providing superior potency, specificity, and duration of proteasome inhibition, and potentially improved clinical activity. Triphase Accelerator is developing marizomib in both intravenous (IV) and oral formulations as a potential best-in-class proteasome inhibitor for hematologic malignancies and solid tumors. The IV formulation has been evaluated in more than 290 patients in multiple clinical studies in patients with solid and hematologic malignancies, either as a single agent or in combination with dexamethasone, a histone deacetylase inhibitor, or an immunomodulatory drug. The Company is currently developing marizomib in combination with pomalidomide and dexamethasone in patients with relapsed and refractory multiple myeloma, and has received Orphan Drug designation for marizomib in multiple myeloma in the United States and the European Union. Triphase

Accelerator is also evaluating an oral formulation in preclinical studies. In addition, Triphase Accelerator is currently evaluating marizomib in a proof-of-concept clinical study in combination with bevacizumab (Avastin®) in patients with Grade IV malignant glioma (glioblastoma).

**About Triphase Accelerator**

Triphase Accelerator is a private drug development company with a primary focus on oncology and with operations in Toronto and San Diego. Triphase Accelerator is dedicated to advancing novel compounds through Phase 2 proof-of-concept clinical studies using a unique, science-based, high-quality model that is faster and more cost-effective than traditional pharmaceutical and biotech industry drug development approaches. Triphase Accelerator was spun out of the Ontario Institute for Cancer Research (OICR), with support from the Fight Against Cancer Innovation Trust (FACIT), MaRS Innovation and MaRS. It has a strategic relationship with Celgene for marizomib. For more information, visit [www.triphaseco.com](http://www.triphaseco.com) or [Linkedin](#).

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