Triphase Accelerator Corporation Announces Orphan Drug Designation in the European Union for Marizomib for Multiple Myeloma

Toronto and San Diego, June 23, 2014 -- Triphase Accelerator Corporation, a private drug development company dedicated to advancing novel compounds through Phase II proof-of-concept, today announced that the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) has adopted a positive opinion recommending marizomib for the treatment of multiple myeloma for designation as an orphan medicinal product in the European Union (EU). Orphan drug designation provides a number of benefits, including 10 years of market exclusivity from product launch in the EU, fee reductions, and access to the central authorization procedure. Triphase also has been granted orphan drug designation for marizomib in multiple myeloma from the U.S. Food and Drug Administration (FDA).

"Obtaining orphan designation for marizomib in the EU for multiple myeloma represents an important milestone in the development of this novel, highly potent proteasome inhibitor," said Frank Stonebanks, founder, president and CEO of Triphase. “We are committed to developing this promising agent through proof-of-concept to fill an unmet medical need for patients with relapsed and refractory multiple myeloma, an often fatal hematologic cancer for which new treatment options are needed."

EMA's Orphan Medicinal Product Designation is designed to promote the development of drugs that may provide significant benefit to patients suffering from rare, life-threatening diseases. In addition to 10 years of market exclusivity, the designation also provides special incentives for sponsors, including eligibility for protocol assistance and possible exemptions or reductions in certain regulatory fees during development or at the time of application for marketing approval.

Similarly, FDA orphan drug designation is intended to encourage companies to develop therapies for the treatment of diseases that affect fewer than 200,000 individuals in the United States. This designation will provide Triphase with seven years of marketing exclusivity for marizomib in multiple myeloma if it is approved by the FDA for such an indication. Prior to FDA approval, orphan designation provides sponsors with the opportunity to obtain grant funding to defray costs of clinical trial expenses, tax credits for clinical research expenses, and potential waiver of application user fees.

About Marizomib
Marizomib is a novel, highly potent proteasome inhibitor that irreversibly targets and inhibits all three proteasome subunits, allowing for more durable and sustained responses. Triphase is developing marizomib in both intravenous (IV) and oral formulations for hematologic malignances and solid tumors. Marizomib has demonstrated activity in a Phase I study in patients with multiple myeloma refractory to lenalidomide or bortezomib. An IV formulation has been evaluated in more than 230 patients in four Phase I studies in patients with solid and hematologic malignancies, either as a single agent or in combination with dexamethasone or an HDAC inhibitor.

Triphase is currently evaluating the IV formulation in an ongoing Phase II clinical trial in combination with dexamethasone in a highly refractory multiple myeloma population, including those refractory to carfilzomib; it is also being tested in a Phase I study in combination with pomalidomide and dexamethasone in relapsed and refractory multiple myeloma. Triphase is evaluating an oral formulation of marizomib in IND-enabling studies.

About Multiple Myeloma
Multiple myeloma is a hematologic cancer in which plasma cells, a type of white blood cell made in the bone marrow, become cancerous, multiply too quickly and accumulate throughout the body. The accumulation of these cancerous plasma cells can form tumors in bones throughout the body. Multiple myeloma can prevent the bone marrow from making sufficient quantities of healthy red blood cells, white blood cells and platelets, which can severely weaken the bones and immune system.

Worldwide, an estimated 750,000 people are living with multiple myeloma. An estimated 103,000 new cases are diagnosed annually, accounting for about 1 percent of all cancers diagnosed and 12 percent of all hematologic cancers diagnosed.

About Triphase
Triphase is a private drug development company with a primary focus on oncology and operations in San Diego and Toronto. Triphase is dedicated to advancing novel compounds through Phase II 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 was spun out of the Ontario Institute for Cancer Research (OICR) and MaRS Innovation, and has a strategic relationship with Celgene for oncology-focused drug development opportunities. For more information, visit www.triphaseco.com or LinkedIn.

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