AMPHIVENA THERAPEUTICS ANNOUNCES ACCEPTANCE OF INVESTIGATIONAL NEW DRUG (IND) APPLICATION FOR AMV564 AND PLANNED PHASE 1 TRIAL INITIATION

Proprietary T-cell Redirecting Bispecific CD33/CD3 Antibody for the Treatment of AML Nears First-in-Human Study

SAN FRANCISCO, CA, August 10, 2016 --- Amphivena Therapeutics, Inc., a developer of cancer immunotherapies, announced today that the U.S. Food and Drug Administration (FDA) has accepted an investigational new drug (IND) application for AMV564, the company's proprietary T-cell redirecting bispecific CD33/CD3 antibody. The company plans to initiate a Phase 1 dose escalation and expansion trial of AMV564 in acute myeloid leukemia (AML) patients this year.

The Phase 1 study will evaluate the safety, pharmacokinetics and pharmacodynamics of escalating AMV564 doses in AML patients. This will be followed by a preliminary evaluation of the antitumor activity of AMV564. Importantly, the study will allow for the identification of the maximum tolerated dose (MTD) of AMV564, as well as the recommended dose of AMV564 to be evaluated in the Phase 2 clinical studies.

"The acceptance of our IND and our planned near-term initiation of the first clinical trial of AMV564 represent key development milestones in Amphivena's efforts to bring a much-needed therapeutic option to AML patients and their physicians," said Jeanmarie Guenot, Ph.D., president and chief executive officer of Amphivena Therapeutics. "Our preclinical program demonstrated impressive cytotoxic activity in AML patient samples and animal models that was both potent and selective, suggesting the potential for a robust therapeutic response with minimal off-target safety concerns. We look forward to initiating our clinical development program for AMV564 and evaluating the compound's potential in patients."

About AMV564

AMV564 is a tetravalent, bispecific TandAb antibody that recruits T-cells to eliminate cancer cells that express CD33, a receptor that is expressed on the majority of AMLs and is present on other hematologic malignancies. AMV564 is bivalent for both CD33 on AML cells and CD3 on T-cells, and maintains the avidity for antigen as found in typical monoclonal antibodies to mediate potent and efficient tumor cell lysis. Results of preclinical studies showed that AMV564 only induced T-cell activation and mediated cytotoxicity in the presence of CD33+ target cells. The compound also demonstrated potent and selective cytotoxic activity in newly diagnosed and relapsed or refractory AML patient samples, independent of CD33 expression level. Additionally, near complete elimination of leukemic blasts from blood, bone marrow and spleen has been observed in an AML patient-derived xenograft model.

About Amphivena

Amphivena Therapeutics, Inc. is a cancer immunotherapy company based in San Francisco, California developing proprietary first-in-class, tetravalent, T-cell redirecting bispecific antibodies for the treatment of hematologic malignancies. The company's lead drug candidate is AMV564, a CD33/CD3-targeting treatment for acute myeloid leukemia (AML), which Amphivena is currently preparing to advance into clinical development. For more information, please visit www.amphivena.com.

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