AMPHIVENA THERAPEUTICS PRESENTS POSITIVE DATA ON NOVEL ACUTE MYELOID LEUKEMIA (AML) IMMUNOTHERAPY AT 2015 ASCO ANNUAL MEETING

Positive Preclinical Study Results Demonstrate Potent and Specific Anti-AML Activity for Amphivena's Proprietary T-cell Redirecting Bispecific CD33/CD3-Targeting Antibodies; AMV-564 Being Advanced into Clinical Development for Treatment of AML

SAN FRANCISCO, CA, June 1, 2015 --- Amphivena Therapeutics, Inc., a developer of cancer immunotherapies, today announced positive data from several preclinical studies characterizing the company's proprietary T-cell redirecting bispecific CD33/CD3-targeting antibodies as potential immunotherapeutics for the treatment of acute myeloid leukemia (AML). Study findings, which demonstrated potent and specific anti-AML activity for the novel antibodies, were presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting. Amphivena also announced selection of a development candidate, AMV-564, based on these compelling preclinical data.

A diverse collection of Amphivena's novel T-cell redirecting, tetravalent, bispecific CD33/CD3-targeting antibodies were evaluated across a rigorous panel of *in vitro* and *in vivo* systems in order to identify an optimal candidate for clinical development. The studies, conducted in collaboration with leading researchers at the Fred Hutchinson Cancer Research Center and the Washington University School of Medicine, were designed to examine the antibodies' stability properties, affinity for CD33 and CD3, and impact on T-cell activation and cytotoxicity against $CD33^+$ AML cells. The ASCO poster presentations (abstracts: 3057, 7067 and 7071) can be found on Amphivena's website at www.amphivena.com.

Key study findings for Amphivena's CD33/CD3-targeting antibodies included:

- Mechanism-based, T-cell activation and proliferation was induced by the tetravalent, bispecific CD33/CD3-targeting antibodies. Importantly, the presence of $CD33^+$ target cells was required for the T-cell activities, demonstrating the potential for minimal off-target safety issues for this antibody platform.

- Potent and selective cytotoxic activity against $CD33^+$ AML cell lines and 27 primary CD33+ AML specimens was observed at pM antibody concentrations. This activity was observed in newly diagnosed and relapsed or refractory AML samples, and was independent of disease stage. For the most potent CD33/CD3 antibodies, activity was independent of the level of CD33 expression.

- Robust tumor growth inhibition and delay in prophylactic and established AML xenograft models using human cancer cell lines and donor T-cells.

- Impressive activity in an AML patient-derived xenograft model with nearly complete elimination of leukemic blasts from all compartments, including bone marrow and spleen, despite the very low number of T-cells present in the patient sample.

"These preclinical studies identified T-cell redirecting bispecific CD33/CD3-targeting antibodies that meet our initial, pre-specified activity and safety profile for an immunotherapeutic clinical candidate for treating AML. Particularly exciting is the breadth and potency of the activity seen in AML patient samples from work done under the direction of Roland B Walter, M.D., Ph.D. at the Fred Hutchinson Cancer Research Center and the impressive level of activity observed in the AML patient-derived xenograft model in research conducted under the direction of John DiPersio, M.D., Ph.D., at the Washington

University School of Medicine. Drs. DiPersio and Walter are two prominent, highly-regarded key opinion leaders in the area of hematologic oncology research and having their work support and validate our internal efforts is gratifying," said Jeanmarie Guenot, Ph.D., president and chief executive officer of Amphivena Therapeutics. "These positive preclinical results represent a key milestone for Amphivena, and we are happy to announce selection of a therapeutic candidate, AMV-564, for clinical development. While these studies highlighted promising therapeutic profiles for a number of our novel antibodies, we believe that AMV-564 provides the most rapid opportunity for successful development."

"The potent *in vitro* and *in vivo* activity of AMV-564 suggests this tetravalent, bispecific antibody may soon be ready for early phase clinical trials," said Dr. DiPersio, M.D., Ph.D., Chief, Division of Oncology, Deputy Director, Siteman Cancer Center, Washington University School of Medicine.

Dr. Walter, M.D., Ph.D., is Assistant Member, Clinical Research Division at the Fred Hutchinson Cancer Research Center and Associate Professor Medicine, Division of Hematology at the University of Washington.

Under terms of Amphivena's ongoing agreement with Janssen Biotech, Inc. (Janssen), Janssen has the exclusive right to acquire Amphivena following approval of an Investigational New Drug (IND) application. As part of the agreement, Janssen has provided Amphivena with an initial upfront payment, as well as contingent payments to Amphivena based on achievement of predetermined milestones.

About AMV-564

AMV-564 is one of Amphivena's proprietary first-in-class, tetravalent, bispecific TandAb antibodies. The novel immunotherapy recruits T-cells to eliminate cancer cells that express CD33, a receptor that is expressed on the majority of acute myeloid leukemias (AMLs) and is present on other hematologic malignancies. AMV-564 is bivalent for both CD33 on AML cells and CD3 on T-cells, forming a T-cell activating complex in the presence of target cancer cells. By maintaining the avidity for antigen as found in typical monoclonal antibodies, AMV-564 mediates potent and efficient tumor cell lysis. AMV-564 also offers pharmacokinetic advantages over smaller, monovalent bispecific constructs due to a molecule size that exceeds renal clearance limits. Amphivena is currently completing IND-enabling studies to advance AMV-564 into clinical development as a treatment for AML.

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 AMV-564, a CD33/CD3-targeting treatment for acute myeloid leukemia (AML), which Amphivena is currently preparing to advance into clinical development. In July 2013, Amphivena raised $14 M in a Series A financing led by MPM Capital. Amphivena also has an ongoing agreement with Janssen Biotech, Inc. that grants Janssen the exclusive right at its discretion to acquire Amphivena following IND approval. For more information, please visit www.amphivena.com.

CONTACTS:

Amphivena Therapeutics, Inc.
Jeanmarie Guenot, Ph.D.
Chief Executive Officer and President
jguenot@amphivena.com

415-994-6455

Vida Strategic Partners (media):
Tim Brons
tbrons@vidasp.com
415-675-7402