FOR IMMEDIATE RELEASE

Amphivena Receives Orphan Drug Designation for AMV564, a Novel CD33/CD3 T-Cell Engagement Therapy for the Treatment of Acute Myeloid Leukemia

SOUTH SAN FRANCISCO – November 29, 2017 – Amphivena Therapeutics Inc., a privately held biotechnology company developing a novel CD33/CD3 T cell engager for the treatment of Acute Myeloid Leukemia (AML) and Myelodysplastic Syndromes (MDS), announced today that it has received Orphan Drug Designation from the U.S. Food and Drug Administration for its lead compound AMV564 for the treatment of AML.

"The FDA's designation of AMV564 as an orphan drug is an important milestone for us that will provide marketing protections and economic benefits at drug approval. Given the unique safety and efficacy profile that is emerging in the clinic, we believe our CD33-targeted T cell engager will be an important drug in the armamentarium for leukemia patients who have limited treatment options today," said Eric J. Feldman, M.D., Amphivena's Senior Vice President of Clinical Development.

Amphivena is conducting a Phase 1 clinical study of AMV564 in relapsed or refractory AML. Amphivena plans to launch a Phase 1 clinical study in patients with MDS in early 2018. The company is also exploring the utility of AMV564 in solid tumors. In preclinical studies, this novel CD33/CD3 bispecific antibody demonstrated potent activity against AML patient samples that was independent of CD33 expression level, disease stage and cytogenetic risk. The antibody eliminated nearly all blasts from bone marrow and spleen in a stringent AML patient-derived xenograft murine model. In addition, Amphivena established a therapeutic window for AMV564 in cynomolgus monkeys, with rapid and sustained elimination of CD33-expressing cells during AMV564 dosing and rapid hematopoietic recovery following dosing.

Orphan Drug Designation is granted by the FDA Office of Orphan Drug Products to products that treat rare diseases. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States. Orphan Drug Designation provides the sponsor certain benefits and incentives, including a period of marketing exclusivity for the first marketing application, if regulatory approval is received for the designated indication, potential tax credits for certain activities and waiver of certain administrative fees.

About Amphivena Therapeutics

Amphivena Therapeutics, founded in 2013, is a private biotechnology company developing AMV654, a CD33/CD3-bispecific T cell engaging antibody for the treatment of AML, MDS and solid tumors. MPM Capital, Amphivena's major shareholder, led a $19.5 M Series A financing, with participation by Aeris Capital and Affimed GmbH. More recently, funds managed by Tekla Capital Management LLC joined the founding investors in a Series B financing. For more information, please visit **www.amphivena.com**.

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