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Amphivena's Human Proof-of-Concept Data for AMV564 in Relapsed/Refractory AML Updated at the European Hematology Association Annual Meeting

South San Francisco, CA – July 1, 2019 -- Amphivena Therapeutics highlighted initial data from the dose-escalation portion of the First-in-Human Phase 1 trial evaluating AMV564 in patients with relapsed or refractory acute myeloid leukemia (AML, AMV564-101, NCT03144245) in an oral presentation June 15 at the 24th European Hematology Association (EHA) meeting in Amsterdam (Abstract S877). The oral presentation of data from 33 patients treated within 9 cohorts demonstrated that AMV564 is active in relapsed or refractory AML and expanded upon the data from 26 patients presented at the Annual Meeting of the American Society of Hematology in December 2018. AMV564 is a bivalent, bispecific (2:2) T cell engager that binds CD33 and CD3 resulting in T cell directed lysis of leukemic blasts and myeloid-derived suppressor cells (MDSCs) without affecting monocytes and neutrophils.

Gail Roboz, M.D., Professor of Medicine, Director of the Leukemia Program, and a member of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine and NewYork-Presbyterian/Weill Cornell Medical Center and a Principal Investigator for the study, presented on behalf of the study team. "While this is a Phase 1 study," she said, "we believe that AMV564 has demonstrated promising monotherapy activity, including a CR, CRi and PR and evidence of durability in a high risk, older patient population on a 14-day dosing regimen. The data show that AMV564 is well-tolerated with no dose limiting toxicities through 250 mcg and only Grade 1 and Grade 2 cytokine release syndrome distinguishing the safety of AMV564 from other drugs in development for myeloid malignancies."

"AMV564 has demonstrated novel clinical activity for a T cell engager by rapidly and selectively eliminating leukemic blasts and rare immature, granulocytic and monocytic MDSCs while sparing normal CD33-expressing cells, including neutrophils and monocytes. High levels of circulating MDSCs are associated with poor prognosis for cancer patients. Our drug's ability to selectively eliminate MDSCs rather than modulating MDSC pathways provides a unique opportunity to evaluate the role of these immune suppressive cells in cancer," said Jeanmarie Guenot, Ph.D., Amphivena Chief Executive Officer and President.

Dr. Roboz has served as a consultant for Amphivena, Celgene, Bayer, Otsuka, Pfizer, Astellas Pharmaceuticals, Argenx, Astex Pharmaceuticals, Hoffman-La Roche, Janssen, Novartis, AbbVie, Sandoz, Eisai, Jazz Pharmaceuticals, Celltrion, Orsenix and Daiichi Sankyo.

About AMV564-101

AMV564-101 is a First-in-Human dose escalation and dose expansion Phase 1 trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of AMV564 in patients with relapsed or refractory AML after 1-2 prior induction regimens (with a standard anthracycline-based regimen or hypomethylating agent) and no more than 2 prior salvage regimens. The

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Phase 1 study is currently open at Washington University School of Medicine, MD Anderson Cancer Center, NewYork-Presbyterian/Weill Cornell Medical Center and Weill Cornell Medicine, Fred Hutchinson Cancer Research Center, The Ohio State University Wexner Medical Center, University of Pennsylvania Medical Center, Northwestern Memorial Hospital, and The Johns Hopkins Hospital.

About Amphivena

Amphivena Therapeutics, Inc. is a private clinical stage immuno-oncology company developing T cell engager therapeutics for myeloid malignancies and solid tumors. Amphivena's lead molecule, AMV564, is in Phase 1 dose escalation and expansion studies for the treatment of AML and myelodysplastic syndromes. Amphivena has raised $77 M to date in Series A, B and C venture financings led by MPM Capital, NanoDimension, Qiming Venture Partners and funds managed by Tekla Capital Management LLC. For more information, please visit www.amphivena.com.

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