Avenge Bio Receives FDA Orphan Drug Designation for AVB-001 for the Treatment of Mesothelioma

NATICK & QUINCY, Mass., June 15, 2023 – Avenge Bio, Inc. ("Avenge"), a clinical stage, oncology-focused biotechnology company developing the LOCOcyte™ Immunotherapy platform for the local administration of potent immune effector molecules to treat solid tumors, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to AVB-001 for the treatment of patients with mesothelioma.

Mesothelioma is a highly symptomatic cancer that primarily affects adults. It occurs in the cells that make up the mesothelium of the pleural and peritoneal cavities, as well as the pericardium and the tunica vaginalis. In 2022, there were approximately 3,000 new cases reported in the U.S. and approximately 2,500 people died from this cancer. Pleural mesothelioma accounts for approximately 85% of new mesothelioma cases, followed by peritoneal mesothelioma (approximately 15%), and pericardium or tunica vaginalis mesothelioma (<1% combined).

Avenge continues to enroll patients in an ongoing Phase 1/2 clinical trial evaluating AVB-001 for the treatment of refractory ovarian cancer. The Phase 1/2 clinical trial is a first-in-human, single-arm, open-label, dose-escalation and expansion study (NCT05538624) designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity of AVB-001 delivered intraperitoneally (IP) to patients with high grade serous adenocarcinoma of the ovary, primary peritoneum, or fallopian tube.

In March 2023, Avenge received positive feedback from the FDA on its preclinical and clinical development plans for pleural malignant mesothelioma. Avenge previously published preclinical data establishing the efficacy and safety of pleural administered AVB-001 for the treatment of pleural malignant mesothelioma. The manuscript, entitled "Activation of adaptive and innate immune cells via localized Interleukin-2 cytokine factories eradicates mesothelioma tumors," can be viewed on the Clinical Cancer Research website.

About LOCOcyte™ Platform

Our LOCOcyte™ allogeneic cell-based immunotherapy platform enables potent localized modulation of the immune system which also precipitates a systemic immune response, allowing us to treat previously intractable cancers. The technology leverages three unique advantages:

(1) Potent immune effector molecules are generated by synthetically engineering allogeneic cells creating a ready-to-use therapy,

(2) Therapy is localized in proximity to the primary tumor site and generates innate and adaptive immune response, and

(3) The immunomodulator trains the patient's immune system generating a robust immune response that seeks and eradicates distal metastasis without systemic toxicity.

About Avenge Bio

Avenge Bio, Inc. ("Avenge") is an oncology-focused biotechnology company developing transformative cell-based immunotherapeutic products for the treatment of intractable solid tumors by incorporating its LOCOcyte™ platform. The LOCOcyte™ platform leverages proprietary engineered cells delivered to the local tumor environment that generate high concentrations of immune effector molecules in proximity to the tumor. This initiates a robust, local, and durable systemic immune response while avoiding toxicities associated with systemic immunotherapies. Avenge's most advanced product candidate, AVB-001, produces native IL-2 immunotherapy and is initially being studied in metastatic peritoneal cancers such as ovarian cancer. Avenge has additional pipeline candidates for the treatment of a wide range of cancers including pancreatic, lung and breast cancers. Avenge was founded in 2019 based upon technology developed in the laboratory of Omid Veiseh, Ph.D. and has an exclusive license from Rice University for this technology. To learn more about Avenge visit: www.avengebio.com and follow us on LinkedIn and Twitter.

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