Avenge Bio Receives FDA Fast Track Designation for AVB-001, a Novel Cell Therapy Leveraging the LOCOcyte™ Immunotherapy Platform

- *Regulatory Designation includes platinum-resistant, high grade serous adenocarcinoma of the ovary, primary peritoneum or fallopian tube*
- *Phase 2 Dose expansion trial expected to initiate in 1H 2024*

NATICK & QUINCY, Mass., October 2, 2023 - Avenge Bio, Inc. ("Avenge" or the "Company"), a biotechnology company developing the LOCOcyte™ Immunotherapy platform for the precision administration of potent immune effector molecules to treat solid tumors, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for AVB-001 for treatment of patients with relapsed resistant/refractory ovarian cancer.

"We are extremely pleased to receive the FDA Fast Track designation for AVB-001 based on FDA's review of our preclinical and emerging clinical data. The Fast Track designation has been provided for platinum-resistant, refractory ovarian cancer, and acknowledges the potential for AVB-001 to treat this significant unmet medical need," said Michael Heffernan, CEO at Avenge Bio.

FDA Fast Track program is designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fulfill an unmet medical need. The Fast Track designation is available not only where treatments do not exist, but also for drugs that demonstrate a potential advantage over available therapies. Once granted Fast Track designation, the FDA increases the frequency of meetings to discuss the development, trial design, clinical data, and submission of the Biologics License Application (BLA).

In January 2023, Avenge announced the initiation of an open-label, First-in-Human, Phase 1/2, multicenter study (NCT05538624) designed to evaluate the safety and efficacy of AVB-001. AVB-001 is an encapsulated cell product engineered to produce native human interleukin-2 (hIL-2) and is delivered intraperitoneally (IP) to patients.

In addition to advancing the lead clinical trial in ovarian cancer, Avenge is also developing AVB-001 for additional conditions of high unmet needs in other peritoneal malignancies and pleural cancers.

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 base 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 , X, or Instagram.

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