Avenge Bio Receives Positive Feedback from Pre-IND FDA Meeting on Development Path for AVB-001 Mesothelioma Program and Provides Pipeline Update

NATICK & QUINCY, Mass., March 9, 2023 – Avenge Bio, Inc. ("Avenge"), a clinical stage, oncology-focused biotechnology company developing the LOCOcyte™ Immunotherapy platform for the precision administration of potent immune effector molecules to treat solid tumors, today announced that it completed a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration ("FDA") with respect to AVB-001 for the treatment of pleural malignant mesothelioma, and provided a corporate update.

AVB-001, developed in the LOCOcyte™ platform, consists of proprietary engineered allogeneic human cells. The cells are encapsulated in a pro-inflammatory biomaterial that are delivered to the local tumor environment and generate high, sustained concentrations of human IL-2. The product initiates a robust and durable, local and systemic immune response while avoiding toxicities associated with systemic immunotherapies.

Pipeline Updates:

- **Preliminary feedback received from the FDA on future development of AVB-001 for the treatment of pleural malignant mesothelioma.** Avenge obtained guidance from the FDA on its preclinical and clinical development plans and remains on track to submit an IND in the second half of 2023. 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," and can be viewed on the *Clinical Cancer Research* website.
- **Continue to enroll patients in ongoing Phase 1/2 clinical trial evaluating AVB-001 for the treatment of refractory ovarian cancer**. In January 2023, Avenge announced the dosing of the first patient in 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. In this clinical trial, AVB-001 is delivered intraperitoneally (IP) to patients with high grade serous adenocarcinoma of the ovary, primary peritoneum, or fallopian tube. Avenge plans to provide an update on the program in the second half of 2023.
- **Continued advancement of additional development programs leveraging LOCOcyte™ platform**. Avenge continues to advance additional development programs in preclinical studies including AVB-002, an IL-12 program in development for multiple peritoneal cancers such as pancreatic cancer. In addition, Avenge is building out its pipeline via applying its LOCOcyte™ technology to a number of additional targets.

“We greatly appreciate the FDA's guidance as we continue to advance AVB-001 for the treatment of pleural malignant mesothelioma, a disease with significant unmet medical need”, said Michael Heffernan, Co-Founder and Chief Executive Officer of Avenge Bio. “2023 is a transformational year for Avenge as we continue to enroll patients for our lead clinical program in refractory ovarian cancer and further build our pipeline of products leveraging the LOCOcyte™ technology.”

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 leverage 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 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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