

Avenge Bio Announces FDA Clearance of the AVB-001 IND for the Treatment of Ovarian Cancer, a Novel Cellular Therapy Leveraging the LOCOcyte™ Immunotherapy Platform

Avenge Bio expects to initiate a Phase 1 clinical trial in the second half of 2022 for patients with metastatic peritoneal cancers with an initial focus on platinum-resistant ovarian cancer

NATICK, Mass, August 3, 2022 – Avenge Bio, Inc. (“Avenge Bio,” “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 Food and Drug Administration (“FDA”) cleared the Investigational New Drug (“IND”) application for AVB-001 in peritoneal malignancies.

The LOCOcyte™ platform leverages immunomodulators and biomaterials for a synergistic impact in a single, controlled, allogeneic cell therapy. AVB-001 is the first clinical implementation of the platform, encapsulating cells engineered to secrete native IL-2 in immune-activating alginate capsules. The first-in-human clinical trial is the intraperitoneal administration of AVB-001 for the treatment of platinum resistance ovarian cancer, a condition with very limited treatment options.

“We are very pleased to be advancing AVB-001 into the upcoming clinical trial as a potential treatment for patients with metastatic ovarian cancer, a life threatening disease. The FDA’s clearance of our IND represents a significant milestone for Avenge and the first to be cleared leveraging the LOCOcyte™ technology platform,” said Michael Heffernan, Chief Executive Officer of Avenge Bio.

“Ovarian cancer is one of the most difficult cancers to treat. It is typically not detected until later stages, and most patients will recur after an initial treatment, which is often fatal. As a clinician, I am looking forward to the potential impact for these patients. Patients with metastatic peritoneal cancer are uniquely positioned to benefit from this novel cellular therapy,” added Dr. Claudio Dansky Ullmann, Avenge Bio’s Chief Medical Officer.

The Phase 1, multi-center clinical trial is expected to be initiated in the second half of 2022 and will evaluate the tolerability of AVB-001, determine a recommended dose for Phase 2, measure immunological changes in the blood and peritoneal environment, and assess anti-tumor activity.

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, 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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