AVM Biotechnology Awarded $2 Million National Cancer Institute SBIR Phase II Grant from the National Institutes of Health to Advance AVM0703 in Cancer

June 14, 2022

Seattle, WA – Business Wire - AVM Biotechnology, a clinical stage company advancing AVM0703 in the treatment of Non-Hodgkin's Lymphoma (NHL)/Leukemia, today announced that it has been **awarded a Phase II Small Business Innovative Research (SBIR) grant**. This **$2 million** National Cancer Institute (NCI) grant will assist in the continuation of the company's existing clinical trial (AVM0703 for Treatment of Leukemia or Lymphoma, NCT04329728).

This Phase II grant has been awarded for continued support of the adaptive-design, expansion cohort clinical trial of AVM0703 for "no-option", Relapsed/Refractory (R/R) NHL/Leukemia patients. The study is currently enrolling at City of Hope, UCLA, Norton Cancer Institute, and the University of Texas Southwestern. Additional sites are being brought on-line.

AVM0703:

- is a **small molecule** which triggers the production and release of **endogenous bispecific gamma delta TCR+ invariant TCR+ Natural Killer T-like cells** (AVM-NKT).
- induces AVM-NKT cells **rapidly** in the blood following **a single dose**.
- is currently the subject of an adaptive design expansion cohort clinical trial with the dose escalation phase nearing completion and the **efficacy phase projected to commence soon.**

In the ongoing dose escalation phase, which included 11 highly refractory patients who had been heavily pretreated averaging 5.3 prior lines of therapy with 6 of 11 having failed hematopoietic stem cell transplantation (HSCT) or CAR-T, results included:

- **100% clinical response** at 18 mg/kg target Ph II dose, with durable partial response/stable disease ongoing out to greater than 9 months in 1 patient
- Of 10 evaluable patients from the dose-escalation; **4 experienced partial response and** 2 other patients subsequently **reached complete remission.**
- An additional **20%** achieved **stable disease** or significant clinical response including **durable vision restoration** in 1 patient.

One heavily pretreated patient with T-cell lymphoma who did not meet inclusion/exclusion criteria received AVM0703 under an FDA-approved Compassionate Use Program. That patient has experienced a **very good partial response**.

The drug has been well-tolerated with no reported Dose Limiting Toxicities (DLT's) or grades 4 or 5 adverse events. AVM0703 also **potentiates chemotherapy and CAR-T** response in pre-clinical models.

NHL is the 7th most common cancer in the US with over half of the 77,240 diagnosed annually over the age of 65. Even with treatment, disease recurs or relapses in approximately 50% of these patients and many become refractory to additional treatment. Patients can undergo many lines of various therapies including chemotherapy, radiation, CAR-T and HSCT which can be associated with significant toxicities and poor outcomes with many relapsing and requiring additional treatment. Based on its **strong safety profile and clinical response, AVM0703 presents an appealing alternative to these therapies.**

"AVM0703 represents an exciting new treatment option for NHL patients who have failed other therapies or who do not qualify for further chemotherapy, radiation, or cell therapies, including CAR-T. In addition to improvement in disease status, several patients treated with AVM0703 in the dose-escalation phase of the study have qualified for other treatments they had formerly been excluded from accessing.", said Joe Luminiello, CEO.

AVM Biotechnology previously received a Phase I NCI grant from the National Institutes of Health (NIH) to study the use of AVM0703 as a preconditioning agent to allow safe and efficient delivery of therapeutic immune cells for cancer treatment. The company has requested **breakthrough therapy designation** and plans for accelerated approval for **commercial launch in mid 2024**.

About AVM Biotechnology

AVM Biotechnology is a clinical stage company developing AVM0703 for cancer and autoimmunity diseases as a commercial product. The basis for these programs is the **endogenous mobilization and activation of AVM-NKT cells** by a glucocorticoid-receptor-independent mechanism with the administration of AVM0703. While the full potential of these cells continues to be explored by AVM scientists, it is clear these cells could **play a significant role in several diseases** since they **home to distressed phosphoantigen presenting cells**. AVM Biotechnology has an experienced leadership team, transformative science, robust intellectual property protection to 2040 and is poised to bring its innovations to market for the benefit of patients in need.

For information, contact Jena Dalpez jdalpez@avmbiotech.com, +1 206 906-9922 or visit us at AVM Biotechnology.

Forward Looking Statement

This contains certain statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not relate strictly to historical or current facts and they may be accompanied by words such as "could," "would," "may," "potentially," "suggest," "believes," "expects," "should," and similar words or expressions. These forward-looking statements reflect our current views as of the date this is published, and are subject to risks, uncertainties, assumptions, changes in circumstances, and other factors; drug development and commercialization are highly risky and early clinical results in animals or humans may not reflect the full results from later stage or larger scale clinical trials. These forward-looking statements are subject to risks and uncertainties that could cause our actual results, performance, and expectations to differ materially from those expressed or implied by these statements, including statements about: future and ongoing drug development and timing; the applications of drugs to specific diseases; the potential for ongoing preclinical or clinical trial results; FDA or other regulatory findings and approvals; potential market opportunities; and the

occurrence of future events or circumstances. There are risks and uncertainties involving and not limited to our ability to progress in our research and development efforts, complete clinical testing, achieve our expected results, commercialize our products, avoid infringement of patents, trademarks and other proprietary rights of third parties, protect products from competition, navigate the political environment, maintain sufficient capital and funding, avoid problems with our manufacturing processes, maintain our operations, and obtain regulatory approval to sell and market the drugs in the United States and elsewhere. The reader should not place any undue reliance on such forward-looking statements. We have no obligation to release publicly the results of any revisions to any of our forward-looking statements to reflect events or circumstances after the date these statements are made or to reflect the occurrence of unanticipated events, except as may be required by law.