AVM Biotechnology Announces Full Enrollment of First Cohort of Relapsed/Refractory Non-Hodgkin's Lymphoma Patients dosed with AVM0703 at major Cancer Centers in USA

April 7, 2021 – Seattle, AVM Biotechnology announced today that the first cohort has been fully enrolled in their clinical study (NCT04329728 "The WWRD Study"). All three patients had failed multiple prior therapies, and one had failed two transplants. These patients are reportedly all doing very well, and one was quoted as saying, "I feel great!" Three major US Cancer Centers are actively enrolling study participants. AVM Biotechnology is excited to advance AVM0703 to the next dose level cohort of no-option lymphoma patients. The drug has been well tolerated, without safety issues, as expected. The study is an adaptive design/expansion cohort trial such that cohort enrollment of relapsed/refractory Non-Hodgkin's Lymphoma patients for the pivotal trial can immediately follow the dose-escalation phase.

Since originally approving the study, the FDA has approved a reduction in the interval between patients in a cohort, from 7 days to 48-hours and between cohorts, from 21 to 7 days of dosing for the first two cohorts. This reduction was approved in response to drug tolerance data submitted from patients treated under FDA approved compassionate use applications.

"Considering the delay of many clinical studies due to the pandemic, we are gratified to see enrollment occurring so rapidly," said Janet R. Rea, AVM COO. "We are pleased to see these patients tolerate the drug well after failing multiple other therapies and look forward to seeing continued positive results with dose escalation."

The administration of a single dose of AVM0703 is believed to activate the innate immune system to launch novel gamma/delta Natural Killer T cells (NKT cells), and cytotoxic T cells that possess enhanced activity. Once triggered, these cells provide rapid onset of action and response. AVM0703 targets lymphoma while sparing normal lymphocytes, platelets, red blood cells, and stem cells. AVM believes this treatment could reduce the need for transfusions, lower the costs of cancer care associated with managing treatment side-effects, and improve quality of life for lymphoma patients.

"AVM0703 represents an entirely new approach for cancer and non-cancerous diseases. It has the potential to be a true game-changer. I am encouraged by the pre-clinical data and look forward to seeing results of this pivotal trial," said Dr. William Matsui, MD, Deputy Director of Livestrong Cancer Institute.

AVM0703 is available under Expanded Access or Compassionate Use guidelines.

About Non-Hodgkin's Lymphoma

Non-Hodgkin's Lymphoma, a broad heterogeneous constellation of lymphoproliferative disorders, is the seventh most common cancer in both men and women, affecting an estimated 77,240 people in the US each year. The overall five-year survival rate is approximately 72%, and over half of the newly-diagnosed cases are in people over age 65 years. Remission following initial established treatment is common, but the disease typically recurs or relapses in as many as 50% of the patients within two years,[1] and in some patients, their disease is "refractory," or resistant to additional treatment. Second-line or so-called salvage therapy in these patients consists of stronger chemotherapy "cocktails" or, more recently, cell therapy or hematopoietic cell transplantation. Both approaches can have significant and serious side effects, and the response rates to salvage chemotherapy range from 26%[2] to 45%[3], with 50% of patients proceeding to autologous stem cell transplant (ASCT). Four-year survival rates are less than 40% utilizing salvage chemotherapy and 60% for those who then undergo ASCT.[3] Treatments and associated side effects, coupled with the medical fragility associated with these patients, leaves many of them no treatment options, i.e., "no-option". AVM Biotechnology is committed to providing an option to these patients.

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Notes to Editors

1. Chao MP, Treatment challenges in the management of relapsed or refractory non-Hodgkin's lymphoma – novel and emerging therapies. *Cancer Manag Res. 2013;5:* 251–269.
2. Crump M, Neelapu S, Farooq U, et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. *Blood*. 2017;130(16):1800-1808.
3. Kuruvilla J, MacDonald D, Kouroukis, C, et al. Salvage chemotherapy and autologous stem cell transplantation for transformed indolent lymphoma: a subset analysis of NCIC CTG LY12. *Blood*. 2015;126(6):733-738.