Company Overview

AVM Biotechnology – a clinical stage company - is advancing its patent pending, innovative high dose injectable dexamethasone formulation (AVM0703) in an FDA approved clinical trial (NCT04329728) to treat lymphoma/leukemia. The Company also has an approved clinical study (NCT04366115) for treatment of Acute Respiratory Distress Syndrome (ARDS) caused by either Influenza or COVID-19 and is pursuing public funding to support this indication. Furthermore, individual patients have been treated under FDA approved Compassionate Use INDs (glioblastoma and prostate cancer). The drug was well-tolerated.

Lead Molecule AVM0703

AVM0703 product is unique in that it may allow the safe administration of a single high dose of dexamethasone (up to 21 mg/kg) to patients. Generic dexamethasone formulations contain benzyl alcohol and/or parabens that prevent the safe use of these generics at high doses. Our single, high dose of dexamethasone rapidly activates the innate immune system to launch gamma/delta+ Natural Killer T Cells (NKT cells) and cytotoxic T cells with augmented activity compared to ordinary NKT and cytotoxic T cells.

Clinical Pathway

Dexamethasone was originally approved by the FDA in 1958, thereby positioning the anticipated regulatory approval of AVM0703 via the accelerated 505(b)(2) pathway. The FDA supported an adaptive design/expansion cohort pivotal clinical trial design for AVM0703-001 for no-option cancer patients, which further speeds commercial approval for AVM0703 by eliminating distinctions and regulatory submissions between clinical trial phases. AVM0703 can also be administered on an out-patient basis, protecting cancer clinical trial progress should COVID-19 continue to disrupt in-patient trials.

Platform Therapy

The activity of AVM0703 activated/mobilized immune cells is not dependent on cancer or virus expression of specific markers, in contrast to competitor drugs. Natural Killer (NKT) cells are programmed by nature to eliminate abnormal cells including cancer, infected cells and autoreactive lymphocytes. Once triggered, the NKT cell properties provide rapid onset of action and complete response within 2 to 7 days. T cells provide long-term immune system "memory". Hence AVM0703 can be viewed as a platform product, with multiple indications, including cancer, infectious and autoimmune diseases. The novel AVM0703 activated/mobilized NKT and cytotoxic T cells are also being developed as a follow-on 'off- the-shelf' cell therapy product.

Non-Dilutive Grant Awards

AVM has been awarded two Phase I NIH Small Business Innovation Research grants in 2019 (National Institute of Diabetes and Digestive and Kidney Disease [NIDDK] and the National Cancer Institute [NCI]). Successful execution of Phase 1 positions AVM to apply for larger Phase II grant applications in 2021.

Intellectual Property

AVM holds seven worldwide patent families directed to AVM0703: six method of use/composition of matter families and one composition of matter family. Four of the patent families have already been granted/allowed. AVM has developed a proprietary and successful patenting strategy that has enabled third party challenges to be readily overcome, resulting in granted claims and patent protection currently that should extend out to 2040.

Indications

Oncology
Infectious Diseases
Autoimmune Diseases
Regenerative Medicine

Clinical Trial Status

Trial NCT043299728 for treatment of relapsed/refractory Non- Hodgkin's Lymphoma (NHL) is open for enrollment.

Compassionate Use

AVM0703 is available free of charge. We also provide assistance to the physician in obtaining an FDA approved compassionate use IND.

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Theresa A. Deisher, Ph.D. - Founder & CSO, AVM Biotechnology

Gary Grohmann, Ph.D., Director Immunisation Coalition & Director/Founder Environmental Pathogens. Former Director Immunobiology TGA

Scientific and Clinical Advisory Board/Consultants

Frank Buttgereit, M.D. Senior Consultant and Deputy Director, Department of Rheumatology and Clinical Immunology, Charité Universitätsmedizin Berlin. Professor of Rheumatology, Charité Universitätsmedizin Berlin

Gianpietro Dotti, MD. Professor; Director Cancer Cellular Immunotherapy, University of North Carolina-Chapel Hill, North Carolina. Department of Microbiology and Immunology

John Harlan, M.D. Professor Emeritus of Medicine at the University of Washington, former Head of the Division of Hematology at UW and Chief of Hematology-Oncology at Harborview Medical Center

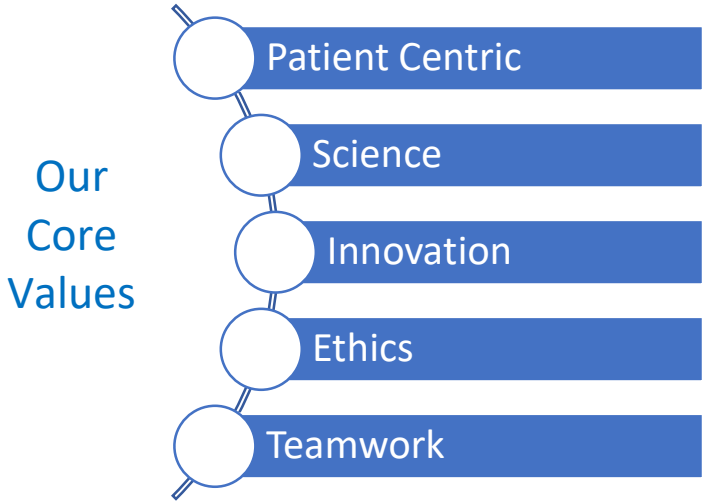
Gustavo Mahler, Ph.D. Managing Partner at Dynamk Capital, Former CEO of AGC Biologics. Under his leadership as CEO of AGC Biologics, the company grew to become a leader in biologics contract development and manufacturing with operations in the United States, Europe, and Asia

William Matsui, M.D. Deputy Director of the Livestrong Cancer Institute, Professor in the Department of Oncology, Dell Medical School, Austin, Texas

Gordon Roble, D.V.M., M.B.A. Director of Comparative Medicine at Fred Hutchison Cancer Research Center

AVM0703 Advantages

- Single acute treatment with potential to repeat at monthly intervals if required
- AVM0703 uniquely induces novel gamma/delta+ Natural Killer T cells (AVM_NKT) that have direct effect on cancer and autoreactive immune cells
- Potential platform technology for cancer, infectious and autoimmune diseases with a direct effect on cancer cells, infected cells and autoreactive immune cells
- Onset of action within 6 hours
- Patient response expected within 2-7 days
- Targets lymphoma while sparing normal lymphocytes unlike rituximab which kills normal lymphocytes
- Spares platelets, red blood cells and stem cells which could reduce the need for transfusion and provide options to patients who will not accept transfusions
- In pre-clinical models, AVM0703 reduces chemotherapy dose by 50% while maintaining efficacy
- 505(b)(2) pathway with accelerated time to approval and market



AVM Biotechnology

AVM is revolutionizing the future of Immunotherapy. AVM's lead compound AVM0703 is the subject of an adaptive design/expansion cohort pivotal clinical trial for treatment of no-option cancer patients.

AVM0703 activates the innate immune system to launch gamma/delta+ Natural Killer T Cells (NKT cells) and cytotoxic T cells with augmented activity for multiple indications.

Defined Regulatory Pathway

AVM0703 can be approved by the 505(b)(2) pathway with accelerated time to approval and market. AVM will also seek accelerated approval and orphan drug status for select indications.

Further Information

Obtain further information about AVM from Jena Dalpez at: jdalpez@avmbiotech.com