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.

Compassionate Use Program

Compassionate use or expanded access programs are designed to make investigational medical products available as early as possible to patients without therapeutic options, because they have exhausted or are not a good candidate for approved therapies and cannot enter a clinical trial. Expanded access refers to the use of investigational drugs outside of a clinical trial, where the primary intent is treatment, rather than research. The purpose of our compassionate use program is to make AVM0703 available to those patients who have exhausted other treatment options and who do not meet the criteria to enroll in a clinical trial. It is intended to improve access to AVM0703 for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options. We provide AVM0703 as well as regulatory templates free of charge for FDA approved Compassionate Use (Expanded Access) applications. AVM Biotechnology has template documents to make the submission process to the FDA straightforward. The Western Institutional Review Board (WIRB) provides pro bono services, i.e., a review of the protocol, informed consent and other study -related documents, in support of these applications. Dr. Ed Loniewski is AVM's Chief Medical Officer (CMO) for our Compassionate Use Program. This program is also included in the Reagan-Udall Foundation of the FDA, which provides a searchable database of diseases and companies with Compassionate Use Programs.

Physician Instructions

As the requesting physician you are the sponsor and principal investigator of expanded use and must apply to the FDA for a single-use Investigational New Drug number (IND).

There are 7 simple steps for physicians.

1. Contact the FDA for a single patient compassionate use Investigational New Drug (IND) number.
2. Complete FDA form 3926.
3. Obtain an Informed Consent from the patient or patient advocate.
4. Set up an Institutional Review Board meeting.
5. Request a Letter of Authorization (LOA) from AVM Biotechnology.
6. Send the documentation to the FDA.
7. Send all information to AVM Biotechnology and set up a date and time for the treatment.

You can easily apply to AVM for access to our treatment by completing a Compassionate Use Application and download the Non-Disclosure and Confidentiality Agreement. Print and sign these documents. Please scan and email to: compassionateuse@avmbiotech.com, or fax them to AVM at 206.424.8701. Once we receive the signed Non-Disclosure and Confidentiality Agreement, we will supply you with our Investigator's Brochure and Pharmacy Manual. Our Chief Medical Officer, Dr. Ed Loniewski is available to assist you throughout the process.

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 in obtaining an FDA approved compassionate use IND.

Email eloniewski@avmbiotech.com for more information

Management & Contact Info

Theresa A. Deisher, Ph.D.
Founder & CEO
tdeisher@avmbiotech.com

Janet R. Rea, M.S.P.H.
Chief Operating Officer
jrea@avmbiotech.com

Gary Grohmann, Ph.D., FASM
Chief Regulatory Officer

Terry Kopp
VP of Investor Relations

Ed Loniewski, D.O.
Chief Medical Officer

Board of Directors

Patient Instructions

Accessing the AVM Biotechnology Compassionate Use Program is straightforward.
Step 1 Ask your physician to read the Physician Instructions for Compassionate Use. Step 2 Encourage your physician to complete the FDA form 3926 and schedule a review by the Institutional Review Board (IRB) of your treating facility.
Step 3 Ask your physician to complete the Compassionate Use Application.
Step 4 Ask your physician to contact AVM Biotechnology for a Letter of Authorization.

Kids vs. Cancer is a non-profit organization with very useful information to help you through this process at Compassionate Use Navigator.

The cost of this medication is provided free of charge to your physician. We also work you're your doctor to provide support to properly understand the dosing, potential side effects and the potential methods to prevent and or treat the side effects.

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
- 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

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, M.D. - Director of the Immunotherapy Program at the University of North Carolina Lineberger Comprehensive Cancer Center and professor in the Department of Microbiology and Immunology at UNC-Chapel Hill. He received his medical degree from the University of Milan in Italy with a post-doctoral fellowship from Baylor College of Medicine in Houston.

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.

Overview

Visit:
www.avmbiotech.com/compassionateuse

Are you a Patient or Provider?

Patient:
Contact your provider

Provider:

- Contact AVM Compassionate Use Medical Director
- Sign CDA/NDA*
- Discuss case with Medical Director
- Obtain Letter of Authorization (LOA)* (from AVM) Protocol*, IB*, Informed consent* documents
- Prepare provided application forms for IRB
- Protocol+ IB + IC to WIRB
- WIRB Approval + Protocol + IB +Application + LOA to FDA
- Once approved by the FDA, provide letter, shipping information for drug to AVM
- Drug ships within 24-48 hours
- One-on-one personalized assistance to expedite process

*forms provided by AVM Biotechnology