Company Overview

AVM Biotechnology – a clinical stage company - is advancing its patent pending, innovative very high dose injectable dexamethasone formulation (AVM0703) in an FDA approved clinical trial (NCT04329728) for lymphoma/leukemia patients. 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 funds 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.

AVM0703

AVM0703 triggers the production and release of highly active and powerful novel immune cells. A single suprapharmacologic dose of AVM0703 activates the body's production of natural supercharged immune cells. These gamma-delta AVM_NKT cells have unique properties and appear rapidly following a single dose of AVM0703. While the full potential of these cells continues to be explored by AVM, it is clear they have the potential to play a significant role in several diseases.

Compassionate Use Program (aka "Expanded Access")

Compassionate Use or Expanded Access programs are designed to make investigational medicinal products available to patients who have exhausted other treatment options; who do not meet the criteria to enroll in a clinical trial; and have a serious or immediately life-threatening disease(s) or condition. The FDA's Expanded Access Program provides a straightforward means for these patients to obtain potential therapies, such as AVM0703.

AVM will assist physicians in requesting permission from the FDA for a single patient IND using AVM0703. The FDA typically responds quickly to these requests. Additionally, AVM has arranged with The Western Institutional Review Board (WIRB) to serve as the IRB for each request at no cost.

AVM0703, the study protocol, Investigator Brochure [IB] and Informed Consent [IC] template, as well as regulatory templates for the application are provided free of charge. Dr. Ed Loniewski is AVM's Chief Medical Officer (CMO) for the Compassionate Use Program and is available to provide any needed assistance. 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 - *AVM Processes Requests Urgently*

The requesting physician is considered the sponsor and principal investigator and must apply to the FDA for a Single-Patient Investigational New Drug number (IND). Dr. Ed Loniewski, Chief Medical Officer, is available to provide assistance throughout the process

1. Complete the Compassionate Use Application and download the Non-Disclosure and Confidentiality Agreement. Sign these documents (either wet signature or electronically) and email both to AVM Biotechnology (compassionateuse@avmbiotech.com).
2. Contact Dr. Ed Loniewski, AVM Chief Medical Officer (eloniewski@avmbiotech.com). Once the information from #1 above is obtained, he will provide additional documentation information (e.g., Protocol, IB, IC, FDA form 3926, Pharmacy Manual, etc.) for the application.
3. Contact the FDA for a Single-Patient compassionate use Investigational New Drug (IND) number. Use this IND number on all correspondence.
4. Request a Letter of Authorization (LOA) from AVM Biotechnology.
5. Submit the documentation to WIRB or local IRB for review.
6. Submit the documentation (completed form 3926, Protocol, IB, IC, IRB approval and the LOA to the FDA and send an electronic copy to AVM Biotechnology.
7. Provide an electronic copy of the FDA approval letter to AVM Biotechnology and address for drug shipment.

Additional information can be obtained from the FDA Website here: https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use.

Indications

Oncology
Infectious Diseases
Autoimmune Diseases
Regenerative Medicine

Clinical Trial Status

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

Compassionate Use

AVM0703 and assistance with obtaining an FDA approved compassionate use IND are provided free of charge.

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

Terry Kopp
VP of Investor Relations

Ed Loniewski, D.O.
Chief Medical Officer

Patient/Family Instructions

Accessing the AVM Biotechnology Compassionate Use Program is straightforward. Patients and their families, however, may not directly request the use of AVM0703 for compassionate use from the FDA. The request needs to be initiated by the physician.

Patients and families can play a role, by encouraging the physician to work with AVM Biotechnology to obtain FDA approval for compassionate use, for example, by referring the physician to the Physician Instructions, which can also be found on the AVM Biotechnology website.

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

The cost of this medication is provided free of charge to your physician. AVM works with the doctor 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.

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 and Chief Medical Officer, Dr. Ed Loniewski
- Sign and return CDA/NDA*
- Discuss case with Medical Director
- Request a Single-Patient IND number from the FDA
- Obtain Protocol*, IB*, IC template* and Pharmacy Manual* from AVM
- Submit Protocol, IB and IC template to the IRB
- Request a Letter of Authorization (LOA) from AVM
- Submit the Protocol and IRB approved IC with the approval letter, LOA and FDA Form 3926 to the FDA and a copy to AVM
- Provide FDA approval letter and shipping information (for the drug) to AVM
- Drug ships within 24-48 hours following IRB approval

** provided by AVM Biotechnology*

AVM provides one-on-one personalized assistance for this process