AVM Biotechnology to treat COVID-19 and Influenza ARDS with its “supercharged” version of dexamethasone

AVM to proceed with clinical trials in treatment of COVID-19 demonstrating the broad potential of AVM’s lead drug AVM0703

SEATTLE, WA, USA, September 16, 2020 /EINPresswire.com/ -- AVM Biotechnology has received FDA permission to proceed with clinical trials to evaluate its proprietary drug AVM0703 in the treatment of Acute Respiratory Distress Syndrome (ARDS) mediated by COVID-19 or Influenza patients. This is AVM’s second “safe to proceed” clinical trial authorization from the FDA within the past six months and demonstrates the broad potential of AVM’s lead drug.

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> *Janet R. Rea, COO AVM Biotechnology*

The previously approved study will evaluate AVM0703 in refractory/relapsed Non-Hodgkin’s Lymphoma patients. This second study consists of two different ARDS patient populations: one with COVID-19-mediated moderate to severe ARDS and the other with Influenza-mediated severe ARDS.

AVM0703 is a novel and proprietary formulation of high concentration of dexamethasone. In addition to its recognized immunomodulatory properties, an acute high or suprapharmacologic dose of AVM0703 mobilizes highly active Natural Killer T- (NKT) and cytotoxic T- cells and dendritic cells. Within 6 hours of a single administration, there is evidence that AVM0703 “kick-starts” additional NKT cell activation. These cells have robust activity against very aggressive difficult-to-treat cancer models; this is directly relevant to COVID-19- and Influenza-mediated ARDS because NKT cells are programmed to eliminate abnormal cells, whether cancer or virus-infected.

Although generic formulations of dexamethasone are available, and daily low dosing has become a standard of care for moderately to severely ill COVID-19 patients, generic dexamethasone cannot be used at the high doses necessary to activate Natural Killer T (NKT), cytotoxic T and dendritic cells, and to stimulate monocyte ablation and reduce neutrophils. The excipients in these generic formulations exceed safe levels at the required doses needed to

activate these immune cells. Importantly, one single dose of AVM0703 triggers this critical immune system activation.

While vaccines may play a part in thwarting COVID-19, it is entirely possible that COVID-19 infection will still occur in a significant number of people. Even with Influenza vaccines and antiviral drugs, a minimum of 17,000 Influenza patients develop ARDS in the USA each year. Therefore, therapies such as AVM0703 will most likely play a critical and continuing role in the future treatment of these patients.

“Quickly harnessing the body’s own immune system to produce its own Natural Killer and cytotoxic T-cells and its own dendritic cells is appealing on many levels in treating seriously ill patients. Doing so has potentially broad applications in other diseases, including cancers.” Janet R. Rea, AVM Biotechnology COO.

Rapid elimination of infected monocytes in COVID-19 patients could reduce ICU stays and decrease long-term lung damage. NKT mobilization could also provide long-term T-cell immunity. Due to its striking immunomodulatory properties, AVM0703 may have therapeutic effects in a variety of blood cancers, solid tumors, and infectious diseases such as COVID-19 and Influenza. Because NKT cells eliminate virus-infected cells independent of the strain or type of virus, this could provide immediately available therapy for future pandemics from any virus.

AVM Biotechnology is led by Dr. Theresa Deisher, a biotech veteran with a productive history including 47 patents and three discoveries in clinical trials. Its COO, Janet R. Rea, has a proven track record working with federal regulators and successfully bringing drugs to market. The Executive Board is comprised of world leaders in the areas of respiratory illness, regulatory affairs, and vaccine development, and AVM is guided by a global Advisory Board including well-respected leaders in the areas of cancer and immunology. The company has received two SBIR grants, has filed for five worldwide Methods of Use patent families, has a worldwide Composition of Matter patent pending, and is committed to developing products that improve outcomes without additional suffering. They believe side effects from treatments should never be worse than the diseases themselves. This approval to begin an additional trial utilizing AVM0703 to treat ARDS patients is an exciting further step in support of that mission.

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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 patients, 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.

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