"Supercharged" Dexamethasone is the Future of Immunotherapy

Dexamethasone reportedly part of President Trump's Treatment

SEATTLE, WA, US, October 7, 2020 /EINPresswire.com/ -- As part of the standard of care treatment protocol, President Trump received dexamethasone for his COVID-19 disease, highlighting the value of dexamethasone. Dexamethasone has been widely used since its initial approval in 1958 in treating acute disease. The use of higher dexamethasone doses, with potentially additional and desired immunological effects, is limited due the presence of toxic excipients in the injectable form.

AVM Biotechnology has developed a patent pending, highly-concentrated form of injectable dexamethasone that, when given at suprapharmacologic doses, induces a rapid and striking immune response. AVM has FDA permission to begin clinical trials using AVM0703 to treat patients with COVID-19- and influenza-mediated Acute Respiratory Distress Syndrome (ARDS). Additionally, a second approved trial with AVM0703 in Non-Hodgkin's Lymphoma will be enrolling patients shortly.

AVM Biotechnology also has an active Expanded Access ("Compassionate Use") Program for AVM0703 (https://avmbiotech.com/compassionate-use/), and template documents and guidance for treating physicians to facilitate the application process. AVM0703 can be considered for a single-patient, Physician-sponsored IND for Emergency/Expanded Use.

AVM0703 is a high-concentration and high-volume formulation of dexamethasone sodium phosphate (DSP) for intravenous (IV) infusion. This proprietary formulation does not contain dose-limiting excipients such as benzyl alcohol and parabens found in generic formulations and could possibly be used at up to 21 mg/kg per dose. AVM0703 is administered as a single IV infusion.

Treatment paradigms for seriously ill COVID-19 patients have rapidly evolved. The National Institutes of Health (NIH) recently updated its COVID-19 treatment guidelines to include treatment of up to 6 mg per day of dexamethasone for up to 10 days in patients that require supplemental oxygen, or those who are are mechanically ventilated. Prior to that, the NIH amended the treatment guidelines to recommend low-dose corticosteroid therapy over no corticosteroid therapy in COVID-19 patients with refractory shock, as the value of steroid

treatment was recognized. Individual physicians are also now treating non-hospitalized COVID-19 patients with daily low dose dexamethasone, rapidly expanding the utility of dexamethasone in treating this disease. Standard dexamethasone treatment was included in President Trump's care regimen.

At doses of 6 mg/kg and higher, dexamethasone activates/mobilizes supercharged Natural Killer T- ("NKT") and cytotoxic T- ("cytoT") cells with superior activity against very aggressive cancer models compared to ordinary NKT and cytoT cells, chemotherapy or checkpoint inhibitors. The FDA has approved a clinical trial with AVM0703 in severe ARDS based on its rapid monocyte and neutrophil reduction which could alleviate the pulmonary inflammation so problematic for ARDS patients, and its NKT mobilization. NKT's are programmed by nature to eliminate abnormal cells, whether cancer or virus-infected. Triggering these cells may result in antibody formation, leading to T-cell immunity.

AVM Biotechnology is led by Dr. Theresa Deisher, a biotech veteran with a productive history including 47 patents and four 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 and has eight worldwide patent families that cover the use and formulation of AVM0703 as well as three other AVM Biotechnology programs. They are committed to developing products that improve outcomes without additional suffering, because they believe side effects from treatments should never be worse than the diseases themselves

For more information about AVM0703 please visit: https://avmbiotech.com/infectiousdisease/.

For additional information on the Compassionate Use program, please visit: https://avmbiotech.com/compassionate-use/ or contact Jena Dalpez Jdalpez@avmbiotech.com.

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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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