FDA Approves Accelerated Dosing in Non-Hodgkin's Lymphoma/Leukemia Clinical Trial

AVM Biotechnology eliminates dose cohorts in Non-Hodgkin's Lymphoma/Leukemia clinical trial with FDA approval.

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SEATTLE--(BUSINESS WIRE)--AVM Biotechnology, a clinical-stage company, announced today FDA permission to modify its ongoing clinical study, AVM0703-001, entitled "The WWRD Study: AVM0703 for Treatment of Leukemia or Lymphoma". The initial protocol, a 3 x 3-based design, called for dose escalation of 3 mg/kg for each of the six cohorts, ranging from 6 mg/kg to 21 mg/kg, with a minimum of three patients per cohort as part of an adaptive-design/expansion cohort trial.

The approved protocol modification involves the elimination of three of the cohorts and reduction of the interval between cohorts. Eliminating the 9, 12 and 15 mg/kg dose requirements and moving directly to the anticipated effective clinical dose of 18 mg/kg is important for this study. Preclinical research and compassionate use data indicate 18-21 mg/kg will be the target effective dose for the expansion phase of the study. Bypassing the intermediate dose levels should accelerate completion of the dose-escalation part of the study, enabling the efficacy portion to commence immediately thereafter, much sooner than planned.

"We are pleased that the FDA agreed with our proposal, which leveraged the safety data amassed from the ongoing study and Expanded Access (Compassionate Use) patient data obtained to date," remarked Janet R Rea, MSPH, Chief Regulatory Officer. "This accelerates our clinical development program and propels it toward an earlier NDA submission."

Clinical experience has shown the drug to be well tolerated with mild and self-limiting side effects. Patients have reported feeling "great." The emerging safety profile is promising, to treat these seriously ill patients.

A single dose of AVM0703 triggers the rapid activation and mobilization of novel gamma delta positive Natural Killer T (NKT) cells. NKT cells exhibit properties of both innate and adaptive immunity. AVM-NKT cells home to abnormal cells including cancer and autoreactive lymphocytes sparing platelets, red blood cells and stem cells. These unique AVM-NKT cells could play a significant role in addressing several serious conditions, including various types of cancer and autoimmune diseases such as type 1 diabetes. Preclinical data also indicate AVM0703 can be synergistic with chemotherapy, allowing total cycles of chemotherapy to be reduced while maintaining patient response, thus significantly impacting patient quality of life, treatment compliance, and secondary complications from cancer treatment.

"AVM has developed an entirely new drug that demonstrates a novel mechanism of action related to tissue-bound gamma delta NKT cells. We believe this drug will have great benefit to patients in a wide variety of disease settings," stated AVM Chief Business Officer, Joe Luminiello.

AVM Biotechnology is a clinical-stage company advancing AVM0703 in Non-Hodgkin's Lymphoma/Leukemia as an initial indication as well as autoimmune diseases and other indications. While planning for a direct commercial launch of AVM0703, the company is also developing the AVM-NKT as an 'off-the-shelf' cell therapy product with broad applications. Strategic partnerships are being explored.

AVM Biotechnology's mission is to develop and deliver treatments that save lives and improve outcomes by unlocking the untapped potential of the body's own immune system.

Forward Looking Statement

This contains certain statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not relate strictly to historical or current facts and they may be accompanied by words such as "could," "would," "may," "potentially," "suggest," "believes," "expects," "should," and similar words or expressions. These forward-looking statements reflect our current views as of the date this is published, and are subject to risks, uncertainties, assumptions, changes in circumstances, and other factors; drug development and commercialization are highly risky and early clinical results in animals or humans may not reflect the full results from later stage or larger scale clinical trials. 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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