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LeafBio Announces Acceptance of Investigational New Drug Application for Ebola Therapy ZMapp™

Clears Way for Human Trials of ZMapp in Liberia

February 27, 2015 – SAN DIEGO – LeafBio, the commercial arm of Mapp Biopharmaceutical, announced that it has received approval of its application for an Investigational New Drug (IND) from the Food and Drug Administration (FDA). The acceptance of the IND will allow for clinical trials of the company's Ebola therapy ZMapp™ to begin in Liberia. The U.S. National Institutes of Health and the Liberian government will oversee the clinical trials.

"The trials starting in Liberia offer the opportunity to evaluate the effectiveness of ZMapp™ in a controlled clinical trial ," said Dr. Larry Zeitlin, president of Mapp Biopharmaceutical. "We are optimistic about the therapy's effectiveness and grateful to our staff and all of our public and private partners who have worked tirelessly to get us to this point."

ZMapp™ is a cocktail comprised of three antibodies intended to fight Ebola and was identified in January 2014 as the result of a collaboration between Mapp Biopharmaceutical, Defyrus, Inc, the Public Health Agency of Canada, and the United States Army Medical Research Institute of Infectious Diseases. Mapp Biopharmaceutical is developing the drug in partnership with Defyrus, Inc. The antibodies in the cocktail are currently manufactured in tobacco plants at Kentucky BioProcessing (Owensboro. KY). Development and production of ZMapp™ was supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA), the U.S. National Institute of Allergy and Infectious Diseases, the U.S. Defense Threat Reduction Agency, and the Bill and Melinda Gates Foundation.

Since September 2014, LeafBio/Mapp Biopharmaceutical has partnered with BARDA, under a $25 million contract, to expedite manufacturing of ZMapp™ for potential use in Phase 1 and the aforementioned Phase 2 trial in Liberia. In addition to providing support for the manufacturing of the bulk product, BARDA has also partnered with LeafBio/Mapp Biopharmceutical to provide fill finish capabilities for the final drug under one of BARDA's core services; the Fill Finish and Manufacturing Network. Together, these efforts have resulted in product being available for the master protocol, randomized clinical trial to evaluate the efficacy of ZMapp™.

“This is a significant milestone for Mapp and all those involved,” added Dr. Kevin Whaley, CEO of Mapp Biopharmaceutical. “We have been working toward this moment for more than a decade, and are heartened by the support and responsiveness of the governments and organizations committed like we are to finding treatments for this devastating disease.”

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About Mapp and Leaf Biopharmaceutical*: Mapp Biopharmaceutical was founded in 2003 by Drs. Kevin Whaley and Larry Zeitlin to develop novel pharmaceuticals for the prevention and treatment of infectious diseases, focusing on unmet needs in global health and biodefense. The company has been developing an Ebola therapy for more than a decade and has been working with the United States and Canadian governments to develop this therapy. As these products transition to clinical evaluation, Leaf Biopharmaceutical assumes ownership and commercialization responsibilities.*