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ZMapp™ is Granted Fast Track Status by the FDA

Status May Enable Faster Approval of ZMapp™

September 17, 2015 – SAN DIEGO – LeafBio, Inc. (LeafBio), the commercial arm of Mapp Biopharmaceutical, Inc. (Mapp), announced today that the U.S. Food and Drug Administration (FDA) has granted ZMapp™ "Fast Track" designation for the treatment of Ebola virus disease. "Fast Track" designation is granted to drugs that the FDA determines, based on nonclinical or clinical data, have the potential to address an unmet medical need and that are intended to treat a serious condition. Fast Track designation allows for certain benefits, including opportunities for frequent interactions with the FDA, which may enable designated drugs to reach market sooner. Mapp Biopharmaceutical has been working to develop a therapy to treat Ebola virus for more than a decade.

"We have been consulting frequently with the FDA during the development of ZMapp™ and are grateful for their willingness to work with us to provide interactive review. The formalization of this through Fast Track designation is an important milestone," said Dr. Larry Zeitlin, President of LeafBio and Mapp.

Prior to this designation, the FDA had granted ZMapp™ "orphan drug" designation, which provides financial and other regulatory incentives meant to encourage development of drugs and other products targeted at rare diseases. The goal of both of these designations is to encourage researchers and scientists to research and develop treatments for diseases that may otherwise be overlooked.

Fast Track designation may shorten the path toward filing and obtaining approval of a Biologics License Application, the marketing application that must be filed with and approved by the FDA before ZMapp™ may be marketed in the United States. The designation does not affect the ongoing clinical trial of ZMapp™ currently taking place in West Africa.

"We are gratified to receive this designation for ZMapp™," added Dr. Kevin Whaley, CEO of LeafBio and Mapp. "We are hopeful that this step will accelerate access to ZMapp™ once safety and efficacy are demonstrated to FDA's satisfaction in ongoing clinical trials."

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About Mapp Biopharmaceutical, Inc. and LeafBio, Inc.*: Mapp 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, LeafBio assumes ownership and commercialization responsibilities.*

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