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LeafBio Announces NEJM Publication of ZMapp™ Clinical Trial

Therapy to Treat Ebola Shows Promise

October 12, 2016 – SAN DIEGO – LeafBio, Inc., the commercial arm of Mapp Biopharmaceutical, Inc., announced today that results from the PREVAIL II clinical trial of ZMapp™ for treatment of Ebola Virus Disease (EVD) have been published in the New England Journal of Medicine. ZMapp is a cocktail of three monoclonal antibodies directed against the Zaire strain of Ebola virus responsible for the recent Ebola epidemic centered in West Africa. Based on results of the study, researchers said the drug was well-tolerated and showed promise.

The trial, conducted in Liberia, Sierra Leone, Guinea and the United States, was designed to evaluate the efficacy of ZMapp in treating EVD. The trial compared an optimized standard of care (hemodynamic monitoring, fluid and electrolyte replacement, and general medical support) to optimized standard of care plus ZMapp, with patients randomly assigned to treatment groups. Mortality in the ZMapp-treated patients was 40 percent lower (8 of 36; mortality 22 percent) than the mortality in patients receiving standard of care alone (13 of 35; mortality 37 percent). These mortality differences gave a 91 percent probability that ZMapp was superior to standard of care. However, this difference in mortality did not reach the predefined 97.5 percent probability threshold for declaring statistical significance and a definitive demonstration of ZMapp efficacy, likely due to a smaller-than-intended sample size: due to the waning of the epidemic, the trial only enrolled 72 patients, a fraction of the planned enrollment of 200. The frequency of subjects with serious adverse events (SAEs) was similar between the two groups: 30.6 percent versus 37.1 percent in the ZMapp-containing arm and standard of care alone, respectively. Only one SAE (hypertension) in ZMapp recipients was judged related to the infusion itself.

“The outcome of this truncated study is supportive of ZMapp’s antiviral activity in humans. Based on the preclinical and clinical results to date, Mapp will vigorously pursue further development and licensure of ZMapp as a treatment for Ebola,” said Dr. Kevin Whaley, CEO of Mapp Biopharmaceutical.

In light of these results, the U.S. Food and Drug Administration (FDA) has approved an Expanded Access Protocol (EAP) for ZMapp, allowing Mapp Biopharmaceutical to continue to make ZMapp available to patients during the product’s ongoing development. Mapp Biopharmaceutical also will make appropriate regulatory submissions in the three West African countries that participated in PREVAIL II, and will make ZMapp available to Ebola patients wishing to have access to this experimental treatment in participating countries. The EAP is being funded by the Biomedical Advanced Research and

Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.

"The results are certainly encouraging," said Dr. Martin Friede, the Coordinator of the Initiative for Vaccine Research for the World Health Organization. "The PREVAIL II results suggest ZMapp is most effective when patients have lower viral titers which is generally earlier in the course of disease, so in the event of future outbreaks my hope is that the availability of ZMapp would encourage symptomatic individuals to come to treatment units early in their disease course, increasing the likelihood of effective treatment and reducing transmission in the community. In order for availability of the product to be ensured we encourage Mapp to actively pursue regulatory approval of ZMapp. This study may have significant implications for outbreak control and along with other interventions such as vaccination could contribute to preventing another epidemic of the scale of the West African Ebola outbreak."

The trial was sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health, in partnership with the Ministries of Health of the three affected West African countries, the French Institut National de la Santé et de la Recherche Médicale (INSERM), the Republic of Sierra Leone Armed Forces (RSLAF) and other academic, governmental and non-governmental agencies providing research support within the region.

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About Mapp Biopharmaceutical and LeafBio*: Mapp Biopharmaceutical was founded in 2003 to develop novel pharmaceuticals for the prevention and treatment of infectious diseases, focusing on unmet needs in global health and biodefense. As these products transition to clinical evaluation, LeafBio assumes ownership and commercialization responsibilities.*

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