

Mapp Biopharmaceutical has maintained a low public profile during West Africa's Ebola crisis because we believe the primary focus should be on the urgent need to scale up the resources and personnel required to identify, isolate and treat people infected with the virus. We recognize, however, that there is considerable media interest in ZMapp™, and feel an obligation to be appropriately responsive to public inquiries. The following statement provides detailed information on efforts to produce more ZMapp™.

Current Status of ZMapp™

ZMapp™ is a cocktail of three monoclonal antibodies, essentially requiring three separate manufacturing processes. While there is currently limited infrastructure for plant-made pharmaceuticals (PMPs), as a drug newly identified in early 2014, it is only because ZMapp™ was being manufactured in plants at Kentucky BioProcessing (KBP) in Owensboro, KY, that any ZMapp™ was available for compassionate use.

KBP, an established leader in the manufacture of antibodies produced from plants, recognized the urgency of the issue, made the decision to clear other activities from its production schedule, and in early August began a campaign to manufacture more ZMapp™. On September 2, Mapp received a contract from the U.S. government through The Biomedical Advanced Research and Development Authority (BARDA) to fund continued manufacture and clinical development of ZMapp™ in accordance with FDA rules and regulations. Clinical investigational lots manufactured under this contract will be used in Phase 1-2 clinical studies evaluating the safety and efficacy of ZMapp™.

Our efforts to increase production have focused on the following activities:

1. Improving expression of the antibodies in Nicotiana. With internal resources, Mapp and KBP, together with other companies involved in PMPs, have been evaluating different methods of improving the amount of antibody made in each plant.
2. Establish an optimal therapeutic dose of ZMapp™. The amount of drug used compassionately with Ebola patients earlier this year was likely more than would be required to achieve a therapeutic effect. With support from the Defense Threat Reduction Agency (DTRA), experiments at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) are ongoing to determine an appropriate dose in animals. In collaboration with experts at the Bill & Melinda Gates Foundation, we are analyzing existing and future animal data to better predict the equivalent human dose.
3. Increase manufacturing capacity in plants. Mapp and KBP are actively seeking ways to increase the number of plants that can be used in the manufacturing process.
4. Produce ZMapp™ in an alternative manufacturing system. Together with the Bill & Melinda Gates Foundation and a pharmaceutical partner, an effort to make the ZMapp™ antibodies in Chinese Hamster Ovary (CHO) cells has begun. While offering a slower route than plant production, the infrastructure for manufacturing in CHO cells is well established, which means the potential scale of drug production is greater than the production capacity of existing PMP facilities.