MRMC ORTA, MCMR-JA

Ms. Judit Rius
Doctors Without Borders/Médecins Sans Frontières
333 Seventh Avenue, 2nd Floor
New York NY 1001-5004

21 April 2017

Dear Ms. Rius,

This reply is in response to your letter of January 23, 2017 objecting to the proposed grant of an exclusive license to Sanofi Pasteur for the Zika vaccine developed by the U.S. Army Medical Research and Materiel Command (MRMC), as published in the Federal Register Notice of Intent to Grant an Exclusive License December 9, 2016.

Thank you for your comments and recommendations. Our singular goal is to find the best way to provide a quick, safe, and effective Zika vaccine for our U.S. soldiers and the public while complying with all U.S. laws and regulations. Your objection has been read and considered. Your summarized objections include:

1. “The grant of exclusivity is not a reasonable and necessary incentive to promote innovation and further development of a Zika vaccine.”

2. “The grant of patent exclusivity can hinder innovations for Zika vaccines and doesn’t allow research strategies that promote collaboration and focus on neglected medical needs.”

3. “An exclusive license can be a barrier to ensuring a Zika vaccine will be available and affordable to all who need it.”

In response:

1. The patent license is in accordance with federal laws and regulations, the proposed scope of exclusivity is in the best interest of the U.S. government and the public, and it is a reasonable and necessary incentive to call forth the substantial investment capital, expertise, and capabilities required to bring our nascent and unproven technology through FDA licensure to practical application for public use.
2. The MRMC vaccine is not the only Zika vaccine or solution being supported by the U.S. Government. Other vaccines are being funded by the U.S. Government and there are numerous other companies pursuing recombinant, subunit, live attenuated, nucleic acid and viral vector vaccines. Zika is no longer a neglected medical need. In our view, exclusivity is required to get a company to enter a crowded and competitive preclinical marketplace, especially when the cost of clinical trials is substantial (and may even be higher due to competition for clinical trial sites with high Zika incidence).

3. The U.S. Army lacks the means, expertise, and authority to define "affordable prices" or to set price controls for a potential vaccine that will require great investment and face high risk of failure, so we believe market competition among the Zika solutions can more fairly determine the availability and market for products. Nonetheless, granting an exclusive license, under our existing technology transfer statutory framework, places restrictions and requirements upon the licensee that are designed to protect the public interest.

We appreciate your comments, concerns, and objections. Although the license agreement is not final, we intend to grant an exclusive patent license to Sanofi Pasteur, Inc. as authorized and in accordance with U.S. laws and regulations, provided we determine the terms to be in the best interest of the U.S. Government and the public.

Should you believe that my response does not adequately address your concerns and that you have grounds for appeal, you may submit an appeal within 30 calendar days of receiving actual or constructive knowledge of the basis for the appeal. If the thirtieth calendar day falls on a weekend or Federal holiday, then the appeal will be due the next working day. The procedures for an appeal are found in 37 CFR 404.11 and Appendix B of Army Regulation 70-57.

Sincerely,

Barry M. Datlof
Chief, ORTA