



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NIAID

5601 Fishers Lane
Rockville, MD 20852
Suite 6D, MSC 9804
Tel (301) 496-2644

Feb 25, 2020

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

Subject: Questions/Comments submitted in Response to Federal Register Notice 2020-00721, entitled “Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)”

Dear Ms. Ardizzone,

We confirm receipt of your questions dated Jan 28, 2020 and comments dated Feb 3, 2020 regarding the Federal Register Notice at F.R. Vol.85, No. 12 (pages 3062-3063), entitled Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)” published on January 17, 2020. Prior to posting such notices, NIAID determines the criteria set forth in 37 C.F.R. section 404.7 (a)(1)(ii-iv), have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government’s intellectual property in the field(s) of use as specified.

On January 28, 2020, you asked eight questions concerning this technology, its stage of development and terms that have not yet been negotiated in the event NIAID determines to enter negotiations with TeraImmune for an exclusive license. On February 3, 2020, you raised three points of discussion. NIH has provided answers previously to how we evaluate and make decisions regarding licensing. Funding information is available at report.nih.gov. NIH has also explained which aspects of a license have been and which have not been determined prior to posting a notice in the Federal Register. Other aspects of a proposed license have not yet been negotiated and/or are confidential.

Thank you very much!

Sincerely,

Yogikala Prabhu

Yogikala Prabhu, Ph.D.
Technology Transfer and Patent Specialist
Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Disease/NIH