



Office of Technology Transfer and Development
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Kathryn Ardizzone
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Subject: Comments Submitted in Response to Federal Register Notice 2020-11036 (85 FR 31193), entitled
"Prospective Grant of an Exclusive Patent License: Antibody-Based Therapy for the Treatment
of CD20 Expressing Lymphomas"

Dear Ms. Ardizzone,

Thank you for providing us with your comments regarding the aforementioned Federal Register notice (FRN). As you indicated, your comments were submitted on behalf of two organizations, we kindly request that you share our response with both parties.

Prior to posting the FRN, the NHLBI determined under the criteria set forth in 37 CFR 404.7 that the prospective licensee, Retargeted Therapeutics, was qualified to be granted an exclusive license to the Government's intellectual property in the specified fields of use.

The technology described in the FRN can potentiate the anti-tumor activity of a therapeutic monoclonal antibody, and will provide an alternative therapy for the relapsed and refractory cancer patients. The key target antigens and associated cancers that may benefit from the potentiating effect of the technology are CD20 (lymphoma), CD38 (multiple myeloma), CD33 (acute myeloid leukemia), EGFR (colon cancer), and ERBB2/HER2 (breast cancer). This technology is still in pre-clinical stage of development, no clinical trials have been conducted. Considering the magnitude of investment required to develop antibody based technologies and the high level of investment risk, we have determined that a degree of exclusivity is an appropriate incentive to the commercial partner. Moreover, the proposed field of use is narrowly drawn to allow other companies to license the patent rights in other fields of use. This strategy will increase the likelihood in fulfilling an unmet cancer immunotherapeutic need for patients with refractory and relapsed disease.

The remainder of your questions and issues are either not relevant to those criteria or have been previously answered multiple times by NIH (we refer you to the letter sent to you by Dr. Mark Rohrbaugh in November 2019).

Sincerely,

A handwritten signature in black ink that reads "Vidita Choudhry". The signature is written in a cursive style with a horizontal line underneath the name.

Vidita Choudhry, Ph.D.
Technology Transfer Manager