**Billing Code 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

# Clinical Development and Commercialization of CD22- Targeting Chimeric Antigen Receptor (CAR) T-Cell Therapies for Children and Young Adults with Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia (ALL)

**AGENCY:** National Institutes of Health, HHS.

**ACTION**: Notice.

**SUMMARY**: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is seeking statements of capability and interest from prospective licensees and potential Collaborators interested in participating in collaborative research under a Cooperative Research and Development Agreement (CRADA) to develop autologous CD22 CAR T-cells (m971BBZ lentivirus transduced) for the treatment of B-cell ALL.

**DATES**: Statements of capability and interest should be submitted via email by September 1, 2020, with a formal proposal due by October 15, 2020.

**ADDRESSES**: Statements of capability and interest should be directed to: Jim Knabb, Ph.D., Senior Technology Transfer Manager, NCI, at 240-276-7856 or Email: knabbjr@mail.nih.gov.

**SUPPLEMENTARY INFORMATION:**

**Collaboration Opportunity:**

NCI is seeking a pharmaceutical or biotechnology company that can effectively and efficiently collaborate on the scientific and commercial development of CD22-CAR. The goal of the collaboration will be the successful transfer of clinical development of CD22-CAR from NCI to the Collaborator, which will be responsible for the rapid scale-up and clinical manufacture of the agent to support the pivotal clinical trial and subsequent BLA. The selected Collaborator will be responsible for the manufacture and provision of CD22-CAR lentivirus (m971BBZ lentivirus) and autologous CD22-CAR T-cell therapy product in sufficient quantities to complete the pivotal

clinical trial. The selected Collaborator will prepare and submit a BLA to the FDA for CD22-CAR following the completion of the pivotal trial.

Subject to federal statutes and NIH guidelines including those governing the establishment of CRADAs (15 U.S.C. 3710a) and the licensing of federally owned inventions (35 U.S.C. 207), it is anticipated that the Collaborator will pursue an exclusive or nonexclusive commercialization license to the CD22-CAR. Additionally, NCI is able to offer a CRADA Collaborator the right to use any and all data developed during the course of the collaboration for commercial development of the agent, as well as access to existing CD22-CAR clinical study data and regulatory documents for commercial development of the agent.

Interested parties may sign a confidential disclosure agreement to obtain additional clinical data for its evaluation of the collaboration.

Roles of Collaboration Partners:

The roles of the National Cancer Institute in the CRADA may include but are not limited to the following:

1. NCI will provide intellectual, scientific, and technical expertise and experience related to the ongoing development of CD22-CAR.
2. NCI will continue to support clinical manufacture and development of CD22-CAR pending transition of manufacturing to an appropriate site by the commercial partner and will make data available to the Collaborator as appropriate.
3. NCI will collaborate in the design of protocols and the evaluation of results.
4. NCI will provide all clinical data in its possession to Collaborator to support FDA regulatory filings.

The roles of the CRADA Collaborator will include, but are not limited to the following:

1. The Collaborator will provide clinical development strategy and financial and other support for the collaborative development leading to BLA filing and FDA approval of CD22-CAR.

2. The Collaborator will provide intellectual, scientific, and technical expertise or experience to the development of CD22-CAR.
3. The Collaborator will provide sufficient clinical supply of autologously-derived CD22 CAR T-cell therapy product for all clinical trials under the CRADA; this includes additional trials that may be needed for licensing as well as trials required to meet clinical need for pediatric patients prior to licensing.
4. The Collaborator will prepare and submit regulatory documents to FDA, culminating in the submission of a BLA for CD22-CAR.
5. The Collaborator will demonstrate its capability of providing a commercial supply of CD22-CAR in a timely manner.

**Selection Criteria:**

Interested parties should notify the NCI of their interest in filing a formal proposal no later than September 1, 2020. Potential licensees/CRADA Collaborators will have until October 15, 2020 to submit a formal proposal. Additional proposals will be considered after the posted deadline in the event that a Collaborator, meeting the necessary criteria, is not found during the initial posted time period. Selection criteria for choosing the CRADA Collaborator shall include, but not be limited to:

1. Possession of or access to the resources needed to support and perform the activities required to expeditiously commercially develop CD22-CAR (e.g. facilities, personnel and expertise), including preparation and submission of regulatory documents;
2. Demonstrated ability to access the expertise required for successful commercial development of biologically active anti-cancer agents, with an emphasis on adoptive cell therapies;
3. Demonstration of the necessary resources to produce and supply autologously-derived CD22-CAR in a timely manner for clinical trials at the NCI and additional clinical sites;

4. Demonstration of access to financial resources required to support the CRADA collaboration and to successfully support the development of CD22-CAR for commercial sale;
5. Willingness to cooperate with the NCI in the timely publication of research results;
6. Willingness to accept the legal provisions and language of the CRADA and commercial license with only minor modifications, if any;
7. Willingness to pursue a commercial license to the CD22-CAR in accordance with federal statutes; and
8. The agreement to be bound by the appropriate HHS regulations relating to human subjects.

**Proposal content:**

Please submit a proposal outlining your qualifications as a licensee/CRADA Collaborator for the advertised opportunity. Include any relevant information, however, please address the following in your proposal submission:

1. Describe the type and level of resources you have available to commit to a CRADA collaboration with the NCI, including, but not limited to the following:

a. What is your current capacity for production of CD22-CAR lentiviral vector and autologous T-cell product?
b. Are you able to fund several potential clinical trials?
c. Would you be willing to provide funding to the NCI to support the collaboration?

Please describe the company's related experience in the development of therapeutics, specifically:

a. Describe any experience or expertise with the development of adoptive cell therapy-based therapeutics, preferably autologous T-cell therapeutics.
b. Describe related experience with FDA approval and commercialization of adoptive cell therapy-based therapeutics, preferably autologous T-cell therapeutics.

c. Describe any experience determining administration of autologously-derived T-cell therapeutics.

d. Describe any other collaborations with Federal or academic laboratories.

Please provide relevant company information, including:

a. Related Product Portfolio

b. Current Related Product Pipeline

c. Annual Revenues/financial resources

d. Size of company/affiliated companies

Dated: July 23, 2020.

**Richard U. Rodriguez,**

*Associate Director,*

*Technology Transfer Center,*

*National Cancer Institute.*

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