Note: NIH provides this sample for educational purposes to demonstrate how access plans could be prepared in different contexts and conform to the requirements of the IRP Access Planning Policy. This sample is not intended to be used as a template, and its use does not guarantee approval by NIH.

The technology described in this plan is hypothetical and does not intentionally reflect any current or former NIH license. The sample stands alone, outside the context of a full license or application, but applicants may cross-reference information from other parts of their application in their access plan. This sample reflects an access plan prepared before FDA approval of the licensed product (or a foreign equivalent). NIH would maintain the confidentiality of such an access plan, along with other license information and reports, as permitted by applicable law.

This sample access plan is written from the perspective of an established company that has other product(s) on the market. It is merely one example, and a commercially reasonable plan from an early-stage startup, for example, might look different.

Sample Access Plan from established company – Adoptive Cell Therapy (ACT)

Basic information:
Type of license: exclusive
Licensed product contemplated: treatment for leukemias and lymphomas
Type of product: therapeutic

I. Product description

Autologous T cell therapy products engineered from T cell receptors targeting CD22 for the treatment of leukemias and lymphomas. NIH clinical trials have demonstrated safety, tolerability, and preliminary clinical activity in certain blood cancers.

II. Anticipated patient population

We aim to develop a therapeutic for adults and children with late-stage leukemia or non-Hodgkin lymphoma who have not responded to first-line treatments. As of 2022, there were over 500,000 people in the U.S. living with or in remission from leukemia, and over 835,000 people in the U.S. living with or in remission from non-Hodgkin lymphoma.[1] In 2025, it is estimated there will be over 66,000 new cases of leukemia and over 80,000 new cases of non-Hodgkin Lymphoma.[2]

The Midwest and the South have higher mortality rates from leukemias and lymphomas relative to other parts of the country.[3] Patients in these regions may face barriers to accessing health care

[1] https://seer.cancer.gov/statistics-network/explorer/application.html?site=90&data_type=5&graph_type=11&compareBy=sex&chk_sex_1=1&chk_sex_3=3&chk_sex_2=2&series=9&age_range=1&advopt_precision=1&hdn_view=1#resultsRegion1.
[2] https://seer.cancer.gov/statfacts/html/nhl.html.
[3] United States Cancer Statistics - Mortality: 1999 - 2023, WONDER Online Database. United States Department of Health and Human Services, Centers for Disease Control and Prevention; 2025. Accessed at

facilities that can administer specialized adoptive cell therapies.[4] As described below, our investments in a new manufacturing facility will be designed to increase availability and access to these therapies for patients living in more regions of the country.

III. Other products, tools, facilities, or unique resources necessary for use

Adoptive cell therapies (ACTs) require complex administration, including specialized providers and equipment, and intensive clinical procedures and follow-up care. Patients often need to secure transportation, lodging, and caregiving accommodations to receive ACTs. Varying insurance coverage may also limit patient access.

Additionally, manufacturing this type of therapy requires state-of-the-art facilities, specialized staff, and time-sensitive processes for production, storage, and distribution of individualized therapies. Manufacturing also depends on reagent availability and skilled workforce. Cold chain is required for distribution.

We recognize that supply-chain disruptions and manufacturing delays can have life-threatening consequences for patients. Additionally, prolonged vein-to-vein time (the time from T cell collection to therapy administration) due to manufacturing delays often necessitates bridging therapy, which can complicate care and increase patient burden.

IV. Strategies to promote patient access

Manufacturing Investments

Timely and high-quality manufacturing will be crucial to patients' ability to benefit from this therapy. Thus, we plan to make significant investments to expand our manufacturing capacity within the next 5 years, if we are granted this license. We would initially manufacture this product in our existing facility outside San Diego, California. And we are in the early stages of exploring a new 4,500 sq. ft. manufacturing facility in Indiana, which would encompass product development, clinical trial production, and commercial product manufacturing. This would expand patient access by increasing the number of available commercial production slots and bolstering sustainability of our development pipeline. We estimate this would allow us to more than double our production capacity within the next 10 years.

Additionally, we will invest a portion of our R&D budget to optimization studies for our manufacturing systems, including automation solutions, quality assurance testing and product control, and predictive systems to identify and rectify supply chain bottlenecks. These investments will allow us to scale more easily to meet rising demand. By selecting a Midwestern site for our new facility, we will also aim to reduce costs and increase availability in regions with comparatively limited access to these types of therapies.

---

http://wonder.cdc.gov/cancermort-v2022_SR.html on Sep 16, 2025 (query lymphomas and leukemias by region); *see also, e.g.*, https://www.cdc.gov/nchs/state-stats/deaths/cancer.html.

[4] *See, e.g.*, https://ashpublications.org/bloodadvances/article/doi/10.1182/bloodadvances.2024015634/537314/Inequalities-in-CAR-T-Cell-Therapy-Access-for-US

Patient Assistance Program

To address affordability challenges, we will register any resulting approved therapies in our patient assistance program. Through this program, patients who demonstrate unmet financial need can receive assistance with transportation, lodging, meals, caregiving, and other out-of-pocket expenses associated with treatment. The program also includes co-pay support for eligible patients to help cover out-of-pocket treatment costs not covered by insurance. Upon request, we will provide NIH with more information about how many patients are engaged in the program.

--

Our significant investments in and commitment to expanding and improving upon our manufacturing practices, in addition to our robust patient assistance program, promise to increase the availability, sustainability, and cost-effectiveness of our product, while retaining uniform quality and acceptability to patients.