DECLARATION OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.

4. The archived data made viewable and browseable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.

5. The Internet Archive assigns a URL on its site to the archived files in the format http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL] aka an "extended URL". Thus, the extended URL http://web.archive.org/web/19970126045828/http://www.archive.org/ would be the URL for the record of the Internet Archive home page HTML file (http://www.archive.org/) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.

6. Attached hereto as Exhibit A are true and accurate copies of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.

7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: April 1, 2022

Nathaniel E Frank-White

Nathaniel E Frank-White

EXHIBIT A

https://web.archive.org/web/20110924175244/http://www.nejm.org/doi/full/10.1056/NEJMoa1103849

The NEW ENGLAND JOURNAL of MEDICINE

Free Preview PRINT E-MAIL DOWNLOAD CITATION

ORIGINAL ARTICLE

Chimeric Antigen Receptor–Modified T Cells in Chronic Lymphoid Leukemia

David L. Porter, M.D., Bruce L. Levine, Ph.D., Michael Kalos, Ph.D., Adam Bagg, M.D., and Carl H. June, M.D.

N Engl J Med 2011; 365:725-733 | August 25, 2011

We designed a lentiviral vector expressing a chimeric antigen receptor with specificity for the B-cell antigen CD19, coupled with CD137 (a costimulatory receptor in T cells [4-1BB]) and CD3-zeta (a signal-transduction component of the T-cell antigen receptor) signaling domains. A low dose (approximately 1.5×10^5 cells per kilogram of body weight) of autologous chimeric antigen receptor–modified T cells reinfused into a patient with refractory chronic lymphocytic leukemia (CLL) expanded to a level that was more than 1000 times as high as the initial engraftment level in vivo, with delayed development of the tumor lysis syndrome and with complete remission. Apart from the tumor lysis syndrome, the only other grade 3/4 toxic effect related to chimeric antigen receptor T cells was lymphopenia. Engineered cells persisted at high levels for 6 months in the blood and bone marrow and continued to express the chimeric antigen receptor. A specific immune response was detected in the bone marrow, accompanied by loss of normal B cells and leukemia cells that express CD19. Remission was ongoing 10 months after treatment. Hypogammaglobulinemia was an expected chronic toxic effect.

Supported in part by grants from the National Institutes of Health (K24 CA11787901, 1PN2-EY016586, and R01CA120409), the Alliance for Cancer Gene Therapy, and the Leukemia and Lymphoma Society (7000-02).

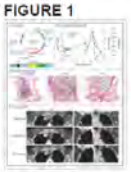
Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

This article (10.1056/NEJMoa1103849) was published on August 10, 2011, at NEJM.org.

We thank Irina Kulikovskaya for the quantitative polymerase-chain-reaction (Q-PCR) assay; Erica Suppa and Casey Krebs for the Luminex assay; Jennifer Wright for Q-PCR assay development; John Scholler for assay development; Tatiana Mikheeva for sample processing; Qun-Bin Xiong for flow-cytometric analysis; Zhaohui Zheng, Julio Cotte, Andrea Brennan, and members of the Clinical Cell and Vaccine Production facility for developing methods for clinical-scale ex vivo lentiviral transduction and for cell manufacturing; the Human Immunology Core for reagents; Boro Dropulic (Lentigen) for clinical-grade vector production; Elizabeth Veloso, Lester Lledo, Joan Gilmore, Gwendolyn Binder, and Anne Chew for assistance in clinical research support; Sharyn Katz for assistance with imaging; and

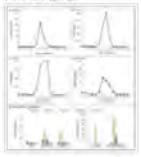
MEDIA IN THIS ARTICLE

FIGURE 1



Clinical Response in the Patient.

FIGURE 2



Serum and Bone Marrow Cytokines before and after Chimeric Antigen Receptor T-Cell Infusion.

ARTICLE ACTIVITY

2 articles have cited this article

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.