DECLARATION OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive. 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 The visitor may select one of those dates, and begin browsing an archived version of the Web.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 For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file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 browser 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 under the laws of the United States of America that the foregoing is true and correct.

DATE: February 15, 2024

Nathaniel E Frank-White

Nathaniel E Frank-White

EXHIBIT A

https://web.archive.org/web/20100609131649/https:/www.clinicaltrials.gov/ct2/show/NCT00473330

A Study of Ranibizumab Injection in Subjects With Clinically Significant Macular Edema With Center Involvement Secondary to Diabetes Mellitus (RISE)

This study is ongoing, but not recruiting participants.

First Received: May 13, 2007 Last Updated: November 2, 2009 History of Changes

Sponsor:	Genentech
Information provided by:	Genentech
ClinicalTrials.gov Identifier:	NCT00473330

Purpose

This study is a Phase III, double-masked, multicenter, randomized, sham injection-controlled study of the efficacy and safety of ranibizumab injection in patients with CSME-CI secondary to diabetes mellitus (Type 1 or 2).

Condition	Intervention	Phase
Diabetes Mellitus Macular Edema	Drug: ranibizumab Drug: sham	Phase III

Study Type: Interventional
Study Design: Allocation: Randomized
Control: Placebo Control
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase III, Double-Masked, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection in Subjects With Clinically Significant Macular Edema With Center Involvement Secondary to Diabetes Mellitus

Resource links provided by NLM:

Genetics Home Reference related topics: X-linked juvenile retinoschisis

MedlinePlus related topics: Diabetes Edema

Drug Information available for: Ranibizumab

U.S. FDA Resources

Further study details as provided by Genentech:

Primary Outcome Measures:

- The primary efficacy outcome measure is the proportion of subjects who gain at least 15 letters in BCVA compared with baseline [Time Frame: 24 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- Mean change from baseline in BCVA score over time [Time Frame: 24 months] [Designated as safety issue: No]
- Mean change from baseline in central foveal thickness (CFT) over time, as assessed on OCT by the central reading center [Time Frame: 24 months] [Designated as safety issue: No]
- Proportion of subjects with resolution of leakage at 24 months, as assessed by the central reading center using fluorescein angiography (FA) [Time Frame: 24 months] [Designated as safety issue: No]
- Mean number of macular laser treatments during 24 months [Time Frame: 24 months] [Designated as safety issue: No]
- Mean change from baseline in the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25) near activities subscale score at 24 months [Time Frame: 24 months] [Designated as safety issue: No]
- Mean change from baseline in the NEI VFQ-25 distance activities subscale score at 24 months [Time Frame: 24 months] [Designated as safety issue: No]
- Proportion of subjects with a three-step change from baseline in the Early Treatment Diabetic Retinopathy Study (ETDRS) scale at 24 months, as assessed by the central reading center using fundus photography [Time Frame: 24 months] [Designated as safety issue: No]
- Mean change from baseline in contrast sensitivity at 24 months, measured by the number of letters read correctly on the Pelli-Robson chart [Time Frame: 24 months] [Designated as safety issue: No]
- Proportion of subjects who gain at least 15 letters in BCVA score compared with baseline at 36 months [Time Frame: 36 months] [Designated as safety issue: No]
- Mean change from baseline in BCVA score over time up to 36 months [Time Frame: 36 months] [Designated as safety issue: No]
- Mean change from baseline in central foveal thickness (CFT) over time up to 36 months, as assessed on OCT by the central reading center [Time Frame: 36 months] [Designated as safety issue: No]
- Mean number of macular laser treatments during 36 months [Time Frame: 36 months] [Designated as safety issue: No]
- Proportion of subjects with a three-step or greater progression from baseline in the ETDRS diabetic retinopathy severity level at 36 months, as assessed by the central reading center using FP [Time Frame: 36 months] [Designated as safety issue: No]
- Mean change from baseline in contrast sensitivity at 36 months, as measured by the number of letters read correctly on the Pelli-Robson chart [Time Frame: 36 months] [Designated as safety issue: No]

Estimated Enrollment: 366
Study Start Date: July 2007

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