AFFIDAVIT 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 The visitor may select one of those dates, and begin browsing an archived version of the Web.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 For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file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 browsable 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.

Samsung Bioepis Exhibit 1057 Page 1
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INTERNET ARCHIVE
archive.org

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

DATE: 01/09/2023

Nathaniel Frank-White

Nathaniel E Frank-White

Please see attached
All Purpose
Jurat form
for additional
Notary Events

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EXHIBIT A

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https://web.archive.org/web/20081107014243/https:/clinicaltrials.gov/ct2/show/NCT00685854

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Ranibizumab Injections to Treat Macular Telangiectasia Without New Blood Vessel Growth

This study is currently recruiting participants.
Verified by National Institutes of Health Clinical Center (CC), April 2008

Sponsored by:	National Eye Institute (NEI)
Information provided by:	National Institutes of Health Clinical Center (CC)
ClinicalTrials.gov Identifier:	NCT00685854

Purpose

his study will examine whether the drug ranibizumab (Lucentis) can help prevent vision loss in people with macular telangiectasia, a condition in which new blood vessels grow in the retina at the back of the eye and can leak. Such changes in blood vessels are seen in other diseases associated with changes in a body chemical called vascular endothelial growth factor (VEGF). Ranibizumab is an anti-VEGF drug that is effective in treating another eye disease, age-related macular degeneration, with similar changes in eye blood vessels.

People 18 years of age and older with macular telangiectasia in both eyes with no new blood vessel growth in either eye may be eligible for this study. They must have vision better than 20/400 in the study eye.

Participants undergo the following procedures:

- Ranibizumab injections in the study eye at least four times over 12 weeks. Depending on the response to treatment and the side effects, additional injections may be given every 4 weeks for up to 1 year. The eye is numbed before the injection and the eye area is cleaned with an antiseptic. Antibiotic drops are used for 3 days following the injection to prevent infection.
- Evaluations before starting treatment, at the time of each injection, and 8 weeks after the last treatment:
  - History and physical examination.
  - Eye examination with dilation, microperimetry and photography: The eye examination measures visual acuity, eye pressure and eye movements. For the microperimetry test, subjects sit in front of a computer screen and press a button when they see a light on the screen. Measurements and photographs of the retina are also taken.
  - Fluorescein and indocyanine green angiography to examine the blood vessels in the eye: A dye called fluorescein or indocyanine green is injected into a vein in the arm. The dye travels through the veins to the blood vessels in the eyes. A camera takes pictures of the dye as it flows through the blood vessels.
  - Pregnancy test: Women who are able to become pregnant have a urine pregnancy test before each ranibizumab injection.

Condition	Intervention	Phase
Macular Telangiectasia	Drug: Ranibizumab	Phase I

Drug Information available for: Ranibizumab

U.S. FDA Resources

Study Type: Interventional
Study Design: Treatment, Non-Randomized, Open Label, Uncontrolled, Single Group Assignment, Safety/Efficacy Study

Official Title: Pilot Study of Intravitreal Injection of Ranibizumab for Macular Telangiectasia Without Neovascularization (MACTEL 2)

Further study details as provided by National Institutes of Health Clinical Center (CC):

Primary Outcome Measures:

- Effect of intravitreal ranibizumab treatment on visual acuity

Secondary Outcome Measures:

- ETDRS BCVA, area of retinal leakage, retinal thickness, area of hypofluoresence, central retinal sensitivity

Estimated Enrollment: 8
Study Start Date: May 2008

Intervention Details:

Drug: Ranibizumab
N/A

Detailed Description:

Retinal telangiectasis is a group of rare, idiopathic retinal vascular anomalies affecting the retinal capillaries in which irregular capillary dilation and incompetence occur in the macula. This is the group 2 in the Gass classification of idiopathic juxtafoveal telangiectasia in which fluorescein angiography showed leakage with capillary dilation. These patients typically are diagnosed in their fifth or sixth decade of life. Both sexes may be affected. Minimal exudation, superficial retinal crystalline deposits, and right-angle venules characterize this disorder. The pathogenesis of the disease is unknown. Because of the leakage of the retinal vessels and also the finding of neovascularization, it is possible that vascular endothelial growth factor (VEGF) may be implicated in this disease.

The purpose of this study is to evaluate the possible role of ranibizumab for the treatment of eight participants with macular telangiectasia with hyperfluorescence on fluorescein angiography, with vision better than 20/400, without neovascularization. The primary outcome of this study will be the proportion of participants that lose 15 letters or more in ETDRS BCVA at 12 months compared with baseline. The secondary outcomes measured at one year will include the proportion of participants who lose 10 letters or more, the mean change in ETDRS BCVA, the change in central retinal thickness, the extent of fluorescein leakage, the change in fundus autofluorescence, change in size of neovascular membrane and the change in central retinal sensitivity. This is a pilot study designed to evaluate the feasibility and potential efficacy of treating patients with macular telangiectasia in a larger, phase III study within the organization of the MAC TEL Research Group, sponsored by the Lowy Foundation. Currently, the research group is enrolling 200 patients affected with this condition for a natural history study in 22 international clinical centers.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

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Criteria

- INCLUSION CRITERIA:
- Participant must understand and sign the informed consent.
- Participant must be at least 18 years of age.
- Participant must have macular telangiectasia in both eyes.
- Participant must have vision loss of better than 20/400 in the study eye.
- Participant must have clear ocular media and adequate pupillary dilation to permit good quality stereoscopic fundus photography.
- All women of childbearing potential must have a negative urine pregnancy test at baseline, and be willing to undergo testing immediately prior to each injection and monthly for at least two months following the last dose of ranibizumab.

EXCLUSION CRITERIA:

- Safety and toxicity of ranibizumab have not yet been investigated in children. Further, it is unlikely that younger participants will be able to comply with all examinations and intravitreal injections. Therefore, participants below the age of 18 will be excluded from participation in the study. This ocular condition is not commonly found in participants below the age of 18.
- Participant has neovascularization in either eye.
- History (within past five years) or evidence of severe cardiac disease (apparent in electrocardiogram abnormalities, clinical history of unstable angina, acute coronary syndrome, myocardial infarction, revascularization procedure within six months prior to baseline, atrial or ventricular tachyarrythmias requiring ongoing treatment).
- History of stroke within 12 months of study entry.
- History within the past 30 days of a chronic ocular or periocular infection (including any history of ocular herpes zoster).
- Current acute ocular or periocular infection.
- Any major surgical procedure within one month of study entry.
- Known serious allergies to fluorescein dye.
- Previous participation in a clinical trial (for either eye) involving anti-angiogenic drugs (pegaptanib, ranibizumab, bevacizumab, anecortave acetate, Protein Kinase C inhibitors, etc.).
- Previous intravitreal drug delivery (e.g., intravitreal corticosteroid injection or device implantation) in the study eye.
- History of vitrectomy surgery in the study eye.
- History of glaucoma filtering surgery in the study eye.
- History of corneal transplant in the study eye.
- Pregnancy (positive pregnancy test) or lactation and premenopausal women not using adequate contraception. The following are considered effective means of contraception: surgical sterilization or use of oral contraceptives, barrier contraception with either a condom or diaphragm in conjunction with spermicidal gel, an IUD, or contraceptive hormone implant or patch.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00685854

Contacts

Contact: Patient Recruitment and Public Liaison Office (800) 411-1222 prpl@mail.cc.nih.gov

Contact: TTY 1-866-411-1010

Locations

United States, Maryland

National Institutes of Health Clinical Center, 9000 Rockville Pike **Recruiting**
Bethesda, Maryland, United States, 20892

Sponsors and Collaborators

National Eye Institute (NEI)

More Information

NIH Clinical Center Detailed Web Page

Publications:

Boulton M, Foreman D, Williams G, McLeod D. VEGF localisation in diabetic retinopathy. Br J Ophthalmol. 1998 May;82(5):561-8.

Aiello LP, Avery RL, Arrigg PG, Keyt BA, Jampel HD, Shah ST, Pasquale LR, Thieme H, Iwamoto MA, Park JE, et al. Vascular endothelial growth factor in ocular fluid of patients with diabetic retinopathy and other retinal disorders. N Engl J Med. 1994 Dec 1;331(22):1480-7.

Amin R, Puklin JE, Frank RN. Growth factor localization in choroidal neovascular membranes of age-related macular degeneration. Invest Ophthalmol Vis Sci. 1994 Jul;35(8):3178-88.

Study ID Numbers: 080147, 08-EI-0147
First Received: May 24, 2008
Last Updated: July 18, 2008
ClinicalTrials.gov Identifier: NCT00685854
Health Authority: United States: Federal Government

Keywords provided by National Institutes of Health Clinical Center (CC):
Macular Telangiectasia
Vascular Endothelial Growth Factor
Ranibizumab
Macular Telangiectasia

Study placed in the following topic categories:
Telangiectasis
Vascular Diseases
Neovascularization, Pathologic
Endothelial Growth Factors

Additional relevant MeSH terms:
Cardiovascular Diseases

ClinicalTrials.gov processed this record on November 05, 2008

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U.S. National Institutes of Health, U.S. Department of Health & Human Services,
USA.gov, Copyright, Privacy, Accessibility, Freedom of Information Act

JURAT ATTACHMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF Tennessee }

COUNTY OF Cheatham }

The foregoing instrument was subscribed and sworn before me this date of 01/09/2023, by Nathaniel Frank-White

This notarial act was an online notarization.

SAMANTHA B. DOMINGUEZ
STATE OF TENNESSEE
NOTARY PUBLIC
COUNTY OF CHEATHAM

ONLINE NOTARY PUBLIC
MY COMMISION EXPIRES: JULY 26 2025

(Notary Seal)

Notary's Signature

Registration No.: 0

Commission Expiration Date: July 26, 2025