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 The visitor may select one of those dates, and begin browsing an archived version of the Web.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 For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file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 B are true and accurate copies of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each file.

INTERNET ARCHIVE
archive.org

7. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE: 02/09/2024

Nathaniel Frank-White

Nathaniel E Frank-White

Please see attached
All Purpose
Jurat form
for additional
Notary Events

EXHIBIT B

https://web.archive.org/web/20060221025443/http:/www.regeneron.com/investor/Regn_BascomPalmer2006.pdf

VEGF Trap Clinical Trial Update

Angiogenesis 2006

Miami

February 3, 2006

ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 5

VEGF Trap

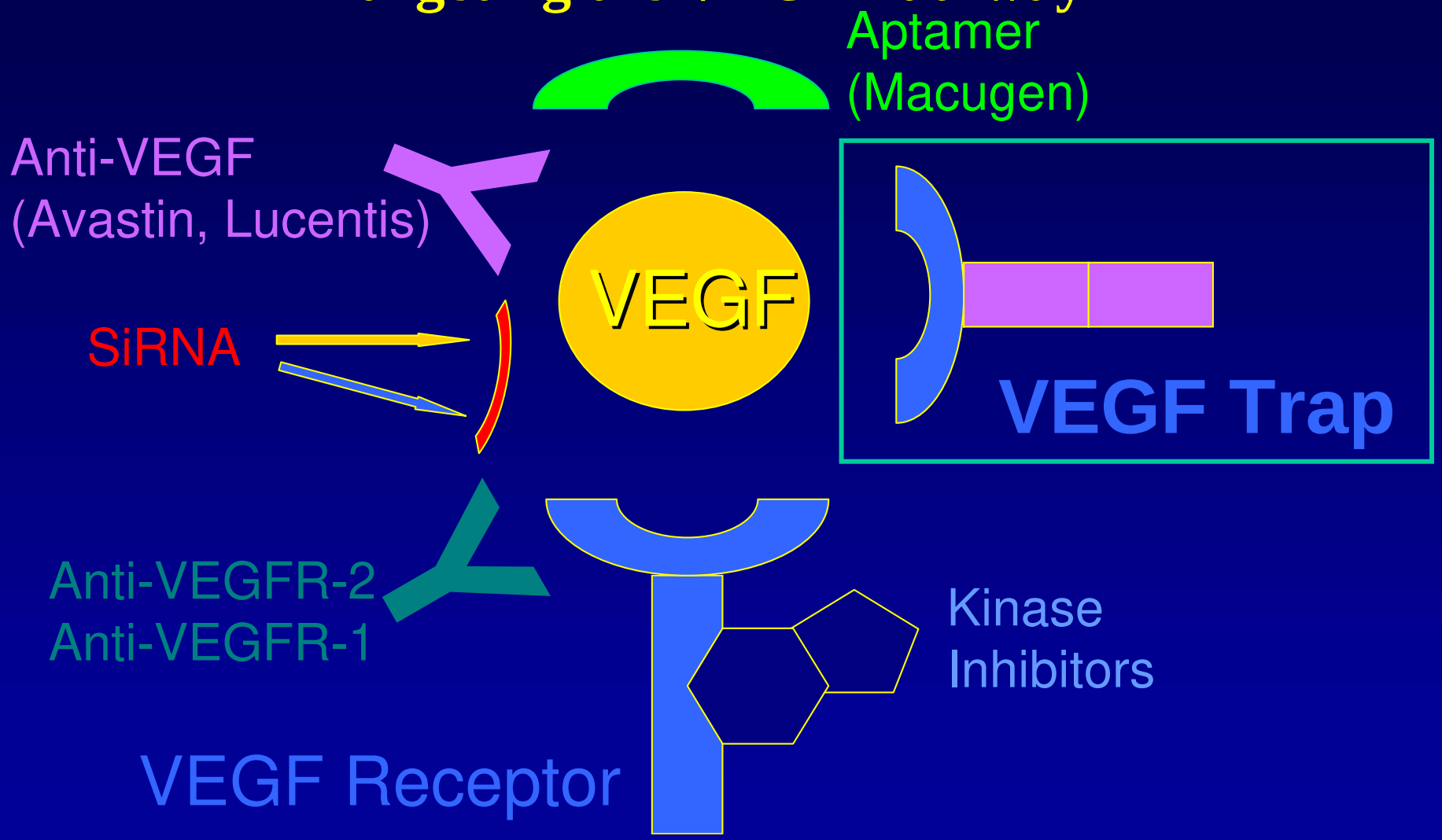
CLinical **E**valuation of **A**nti-angiogenesis in the **R**etina

CLEAR-AMD

CLEAR-DME

ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Targeting the VEGF Pathway



ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Rationale for the Use of VEGF Trap

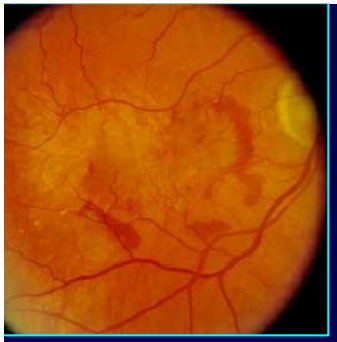
VEGF Blockade has been validated as an anti-angiogenesis approach

VEGF Trap

- Fusion of key domains of VEGF R1 and R2
- Binds PlGF, a potentially important VEGF family member
  All human sequence
- Smaller than an antibody
- 100-1,000 fold higher binding affinity than VEGF antibodies
- Efficacious in multiple preclinical cancer and eye models

ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 8

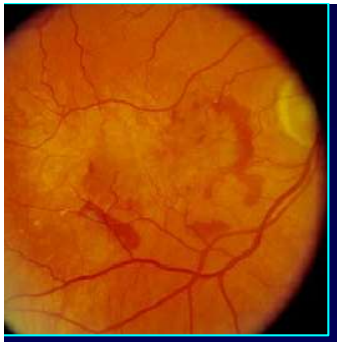


Systemic VEGF Trap: Phase 1

- Randomized, double-masked, placebo-controlled studies using **intravenous** VEGF Trap
- Neovascular AMD
- DME
- Dose ascending (0.3 to 3 mg/kg)
- Primary efficacy endpoint: Decrease in retinal thickness on OCT

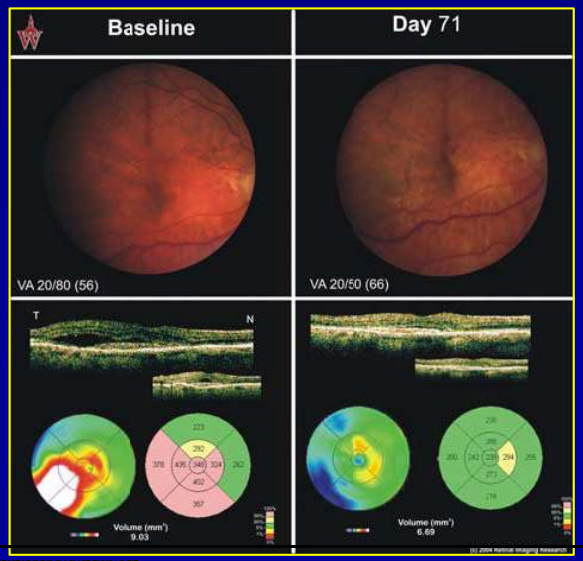
ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 9



Systemic VEGF Trap: Bioeffect

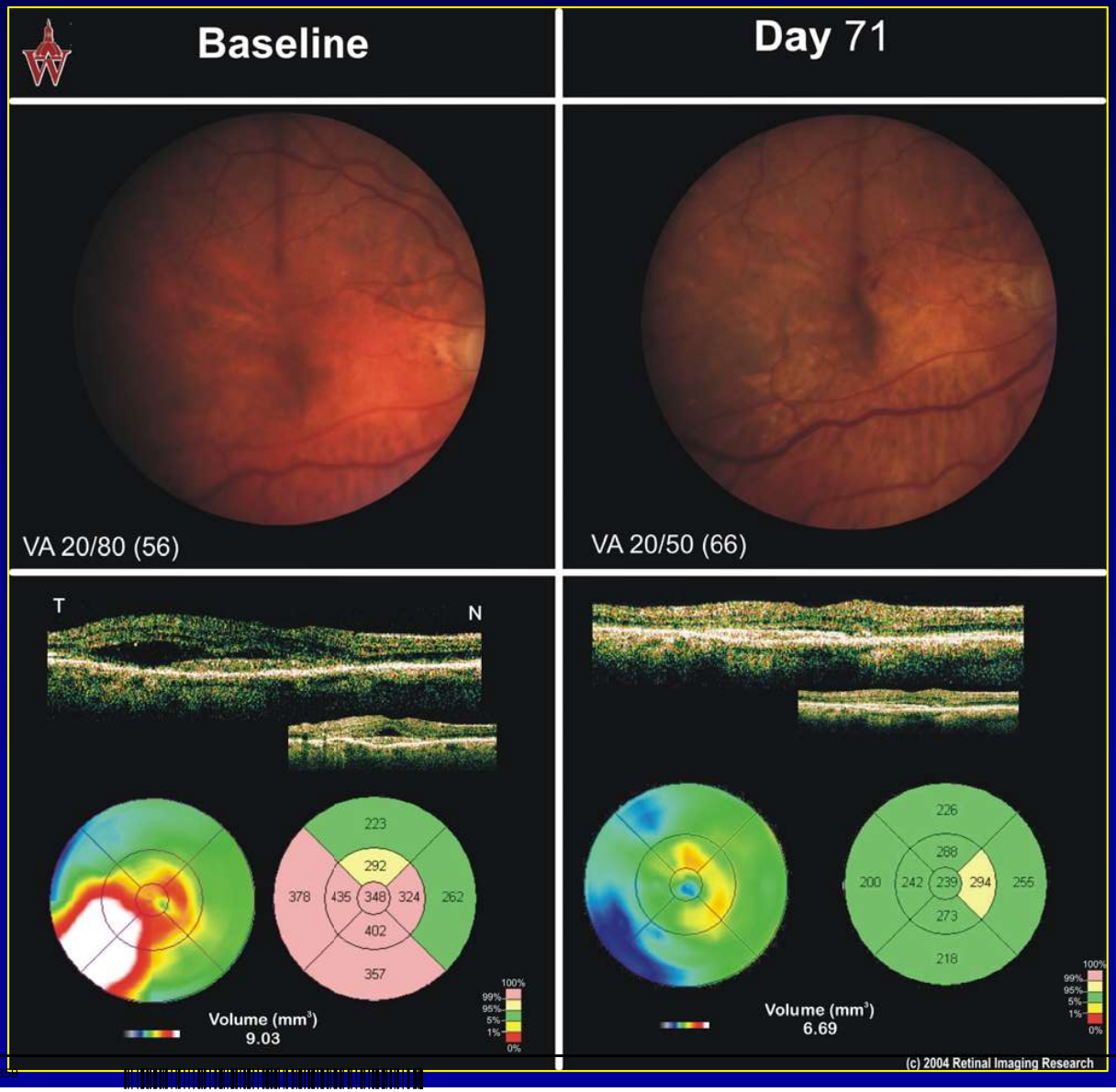
- **Dose-related decrease in retinal thickness on OCT in AMD study**
- **Modest effect seen in DME at the 0.3 mg/kg dose**
- **Both magnitude and duration of effect increased with dose**



ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 10

Systemic VEGF Trap for AMD 1 mg/kg



ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CE30
Notary.net

Systemic VEGF Trap: Safety

- Dose-related increase in blood pressure in the AMD trial
- Hypertension and proteinuria, which appear to be class effects of systemic anti-VEGF agents, were dose-limiting toxicities
- No significant drug-related ocular adverse events were reported

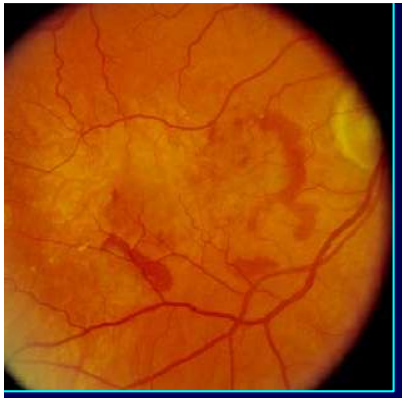
ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 12

Intravitreal VEGF Trap for AMD

- Single, ascending-dose study
- All lesion types <12 DA
- VA <20/40
- Intravitreal administration of doses from 0.05 to 4.0 mg
- Objectives:
  - Safety (maximum tolerated dose): Local, systemic
  - Bioeffect - effect on retinal thickness by OCT

ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

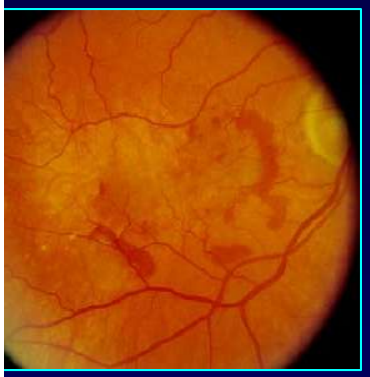


Intravitreal VEGF Trap for AMD: Safety

- 18 patients treated to date
- Maximum tolerated dose has not yet been reached (0.05 to 4.0 mg)
  - No ocular serious adverse events
  - No evidence of inflammation
- No systemic SAEs or changes in laboratory measures
- Study remains ongoing at 4 mg/eye dose level

ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 14



Intravitreal VEGF Trap for AMD: Bioeffect

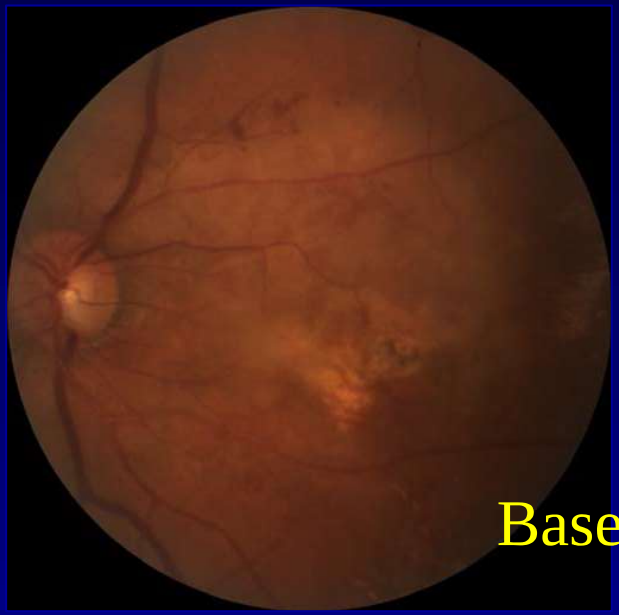
- Retinal thickness evaluated by OCT at central reading center
  - patients with at least 4 weeks of data
- Rapid, substantial decrease in retinal thickness
- Duration appears to be at least 4 weeks

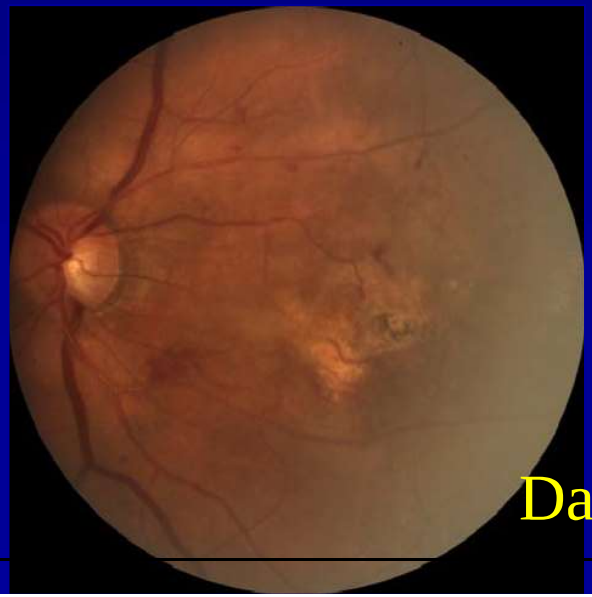
ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 15

Intravitreal VEGF Trap: 0.5 mg

- 76 yo WF
- Bilateral neovascular AMD
  - OD: PDT x 3
  - OS: PDT x 1
- VA
  - OD: 20/400
  - OS: 20/500

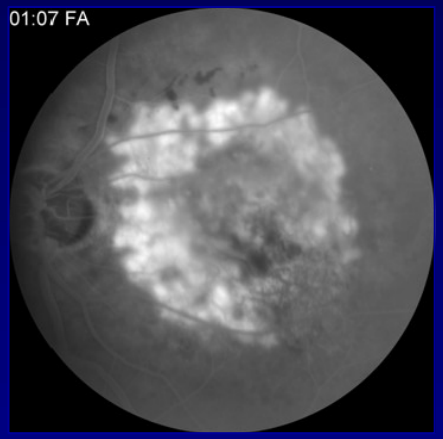


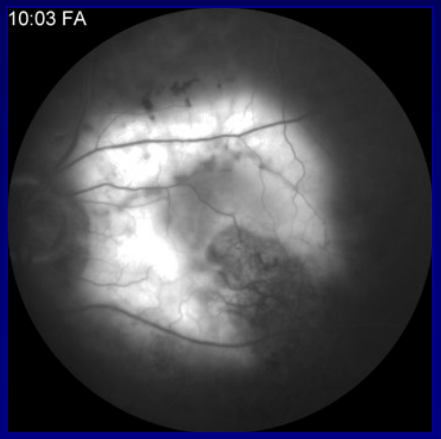


ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

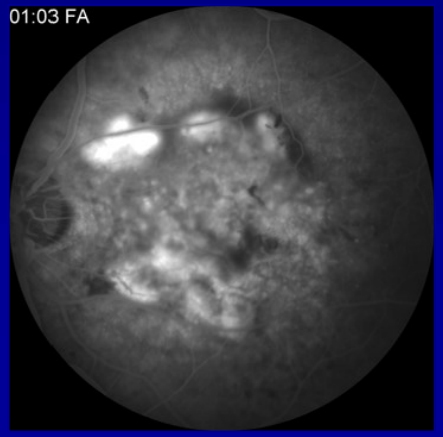
Intravitreal VEGF Trap 0.5 mg

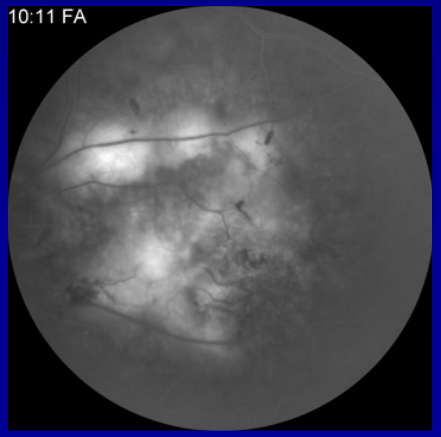
Baseline





Day 85

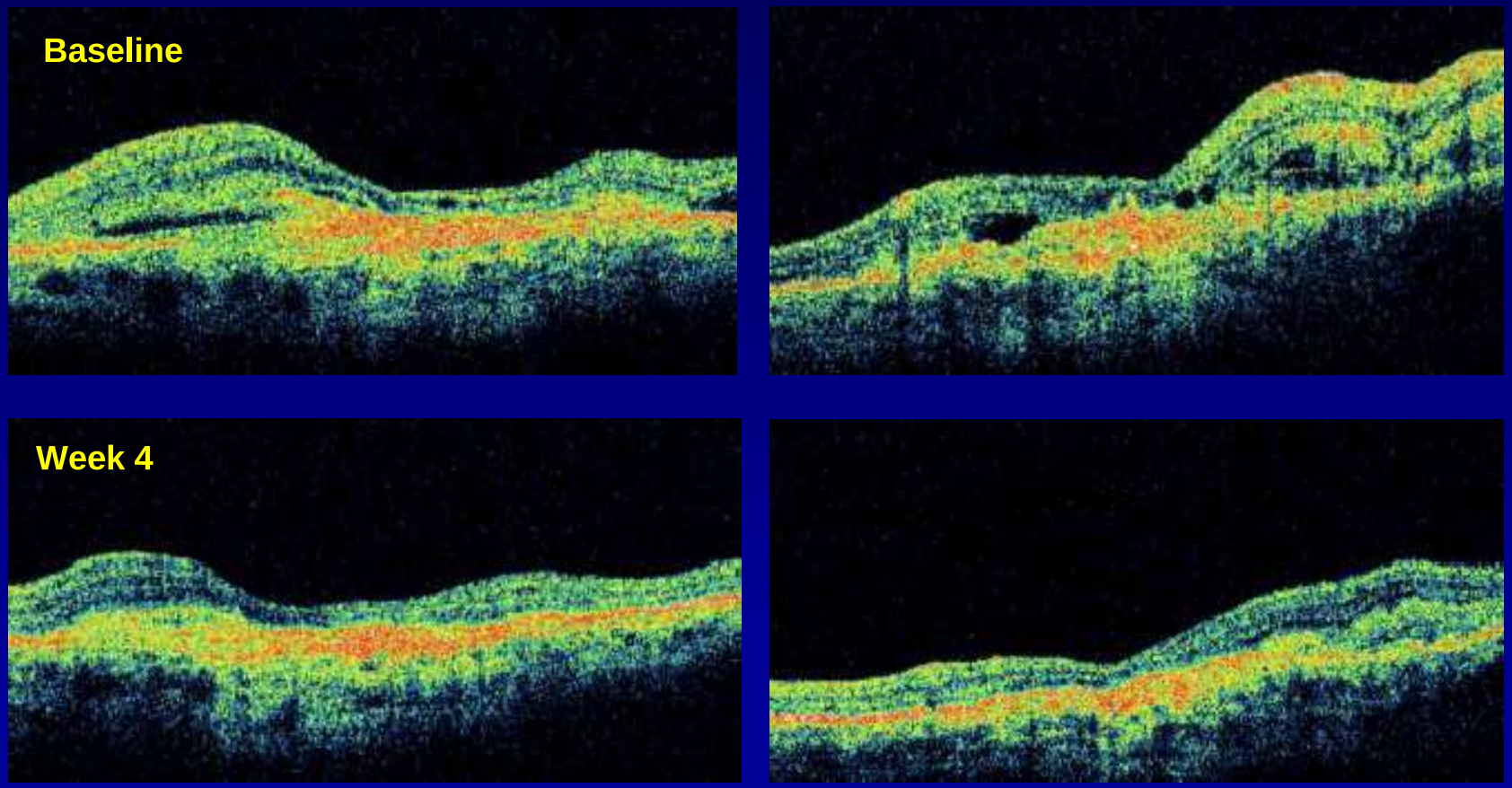




ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Intravitreal VEGF Trap
0.5 mg Single Dose

Horizontal **Vertical**

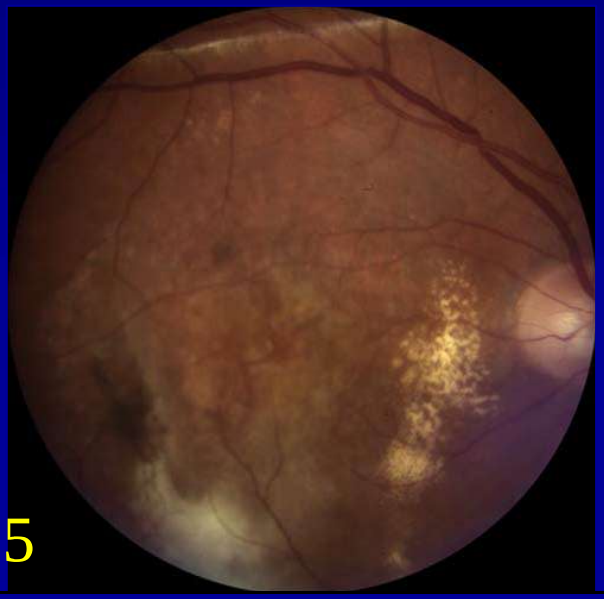


ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 18

Intravitreal VEGF Trap 1.0 mg

Baseline



Day 85

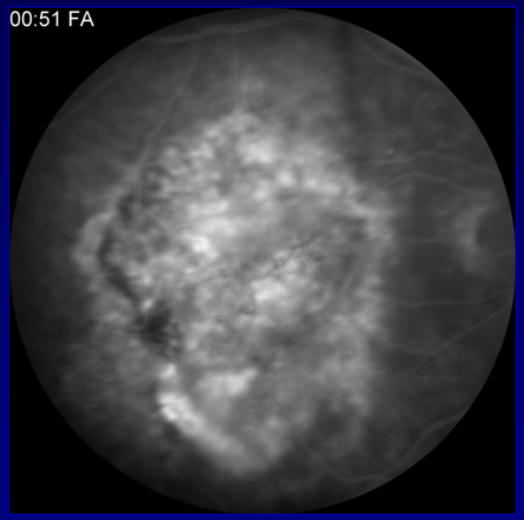
- 84 yo WF
- Bilateral neovascular AMD
  - OD: PDT x 3
  - OS: PDT x 3

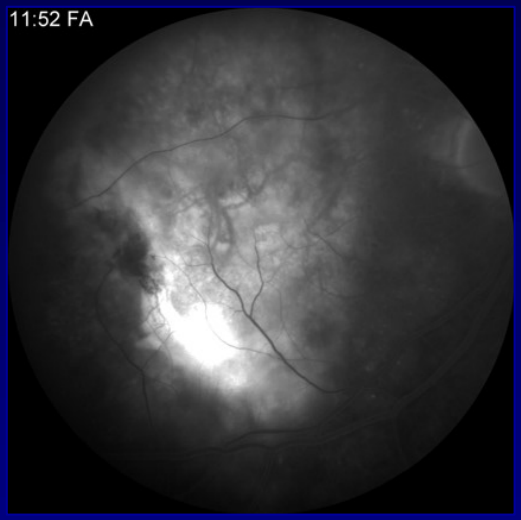
ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 19

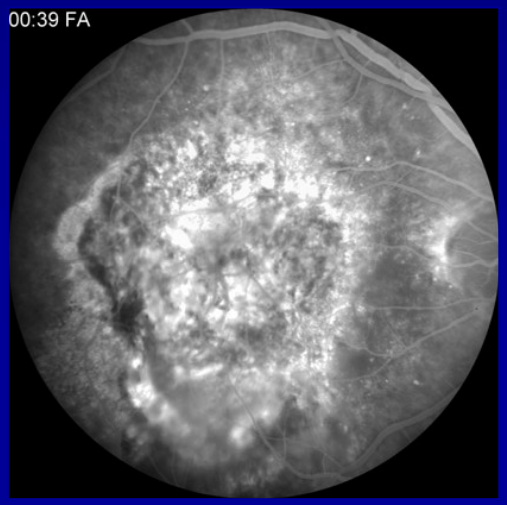
Intravitreal VEGF Trap 1.0 mg

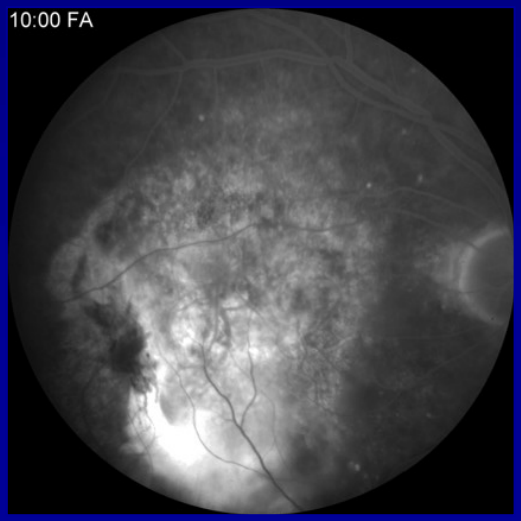
Baseline





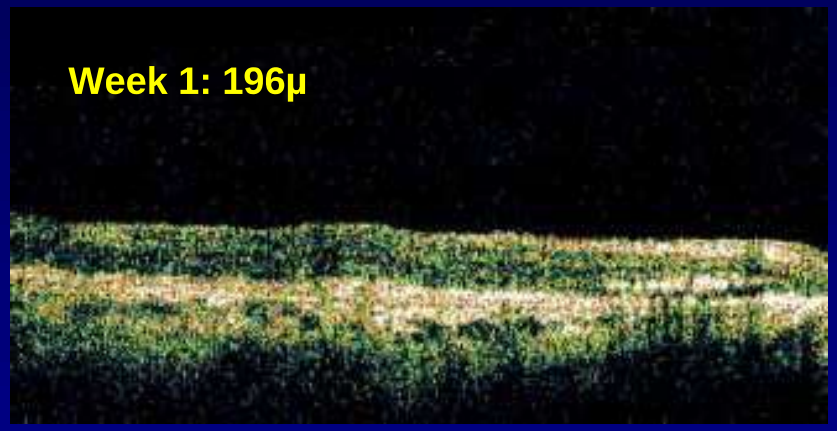
Day 85





ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Intravitreal VEGF Trap 1 mg Single Dose



ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 21

VEGF Trap Clinical Trials: Summary

- Systemic administration, while showing promise of efficacy, not pursued due to toxicity issues (BP, proteinuria)
- Intravitreal Phase 1 safety study:
  - Maximum tolerated dose not reached at doses up to 2 mg/eye
  - 4 mg dose underway
  - Rapid, substantial, and prolonged (up to at least 4 weeks) reduction in retinal thickness demonstrated by OCT
- Next: Additional studies to determine optimal dose and interval
- More complete results: ARVO 2006

ent Id: 11DDCD60-C7B3-11EE-8CBE-294E4867CB59
Notary.net

Samsung Bioepis Exhibit 1011
Page 22

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 Texas }

COUNTY OF Tarrant }

The foregoing instrument was subscribed and sworn before me this date of 02/09/2024, by Nathaniel Frank-White

This notarial act was an online notarization.

NOTARY PUBLIC STATE OF TEXAS
BRITTANY RENE COPELAND
ELECTRONIC NOTARY PUBLIC
STATE OF TEXAS
NOTARY ID: 133645929
COMISSION EXP: MARCH 15 2026

(Notary Seal)

Notary's Signature

Registration No.: 133645929

Commission Expiration Date: March 15, 2026