

VEGF Trap – Eye CLEAR-IT 2 Final Primary Endpoint Results

A Phase 2, Randomized, Controlled
Dose- and Interval-Ranging Study of
Intravitreal VEGF Trap-Eye in Patients
with Neovascular Age-Related Macular
Degeneration

Mylan v. Regeneron, IP
U.S. Pat. 9,669,069, E

Disclosures

- Commercial relationships
 - J. Heier, Regeneron financial support
- Trial registration
 - www.clinicaltrials.gov (NCT00320788)

Angiogenesis Inhibition via VEGF Blockade Unmet Medical Needs Remain Despite Advances in Treatment of Wet AMD

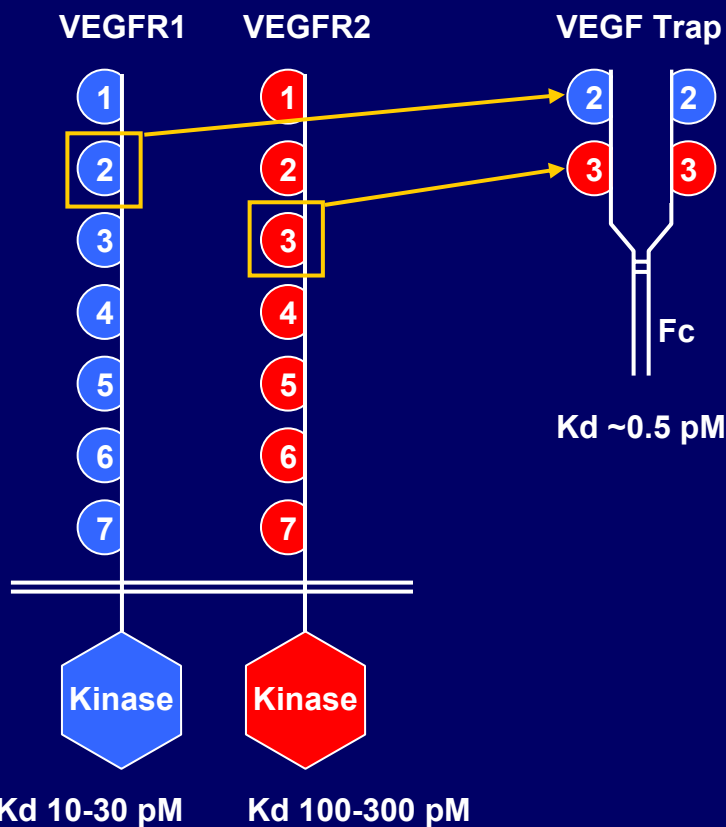
- Ranibizumab (LUCENTIS^{®*}) represents a major advance in AMD treatment
 - The approved regimen of ranibizumab in the U.S., 0.5 mg administered monthly, resulted in the following results at 1 year:¹
 - Prevention of moderate vision loss in 95-96% of patients
 - A ≥ 15 letter (3-line) gain in 34- 40% of patients
 - Mean improvement in visual acuity of 7.2-11.3 letters (~6-10 at month)
 - Vision of $\geq 20/40$ in 39-40% of patients
 - Vision of $\leq 20/200$ in only 12-16% of patients
- A clinical need remains for an agent that can further improve visual acuity
 - Further improvement in visual acuity
 - More patients with vision of $\geq 20/40$
 - Fewer patients with vision of $\leq 20/200$
- A clinical need remains for an agent that improves and maintains visual acuity with a dosing schedule requiring less than monthly injections

* LUCENTIS[®] is a registered trademark of GENENTECH, Inc

1 Rosenfeld, et al., *N Engl. J Med.*, 2006 355(14):1419-31; Brown, et al., *N Engl. J Med.*, 2006

VEGF Trap-Eye*: A Unique VEGF Blocker

Structure of the VEGF Trap



- **Fusion protein** of key human VEGF receptor and human IgG Fc
- **Contains all human** sequences
- **High affinity** and binds tightly than native receptor and monoclonal antibody
- **Blocks all VEGF-A** isoforms and Placental Growth Factor
- **Penetrates all layers** (MW ~110,000)

*VEGF Trap-Eye is specially purified and formulated for intravitreal injection.

IgG=immunoglobulin G; MW=molecular weight; VEGF=vascular endothelial growth factor; VEGFR=vascular endothelial growth factor receptor

CLEAR-IT 2 Study Objectives

- Primary objectives:
 - Assess the effect of intravitreal VEGF Trap-Eye on retinal thickness
 - Assess ocular and systemic safety and tolerability of repeated IVT doses of VEGF Trap-Eye in wet AMD
- Secondary objective:
 - Assess the effect of IVT VEGF Trap-Eye on best-corrected visual acuity in ETDRS letters

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