VEGF Trap-Eye in Wet AMD CLEAR-IT 2: Summary of One-Year Key Results

Presented at 2008 Retina Society Meeting Scottsdale, Arizona September 28, 2008

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

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CLEAR-IT 2: Rationale

- Anti-VEGF therapy has dramatically changed the treatment paradigm for wet AMD
 - Improvement in visual acuity is now an achievable goal of treatment
- A potential limitation of anti-VEGF therapy is the unpredictable durability of vision gain initially achieved with monthly dosing when the treatment interval is prolonged
- VEGF Trap-Eye is a novel anti-VEGF therapy with high binding affinity for VEGF-A and placental growth factor (PIGF)
- CLEAR-IT 2 was designed to assess:
 - Response at 12 weeks to a range of doses administered monthly and quarterly
 - Durability of response with PRN (as-needed) dosing out to 1 year

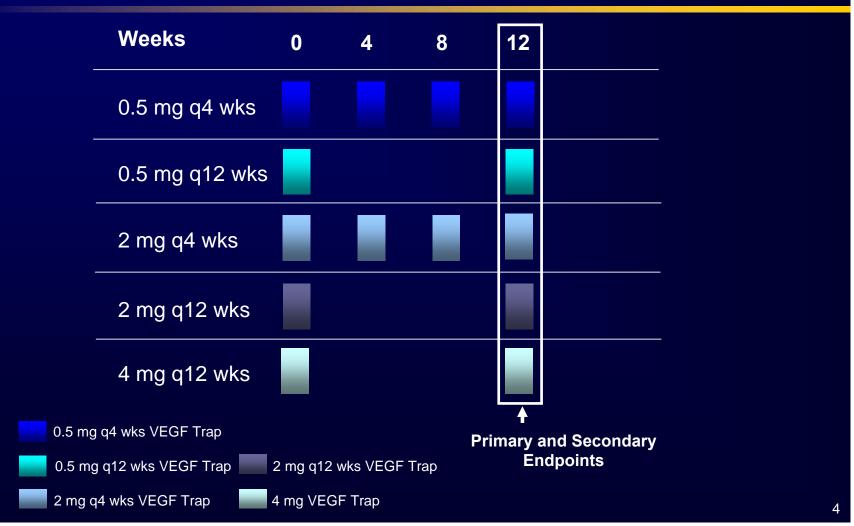
n=32

CLEAR-IT 2: Study Design Randomized, multicenter, double-masked trial N=159 **Subjects randomized** 1:1:1:1:1 4 mg q12 wks 0.5 mg q4 wks 2 mg q12 wks 2 mg q4 wks 0.5 mg q12 wks n=32 n=32 n=32 n=31

Primary endpoint: Secondary endpoint: Fixed dosing to week 12 (primary **Best-Corrected ETDRS Change in Central Retinal/Lesion** endpoint) Thickness (CR/LT) **Visual Acuity (BCVA)** PRN dosing to 1 year Patients were re-dosed at week 12; PRN dosing started at week 16

> Mylan Exhibit 1055 Mylan v. Regeneron, IPR2021-00881 Page 3

Study Schedule (fixed-dosing phase)



Study Schedule (fixed-dosing phase)



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