



## For the Treatment of Wet Age-Related Macular Degeneration

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**Note to Presenters: The text accompanying this set of slides is intended to be a guide. Unless otherwise highlighted in the notes section, presentations are not expected to be verbatim.**

Thank you for joining us for this review of EYLEA® (aflibercept) Injection for the treatment of neovascular or wet age-related macular degeneration.

This program is sponsored by Regeneron Pharmaceuticals.

As a reminder, no CME credits are offered for this program. (CLICK)

Mylan v. Regeneron  
IPR2021-00881  
U.S. Pat. 9,254,338  
Exhibit 2139



## Responding to Unsolicited Requests for Off-Label Information

- FDA Guidance – December 2011
  - “[A] firm that chooses to respond [to unsolicited requests for off-label information] should provide the final response containing the requested off-label information about its product only to the specific individual who requested the information as a private, one-on-one communication.”
- Regeneron intends to comply with this new guidance
- The following presentation will be consistent with the approved prescribing information for EYLEA® (aflibercept) Injection

Regeneron Medical Specialist to present, and then introduce presenting Physician.

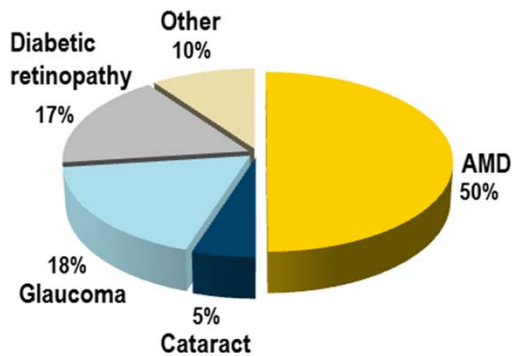
## Neovascular (Wet) Age-Related Macular Degeneration (AMD)

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Let's start by considering where we currently are with wet AMD and its management. (CLICK)

## Wet AMD: Leading Cause of Blindness in the U.S.

Causes of Blindness (U.S., 2002)<sup>1</sup>



### AMD: U.S. Prevalence<sup>3</sup>

- Approx. 200K new cases of wet AMD diagnosed in North America each year
- 1.75 million people with wet AMD
- 1.2 million with wet AMD in  $\geq 1$  eye
- ~3 million with wet AMD by 2020

Wet AMD responsible for 80-90% of legal blindness due to AMD<sup>2</sup>

<sup>1</sup>Resnikoff S et al. *Bull World Health Organ* 2004;82:844-51.

<sup>2</sup>Ferris FL et al. *Arch Ophthalmol* 1984;102:1640-42.

<sup>3</sup>Friedman JS et al. *Arch Ophthalmol* 2004;122:564-72.

This pie chart reminds us that AMD is the leading cause of blindness in the U.S, accounting for half of all cases,<sup>1</sup> with wet AMD accounting for 80-90% of legal blindness among individuals with AMD.<sup>2</sup>

An estimate based on the 2000 U.S. Census was that nearly 2 million people in the U.S. had AMD, of which more than 1 million had wet AMD involving at least one eye, while another 7 million people had early-stage AMD.<sup>3</sup> Projections for 2020 are that nearly 3 million people will suffer from AMD. (CLICK)

<sup>1</sup>Resnikoff S et al. *Bull World Health Organ* 2004;82:844-51.

<sup>2</sup>Ferris FL et al. *Arch Ophthalmol* 1984;102:1640-42.

<sup>3</sup>Friedman DS et al. *Arch Ophthalmol* 2004;122:564-72.

## AMD: A Bilateral Disease<sup>1</sup>

- Bilateral disease results in legal blindness, greater disability, and need for care
- 5-year rates of advanced AMD in fellow eye:

Risk factor	5-year risk <sup>1</sup>
unilateral advanced AMD	15%
unilateral advanced AMD + large drusen in fellow eye	35%
unilateral advanced AMD + large drusen + pigment abnormalities in fellow eye	53%

<sup>1</sup>Age-Related Eye Disease Study Research Group. *Arch Ophthalmol* 2005;123:1570-74.

(Optional Slide)

A survey by the National Eye Institute found that fear of blindness ranks second only to the fear of cancer among Americans.<sup>1</sup> Bilateral involvement is typical in AMD.<sup>2,3</sup> Vision loss due to neovascularization in one eye may be a harbinger of the future for the other eye – and the potential that patients with wet AMD will become legally blind and face even greater disability and increased need for care.

Based on the data from the Age-Related Eye Disease Study (AREDS),<sup>4</sup> 15% of patients with unilateral wet AMD will develop advanced AMD in the contralateral eye within 5 years. That risk increases to 53% when the contralateral eye exhibits large drusen and pigment abnormalities.

The propensity for wet AMD to be a bilateral disease means that we are going to be treating more patients with bilateral neovascularization as the population ages and the prevalence of wet AMD increases. For patients, bilateral wet AMD often means the loss of independence.<sup>5</sup> (CLICK)

<sup>1</sup>Progress in Eye and Vision Research: U.S. Department of Health and Human Services, National Eye Institute. Accessed July 27, 2011, at: [http://222.nei.nih.gov/strategicplanning/NEI\\_Progress-Doc.pdf](http://222.nei.nih.gov/strategicplanning/NEI_Progress-Doc.pdf).

<sup>2</sup>Pai AS-I et al. *Arch Ophthalmol* 2009;127:1339-44.

<sup>3</sup>Wang JJ et al. *Br J Ophthalmol* 1998;82:743-47.

<sup>4</sup>Age-Related Eye Disease Study Research Group. *Arch Ophthalmol* 2005;123:1570-74.

<sup>5</sup>Crues AF et al. *Pharmacoeconomics*. 2008;26:57-73.

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