Phase III clinical trials of brolucizumab in patients with neovascular age-related macular degeneration

What is brolucizumab (also known as RTH258)?

- A human anti-VEGF monoclonal antibody (single-chain antibody fragment), which is a potent inhibitor of vascular endothelial growth factor (VEGF)
- Abnormally high levels of VEGF are key in the development of neovascular age-related macular degeneration (nAMD), leading to the formation of abnormal blood vessels in the retina and subsequent retinal thickening, due to fluid accumulation or breakdown of the blood-retina barrier

What are the HAWK and HARRIER studies?

HAWK and HARRIER are prospective, randomized, double-masked, 2-year ongoing studies to evaluate the efficacy and safety of brolucizumab for the treatment of nAMD:

**HAWK**
- Treatment began in December 2014
- In North America, Europe, Australia, South America, Israel, Asia

**HARRIER**
- Treatment began in July 2015
- In North, Central, and South America, Europe, Australia, and Asia

*Both studies have completed patient recruitment, and are ongoing.*

HAWK and HARRIER are studies called HAWK and HARRIER7, eight, and they call each other HAWK and HARRIER.

Study Overview

**HAWK**
- Began in December 2014
- In North America, Europe, Australia, South America, Israel, Asia

**HARRIER**
- Began in July 2015
- In North, Central, and South America, Europe, Australia, and Asia

**Both studies**
- enroll 1,800 patients
- have 400 study sites
- in North America

Study Design

How was the disease activity assessed?

Disease activity was assessed by the masked investigator. Among patients who received brolucizumab, if the masked investigator determined disease activity to be present, patients were interval adjusted to an 8-week interval if disease activity was assessed by the masked investigator. Among patients whose disease activity was re-assessed by the masked investigator, disease activity was adjusted to an 8-week interval if disease activity was present. Changes to treatment intervals were made at prespecified visits by the masked investigator supported by protocol guidance based on dynamic functional and anatomical characteristics.

References

3. Aflibercept (Eylea®) [summary of product characteristics]. European Medicines Agency; May 2017