Phase 3 BEOVU® (brolucizumab-dbll) injection clinical trials in wet AMD

What is wet AMD?
Wet AMD can develop in those with AMD where abnormal blood vessels grow under the retina, which can lead to vision loss. It is characterized by fluid leakage and has been linked to risks for retinal detachment and eye pain.

What is BEOVU®?
BEOVU® (brolucizumab-dbll) injection is a recombinant humanized monoclonal antibody that binds to the VEGF-A protein, preventing it from binding to its receptor and blocking its ability to stimulate abnormal blood vessel growth.

INDICATIONS AND USAGE
BEOVU® (brolucizumab-dbll) injection is indicated for the treatment of Neovascular (Wet) Age-related Macular Degeneration (AMD) for patients who have previously been treated with an anti-VEGF treatment.

IMPORTANT SAFETY INFORMATION
During Phase 3 clinical trials of BEOVU, antibodies were generated against BEOVU in a small percentage of patients. Treatment-naive patients showed IgG antibodies in 13% of patients. Following initiation of dosing, IgG antibodies were detected in at least one serum sample in 53% to 67% of patients treated with BEOVU. Intraocular in treatment-naive patients. After initiation of dosing, anti-brolucizumab antibodies were detected in at least one serum sample in 93% of patients treated with BEOVU. Please see additional Important Safety Information below.

HAWK and HARRIER

Study overview
The efficacy and safety of BEOVU was compared with aflibercept in 2 global, randomized, double-masked Phase 3 trials of 1459 adults with wet AMD.5,6

Primary Endpoint
The primary endpoint was the proportion of patients achieving a 15-letter or greater improvement in BCVA at 1 year following treatment with BEOVU injection at week 48.

Secondary Endpoints
Secondary endpoints included:
- Mean change in BCVA at week 16
- Areas under the curve 12-months following initiation of treatment with BEOVU
- Retinal fluid thickness (CST): non-inferiority to aflibercept at weeks 12, 24, 48, and 96

Thromboembolic Events
Although there was a low rate of arterial thromboembolic events (ATEs) observed in the BEOVU clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. Arterial thromboembolic events have occurred following intravitreal injections with BEOVU. Proper aseptic injection techniques must always be used when administering BEOVU.

How disease activity was measured:
Visual acuity and anatomical parameters were measured, including retinal fluid and central subfield thickness.

Primary Efficacy Endpoint
The primary efficacy endpoint of the BEOVU clinical trials was the proportion of patients achieving a 15-letter or greater improvement in BCVA at 1 year following treatment with BEOVU injection at week 48.

Secondary Endpoints
Secondary endpoints included:
- Mean change in BCVA at week 16
- Areas under the curve 12-months following initiation of treatment with BEOVU
- Retinal fluid thickness (CST): non-inferiority to aflibercept at weeks 12, 24, 48, and 96

Clinical trials
The efficacy and safety of BEOVU were studied in patients  with wet AMD in 2 pivotal Phase 3 clinical trials, HAWK and HARRIER.5,6

HAWK
- Study sites in the Americas, New Zealand, China, India, Taiwan, and Japan
- 729 patients randomized
- Patients started treatment at week 0 and received aflibercept injections every 4 weeks
- Protocol deviation allowed for flexible dosing every 8 weeks

HARRIER
- Study sites across Europe, Israel, Australia, and Japan
- 730 patients randomized
- Patients started treatment at week 0 and received aflibercept injections every 8 weeks
- Protocol deviation allowed for flexible dosing every 8 weeks

The efficacy and safety of BEOVU were compared with aflibercept in 2 global, randomized, double-masked Phase 3 trials of 1459 adults with wet AMD.5,6

BEOVU® (brolucizumab-dbll) injection
- A recombinant humanized monoclonal antibody
- Indicated for the treatment of Neovascular (Wet) Age-related Macular Degeneration (AMD)

Antivascular Endothelial Growth Factor (VEGF) inhibitors
- May reduce the risk for retinal detachment
- May reduce the risk for eye pain

Efficacy & Effectiveness
Efficacy and effectiveness results are based on the patient populations that received both treatments for the full duration of the study.

Dose-Response
Dose-response results are based on the patient populations that received both treatments for the full duration of the study.

Safety
Safety results are based on the patient populations that received both treatments for the full duration of the study.

Important Safety Information
Please see full Prescribing Information here.

References