Novartis provides update on use and safety of Beovu® in patients with wet AMD

Mar 11, 2020

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Patient safety is at the heart of everything we do. Whenever adverse events are reported, we take them seriously and investigate them thoroughly.

As previously shared, our global safety organization is conducting a comprehensive review of a limited number of events reported as severe vision loss, retinal artery occlusion and/or vasculitis in patients treated with Beovu, including cases where patients had previously received other VEGF inhibitors.

To date, the data continue to support an overall favorable benefit-risk profile for Beovu. The rate of the reported post-marketing events remains consistent with or below the approved prescribing information. In the registration trials, the incidence of vision loss was comparable between Beovu and aflibercept. Currently, there is no validated new or changed safety signal. We are conducting an ongoing assessment of the onset and severity of the reported post-marketing events in comparison to those observed in the clinical trials.

While Novartis' review is ongoing, we will provide weekly updates to share the status and findings for healthcare professionals on brolucizumab.info.

March 2, 2020

As of March 2, 2020, more than 57 000 Beovu® (brolucizumab) vials for injection have been shipped to prescribing physicians in the US[1]. To date, the safety data continue to support a favorable benefit-risk profile for Beovu[2,3].

Beovu is approved for the treatment of wet age-related macular degeneration (wet AMD) by the US Food & Drug Administration (FDA), the European Commission (EC), Swissmedic and the Australian Therapeutic Goods Association (TGA)[4-7]. The safety of Beovu has been demonstrated in an extensive Phase III program, including more than 1 800 patients worldwide across 400 study sites[2].

As with all medicines, adverse events can occur, which is why we continuously monitor the safety of our products for the occurrence of such events. The prescribing information leaflet for Beovu in the US states a 4% rate of intraocular inflammation and a 1% rate of retinal artery occlusion[4]. As of February 28, our global safety organization is conducting a comprehensive review of a limited number of reported cases of severe vision loss, inflammation and potential retinal vasculitis in patients treated with Beovu, including cases where patients had previously received other VEGF inhibitors. We believe the incidence of these events remains consistent with or below the package insert[4]. In the registration trials, the incidence of vision loss was comparable at all letter intervals across Beovu and aflibercept[2,4].

As part of our safety surveillance program, we are conducting a comprehensive product quality review and actively evaluating every case. We are working closely with the reporting physicians and retina specialists to

collect the relevant clinical data and fully understand these events. Furthermore, we are engaging with the Data Monitoring Committee (DMC) for our ongoing global trials and have engaged an external Safety Review Committee (SRC) to further evaluate and advise on the post-marketing cases. The FDA, EMA, Swissmedic, Australian TGA and other health authorities are aware of our review, and we are in the process of informing other regulatory bodies. We commit to sharing the outcome of the review upon completion.

While the review is ongoing and Novartis' classification of these reported adverse events has not yet been established, clinicians' reports suggest that most cases present after the first or second injection of Beovu with patients reporting changes in vision, such as significant increase in floaters or blurry vision, within one to two weeks of treatment.

Based on these preliminary observations and consistent with the approved Beovu product labeling, Novartis reminds physicians to advise patients that in the days following Beovu administration, if the eye becomes red, sensitive to light, painful or develops a change in vision, they should seek immediate care from an ophthalmologist[4].

Physicians are also reminded to act promptly when symptoms are reported by patients, and if clinical signs of intraocular inflammation or changes in vision after Beovu injection are observed, withhold Beovu, perform the appropriate diagnostic evaluation and treat the symptoms or intraocular inflammation as per good medical practice.

As a reminder, Beovu is contraindicated in patients with active intraocular inflammation[4]. Please report any observed or suspected adverse events to Novartis at https://www.report.novartis.com or +1-888-NOW-NOVA (1-888-669-6682) Monday - Friday, 8:30am - 5:00pm ET.

Novartis stands behind the safety and efficacy of Beovu when used as indicated.

References

1. Data on File. Internal Sales Data. Novartis Pharmaceuticals Corporation. February 2020.
2. Dugel P, Koh A, Ogura Y, et al; HAWK and HARRIER Study Investigators. HAWK and HARRIER: Phase 3, multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration. Ophthalmology. 2020;127(1):72-84.
3. Data on file. RTH258 Clinical Study Report. Novartis; 2019.
4. Beovu [US prescribing information] East Hanover, NJ. Novartis: 2019.
5. Beovu [summary of product characteristics] Dublin, Ireland. Novartis: 2020.
6. Beovu [Swissmedic prescribing information] Switzerland. Novartis: 2020.
7. Beovu [prescription medicine decision summary] Australia. Novartis: 2020.

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