Correspondence

Comment on: Is this a 737 Max Moment for Brolucizumab

EDITOR:

WE READ WITH INTEREST THE EDITORIAL TITLED "IS THIS A 737 Max Moment for Brolucizumab."[1] At Novartis, providing safe and effective treatments for patients is our highest priority. Working closely with health authorities around the world, including FDA, we continuously monitor the benefit-risk profile of our medicines. Although other anti–vascular endothelial growth factor (anti-VEGF) agents are available, there are current unmet needs with neovascular AMD (nAMD) treatment that we believe brolucizumab addresses. Moreover, we believe the choice of treatment should ultimately be left to individual treating physicians and their patients, after appropriate evaluation of the benefit-risk profile of the product.

As a greater number of patients were exposed to brolucizumab following FDA approval, Novartis received reports of retinal vasculitis, including retinal occlusive vasculitis. Novartis initiated its own internal review of these postmarketing safety case reports, including the establishment of an external safety review committee (SRC) to provide an independent review of these cases and compare them to events seen in the brolucizumab Phase III trials. Using the terminology defined by the SRC, Novartis concluded a confirmed safety signal of rare adverse events termed "retinal vasculitis" and/or "retinal vascular occlusion" that may result in severe vision loss.

Additionally, Novartis has established a fully dedicated research, drug development, and medical task force who are working with top external global specialists with the goal of examining the following key questions: (1) root cause; (2) identifying at-risk patient characteristics; (3) risk mitigation strategies; and (4) treatment algorithms for these rare events.

Since the launch of brolucizumab, transparency and communication with the retina community have been first and foremost in our minds. In addition to the commissioning of the SRC and the task force, Novartis worked closely with the American Society of Retina Specialists (ASRS) ReST Committee to provide access to postmarketing data to ensure physicians and patients fully understood the risks and benefits associated with brolucizumab. We have also created a global safety website, brolucizumab.info, to provide the latest information and guidance. Other actions included (1) working with health authorities to update the prescribing information worldwide; (2) informing investigators of ongoing clinical trials and asking them to reconsent patients; (3) amending the protocols, informed consent forms, and investigator brochures of all Novartis-sponsored trials; and (4) informing all physicians who request brolucizumab through our Managed Access Program.

Physicians are advised to carefully monitor each patient treated with brolucizumab for evidence of inflammation or other adverse events. It is advised they follow recommendations set forth in/by the brolucizumab label, and specialty societies and organizations, such as the ASRS, regarding management and timing of repeated administrations of anti-VEGF agents. Brolucizumab is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to brolucizumab.

Brolucizumab represents an important treatment option for patients with nAMD. At Novartis, we support individual physicians, who we believe, whether or not they choose to use brolucizumab, are able to make the best treatment choices for their patients.

MARCIA KAYATH
DIRK SAUER
Basel, Switzerland

FUNDING/SUPPORT: THIS STUDY RECEIVED NO FUNDING. Financial Disclosures: Marcia Kayath is an employee of Novartis Pharmaceuticals Corporation. Dirk Sauer is an employee of Novartis AG. All authors attest that they meet the current ICMJE criteria for authorship.

REFERENCE

1. Rosenfeld PJ, Browning DJ. Is this a 737 Max moment for brolucizumab? *Am J Ophthalmol* 2020;216:A7–A8https://www.ajo.com/article/S0002-9394(20)30242-7/fulltext.

Reply to Comment on: Is this a 737 Max Moment for Brolucizumab?

EDITOR:

WE READ THE CORRESPONDENCE BY KAYATH AND SAUER[1] from Novartis Pharmaceuticals with interest. Their letter fails to disclose the recent clarifications in the HAWK and HARRIER trial data, and by doing so they fail to reveal the true risks and benefits for the patients who might be given brolucizumab.

The American Society of Retina Specialists (ASRS) safety review committee (SRC) reviewed the postmarketing cases of intraocular inflammation, retinal vasculitis,

0002-9394/$36.00
https://doi.org/10.1016/j.ajo.2020.06.035