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Novartis completes safety review and initiates update to the Beovu® prescribing information worldwide

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Basel, April 08, 2020 — Patient safety is at the heart of everything we do. Whenever adverse events are reported, we take them seriously and investigate them thoroughly.

As part of its safety surveillance program, Novartis has been actively evaluating post-marketing cases reported as severe vision loss, retinal artery occlusion and/or vasculitis with Beovu® (brolucizumab). We have been working closely with the reporting physicians and retina specialists to get their perspective and collect the relevant clinical and imaging data in a manner compliant with regulatory requirements.

Novartis has now completed its review of these post-marketing safety case reports. This included assessment by an external Safety Review Committee (SRC) chartered to provide independent, objective and thorough scientific review of the reported post-marketing adverse events in comparison to relevant events seen in the Phase III Hawk and Harrier registration trials that were the basis of the approved prescribing information. Based on internal and SRC assessment, Novartis concluded that there is a confirmed safety signal of rare adverse events of *"retinal vasculitis and/or retinal vascular occlusion that may result in severe vision loss." Typically these events occur in the presence of intraocular inflammation.*[*]

Based on this review, Novartis has initiated a safety information update to Beovu prescribing information worldwide. Currently approved prescribing information includes intraocular inflammations, visual acuity decrease (including blindness) and retinal artery occlusion as separate terms. We will work with regulatory authorities to finalize the prescribing information update.

In addition, we are working with our data monitoring committees and informing investigators of ongoing clinical trials. Novartis-sponsored studies will be amended so that protocols, Informed Consent Forms and Investigator Brochures reflect this new safety information. Investigators are also being informed to re-consent patients.

We are committed to continuing to collaborate with the scientific and broader retina community to better understand the root causes and potential risk factors associated with these rare adverse events. Novartis continues to believe Beovu represents an important treatment option for patients with wet AMD, with an overall favorable benefit-risk profile.

We would like to thank all doctors who took the time to upload clinical data and images and we encourage physicians to continue to report any adverse or suspicious events in accordance with local requirements at **https://www.report.novartis.com** (https://www.report.novartis.com). To ensure that healthcare providers have the information they need to manage wet AMD patients, we will continue to provide updates on **https://www.brolucizumab.info** (https://www.brolucizumab.info).

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