Beovu® (brolucizumab-dbll) – New indication

- On May 27, 2022, the FDA approved Novartis' Beovu (brolucizumab-dbll), for the treatment of diabetic macular edema (DME).

- Beovu is also approved for the treatment of neovascular (wet) age-related macular degeneration (AMD).

- The approval of Beovu for the new indication was based on two randomized, active controlled studies (KESTREL and KITE) in 926 patients with DME. In KESTREL, patients were randomized to the following dosing regimens: 1) Beovu 6 mg administered once every 6 weeks for first 5 doses, followed by Beovu 6 mg every 8 or 12 weeks; 2) Beovu 3 mg administered once every 6 weeks for first 5 doses, followed by Beovu 3 mg every 8 or 12 weeks; or 3) Eylea® (aflibercept) 2 mg administered once every 4 weeks for first 5 doses, followed by Eylea 2 mg every 8 weeks. In KITE, patients were randomized to the following dosing regimens: 1) Beovu 6 mg administered once every 6 weeks for first 5 doses, followed by Beovu 6 mg every 8 or 12 weeks; or 2) Eylea 2 mg administered once every 4 weeks for first 5 doses, followed by Eylea 2 mg every 8 weeks. The primary endpoint for both studies was the change from baseline to week 52 in Best Corrected Visual Acuity (BCVA).

    - In both studies, Beovu was non-inferior to Eylea for the change in BCVA from baseline to week 52 and the change from baseline over the period week 40 through week 52.
    - After 5 initial loading doses, the patients in the Beovu arm could have received between the minimum of 2 and maximum of 3 additional injections through week 52. At week 52, the median number of injections given over 12 months was 7 in patients treated with Beovu.

- The recommended dose for Beovu for DME is 6 mg (0.05 mL) administered by intravitreal injection every six weeks (approximately every 39 to 45 days) for the first five doses, followed by 6 mg by intravitreal injection once every 8 to 12 weeks.

    - Refer to the Beovu drug label for dosing for neovascular AMD.