Lucentis® (ranibizumab) – New indication

- On April 17, 2017, Genentech announced the FDA approval of Lucentis (ranibizumab) for the treatment of patients with diabetic retinopathy (DR).

- Lucentis is also approved for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema (DME), and myopic choroidal neovascularization.

- DR, the most common cause of vision loss in people with diabetes, is the leading cause of blindness among adults aged 20 to 74 and affects nearly 7.7 million people in the U.S.

- Lucentis is the first FDA approved drug to treat DR in people who have been diagnosed with or without DME, a complication of DR that causes swelling in the back of the eye.

- The efficacy and safety of Lucentis for the treatment of DR were evaluated in sham-controlled and active-controlled clinical studies of 1,064 patients. The active-controlled study compared Lucentis to panretinal photocoagulation.

    — In the sham-controlled studies, the Lucentis-treated patients demonstrated greater improvements from baseline in DR severity scores vs. the sham treatment groups (9% - 39% vs. 0% - 7%. respectively, $p < 0.05$ for all comparisons).
    — In the active-controlled study, Lucentis-treated patients demonstrated improvements from baseline in DR severity scores. Improvements were observed in patients with and without baseline DME (31.7% - 58.5% and 28.4% - 37.8%, respectively).

- Similar to the recommended dose of Lucentis for the treatment of DME, the recommended dose for the treatment of DR is 0.3 mg administered by intravitreal injection once a month (approximately 28 days).

- Refer to the Lucentis drug label for dosing recommendations for all other indications.