Lucentis® (ranibizumab) – New Indication

- On January 5, 2017, Genentech announced the FDA approval of Lucentis (ranibizumab) for the treatment of patients with myopic choroidal neovascularization (mCNV).
- Lucentis is the first FDA-approved anti-vascular endothelial growth factor therapy to treat mCNV in the U.S.
- Lucentis is also FDA approved for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema (DME), and diabetic retinopathy (non proliferative diabetic retinopathy, proliferative diabetic retinopathy) in patients with DME.
- mCNV affects ~41,000 people in the U.S. and is a vision-threatening complication of pathological myopia. In mCNV, abnormal blood vessels grow directly into the retina, which may break and leak blood or fluid, leading to potentially irreversible central vision loss or blindness.
- Approval of the new indication is based on data from a clinical study of 276 patients randomized to treatment with Lucentis or verteporfin photodynamic therapy (vPDT). The primary endpoint was the mean change in best-corrected visual acuity (BCVA) from baseline to month 3.
    - At month 3, the Lucentis groups had a mean change in BCVA of +12.1 and +12.5 letters from baseline, respectively, vs. the vPDT group, which had a mean BCVA change of +1.4 letters from baseline ($p < 0.01$).
- The recommended dose of Lucentis for the treatment of mCNV is 0.05 mg administered by intravitreal injection once a month (~28 days) for up to 3 months. Patients may be retreated if needed.
- Refer to the Lucentis drug label for dosing recommendations for other indications.