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Genentech, a member of the Roche Group, announced that the US Food and Drug Administration (FDA) approved Lucentis (ranibizumab injection) for the treatment of diabetic retinopathy (DR) in people with diabetic macular edema (DME). DME impacts nearly 750,000 Americans, about 10 percent of people with DR. Lucentis is a vascular endothelial growth factor (VEGF) inhibitor designed to bind to and inhibit VEGF-A, a protein that is believed to play a critical role in the formation of new blood vessels (angiogenesis) and the hyperpermeability (leakiness) of the vessels.

The medicine has been studied in 21 clinical trials worldwide in more than 9,080 patients. Lucentis was developed by Genentech. The company retains commercial rights in the US and Novartis has exclusive commercial rights for the rest of the world. Outside the US, Lucentis is approved in more than 100 countries to treat patients with wet AMD, for the treatment of DME, and due to macular edema secondary to both branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO).

The FDA granted Lucentis Breakthrough Therapy Designation and Priority Review for this indication based on results from the RISE and RIDE Phase III clinical trials. The FDA designates Breakthrough Therapy to a medicine if it is intended to treat a serious or life-threatening disease and if preliminary clinical research suggests it may provide substantial improvement on clinically significant endpoints over existing therapies.

In the press release, Ms Sandra Horning, MD, chief medical officer and head of Global Product Development had

commented that with this approval, people with diabetic macular edema now have a FDA-approved medicine that showed meaningful improvements in retinal damage from diabetes, in addition to the established improvement in vision.