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Novartis to file Lucentis for retinopathy in premature babies

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Novartis has revealed its intent to file anti-VEGF therapy Lucentis for retinopathy of prematurity (ROP), a rare disease in premature infants that often leads to blindness.

The move follows data from the Phase III Rainbow trial, which showed that, despite marginally missing statistical significance for the primary endpoint of showing superiority of the drug to laser surgery, Lucentis (ranibizumab) was found to be “an efficacious, safe and well-tolerated treatment for infants with ROP”.

“With 80% of patients achieving treatment success with 0.2mg Lucentis versus 66% with laser, these data are clinically relevant,” the firm stressed.

"Laser surgery, the current standard of care, works by destroying the tissue in the eye that contributes to the elevation of VEGF. While it is an effective treatment, there is a clear unmet need for innovative ways to treat ROP without destroying retinal tissue,” noted Professor Andreas Stahl, senior physician in Retinal Surgery and Head of the Angiogenesis Research Group at the Eye Center, University of Freiburg, Germany.

“Lucentis demonstrated in the Rainbow study that it is an efficacious and well tolerated option for the treatment of ROP that may offer new hope to parents of this vulnerable patient population”.