US FDA approves Outlook Therapeutics' eye disease drug

The New Jersey-based company was seeking approval for Lytenava to treat wet age-related macular degeneration (AMD), a chronic eye disease that can cause blurred vision and blind spots and is a leading cause of blindness among older adults.

Bengaluru: Outlook Therapeutics said on Friday the U.S. Food and Drug Administration has approved its drug for a type of eye disease that can cause severe vision loss.

The New Jersey-based company was seeking approval for Lytenava to treat wet age-related macular degeneration (AMD), a chronic eye disease that can cause blurred vision and blind spots and is a leading cause of blindness among older adults.

The drug is an ophthalmic formulation of bevacizumab, an FDA-approved antibody therapy that works by inhibiting the growth of abnormal blood vessels that can damage the retina in patients with wet AMD.

The approval marks Outlook's first commercial entry into the U.S. market and validates a years-long regulatory effort that included multiple FDA rejection letters and a successful appeal to the agency's Office of New Drugs, which ultimately agreed with the company on the drug's efficacy.

The company's shares were halted during afternoon trading.

News Source:

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