Translation

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Enrollment of First Patient in Clinical Trials of RBM-007 for Treatment of Exudative Age-related Macular Degeneration

We are pleased to announce that first patient has been enrolled into phase I/IIa trial (named as SUSHI study) of RBM-007 for the treatment of exudative age-related macular degeneration (AMD) at Stanford University in the United States.

This PI/IIa trial is an open label, non-controlled, dose-escalating study assessing mainly the safety and tolerability of a single intravitreal injection of RBM-007 in approximately nine subjects. See ClinicalTrials.gov for more information.
https://clinicaltrials.gov/ct2/show/NCT03633084

AMD is an age-related disorder that affects the macula of the retina. It is the leading cause of blindness in the United States and Europe. All of FDA-approved therapies for exudative AMD act against the same target, Vascular Endothelial Growth Factor (VEGF), which is a major contributor to the pathogenesis of exudative AMD. Although treatments with anti-VEGF drugs have shown dramatic visual benefits for exudative AMD patients, follow-up studies have revealed some limitations. First, the efficacy of anti VEGF drugs is poor in a certain number of patients. Second, even with patients who showed dramatic visual acuity improvement at first step of the treatment, long-term visual outcomes are poor. These factors are thought to involve scarring (fibrosis) of the retinal tissue, but existing drugs do not suppress scarring. In contrast, pharmacological studies of RBM-007 in disease model animals have shown that RBM-007 inhibits not only angiogenesis but also scar formation. These dual effects are novel mechanisms that may provide new therapies for wet exudative AMD patients.

Currently no other FGF2 inhibitors are reported to be in the clinical stage. RBM-007 is the first FGF2 inhibitor administered to human.