Translation

July 23, 2018

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RIBOMIC USA Inc. Safe-to-Proceed Under IND to Initiate Clinical Trials of RBM-007 for Treatment of Age-related Macular Degeneration

We are pleased to announce that the U.S. Food and Drug Administration (FDA) completed the 30-day review of the IND submitted by RIBOMIC USA Inc., a wholly owned subsidiary of RIBOMIC Inc., for the treatment of wet Age-related Macular Degeneration (AMD) using RBM-007, a novel oligonucleotide-based aptamer having potent anti- Fibroblast Growth Factor 2 (FGF2) activity.

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 AMD act against the same target, Vascular Endothelial Growth Factor (VEGF), which is a major contributor to the pathogenesis of wet AMD. Although treatments with anti-VEGF drugs have shown dramatic visual benefits for 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[1]. 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 AMD patients. The substance patent of RBM-007 is already granted in the United States.

As the IND has become effective, RIBOMIC will be proceeding into Phase I/IIa trial (named as SUSHI study) in the United States. The main purpose of the SUSHI study is to investigate the safety and acceptability of RBM-007 Injectable Solution. It is planned to be conducted in a number of patients at several clinical trial sites in the United States.

[1] Rofagha S, Bhisitkul RB, Boyer DS, Sadda SR, Zhang K. Seven-year outcomes in ranibizumab-treated patients in ANCHOR, MARINA, and HORIZON: a multicenter cohort study (SEVEN-UP). Ophthalmology 2013;120(11):2292-99.