FOR IMMEDIATE RELEASE

SignaBlok Receives Orphan Drug Designation from FDA for a First-in-Class TREM-1 Peptide inhibitor for the Treatment of Retinopathy of Prematurity

Shrewsbury, MA, March 26, 2026 – SignaBlok, Inc., a preclinical stage biotechnology company pioneering novel, first-in-class peptide therapies for multiple inflammation-associated diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the Company's TREM-1 peptide inhibitor for the treatment of retinopathy of prematurity (ROP).

"Orphan Drug Designation for ROP represents a significant milestone in the development of our TREM-1 therapy for the treatment of ROP" said Alexander B. Sigalov, Ph.D., President and Founder of SignaBlok. "This decision by the FDA recognizes the potential for a first-in-class, macrophage-targeted TREM-1 peptide inhibitor to address a high unmet need for preterm infants suffering from ROP. We are very encouraged by favorable preclinical efficacy, pharmacokinetic and tolerability data in clinically relevant animal models. These data will be presented at the 2026 annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) to be held in Denver, Colorado, May 3-7, 2026".

The FDA's Orphan Drug Designation program provides orphan status to drugs defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States. Orphan Drug Designation qualifies the sponsor of the drug for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval.

About retinopathy of prematurity (ROP)

ROP affects 50-70% of preterm infants weighing less than 1,500 grams at birth, in several cases leading to blindness. Approximately 400 to 600 infants in the United States become legally blind annually due to ROP. Current treatments do not sufficiently address the medical need with severe cases, necessitating the development of new approaches.

About TREM-1

Triggering receptor expressed on myeloid cells 1 (TREM-1) serves as an inflammation amplifier. As such, TREM-1 is critically involved in the pathogenesis of inflammatory diseases, including ROP. Clinical targeting of TREM-1 is challenging due to multiple and unknown TREM-1 ligands. SignaBlok's TREM-1 inhibitor addresses this challenge by a new, ligand-independent mechanism of action.

About SignaBlok

SignaBlok, Inc. is a Massachusetts-based biotechnology company founded in 2009 to develop innovative, first-in-class therapeutics for targeted treatment of inflammation-associated diseases through the use of two key SignaBlok's proprietary technologies: 1) new mechanism-based approach to inhibition of cell receptors by using innovative, ligand-independent inhibitory peptides (the so-called SCHOOL peptides, the abbreviation coming from the "Signaling Chain HOmoOLigomerization" model of immune signaling); and 2) nature-inspired, multifunctional nanotechnology for targeted drug and/or imaging agent delivery to macrophages. Additional information about SignaBlok is available at www.signablok.com.

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