

EXPANDED ACCESS POLICY: AV-1959R VACCINE

Sponsor: The Institute for Molecular Medicine (IMM)

Investigational Product: AV-1959R (adjuvanted recombinant protein vaccine targeting N-terminal Amyloid-beta, A β ₁₋₁₁, fused to the MultiTEP platform and formulated with Advax-CpG55.2)

Indication: Preclinical Alzheimer's Disease (AD)

IND Number: 30925

1. OVERVIEW AND POLICY STATEMENT

IMM is dedicated to developing disease-modifying immunotherapies to prevent or slow the progression of Alzheimer's disease. Following FDA Fast Track designation for AV-1959R (IND 30925), IMM recognizes the importance of timely patient access to promising investigational therapies.

At the current stage of development, IMM believes AV-1959R is best evaluated in controlled clinical trials. **IMM is therefore not providing AV-1959R through expanded access outside of clinical trials at this time.** Enrollment in the clinical trials is the most appropriate way for eligible individuals to receive AV-1959R.

2. CURRENT STATUS OF DEVELOPMENT

AV-1959R is supported by an extensive preclinical program demonstrating robust anti-A β antibody responses across multiple species, including non-human primates, and reduction of A β pathology in animal models of Alzheimer's disease. In Phase 1, AV-1959R showed a favorable safety profile and robust immunogenicity in healthy volunteers.

The upcoming **Phase 2 study (Protocol US-AV1959R-201)** is evaluating the effect of AV-1959R on brain amyloid and downstream biomarkers in the intended population. Completing this study as quickly as possible is the fastest path to broad patient access; product supply and clinical resources are therefore dedicated to ongoing trials.

3. COMMITMENT TO ACCELERATE ACCESS

IMM intends to expand access to AV-1959R as quickly as the evidence allows. **IMM will promptly review this policy as soon as Phase 2 results or other significant clinical efficacy data become available**, with the goal of offering expanded access to patients who may benefit.

IMM may revise this policy at any time, and posting this policy does not guarantee access to AV-1959R for any individual patient.

4. CLINICAL TRIAL INFORMATION AND INQUIRIES

Patients interested in accessing AV-1959R are encouraged to discuss clinical trial participation with their treating physician. Detailed information regarding trial sites, eligibility criteria, and study protocols is available at [ClinicalTrials.gov](https://clinicaltrials.gov) (Identifier: NCT07827768 / Protocol US-AV1959R-201).

Physicians seeking further information regarding this policy may contact IMM at hm@immed.org. Acknowledgment of professional inquiries will occur within **five (5) business days**.