

ABBV-1758 in Subjects with Early Alzheimer’s Disease: A Combined Multiple-ascending Dose/ Proof-of-concept Study Design

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OBJECTIVE

To evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics—including amyloid removal—of ABBV-1758 in Alzheimer’s disease (AD)

CONCLUSIONS

This multicenter, multi-country, randomized, placebo-controlled, double-blind, dose-finding phase 1b/2 study will enroll approximately 200 patients

This study tests the hypothesis that ABBV-1758 will lead to rapid and robust removal of amyloid plaques from the brains of patients with AD, while maintaining acceptable safety, tolerability, and convenient dosing

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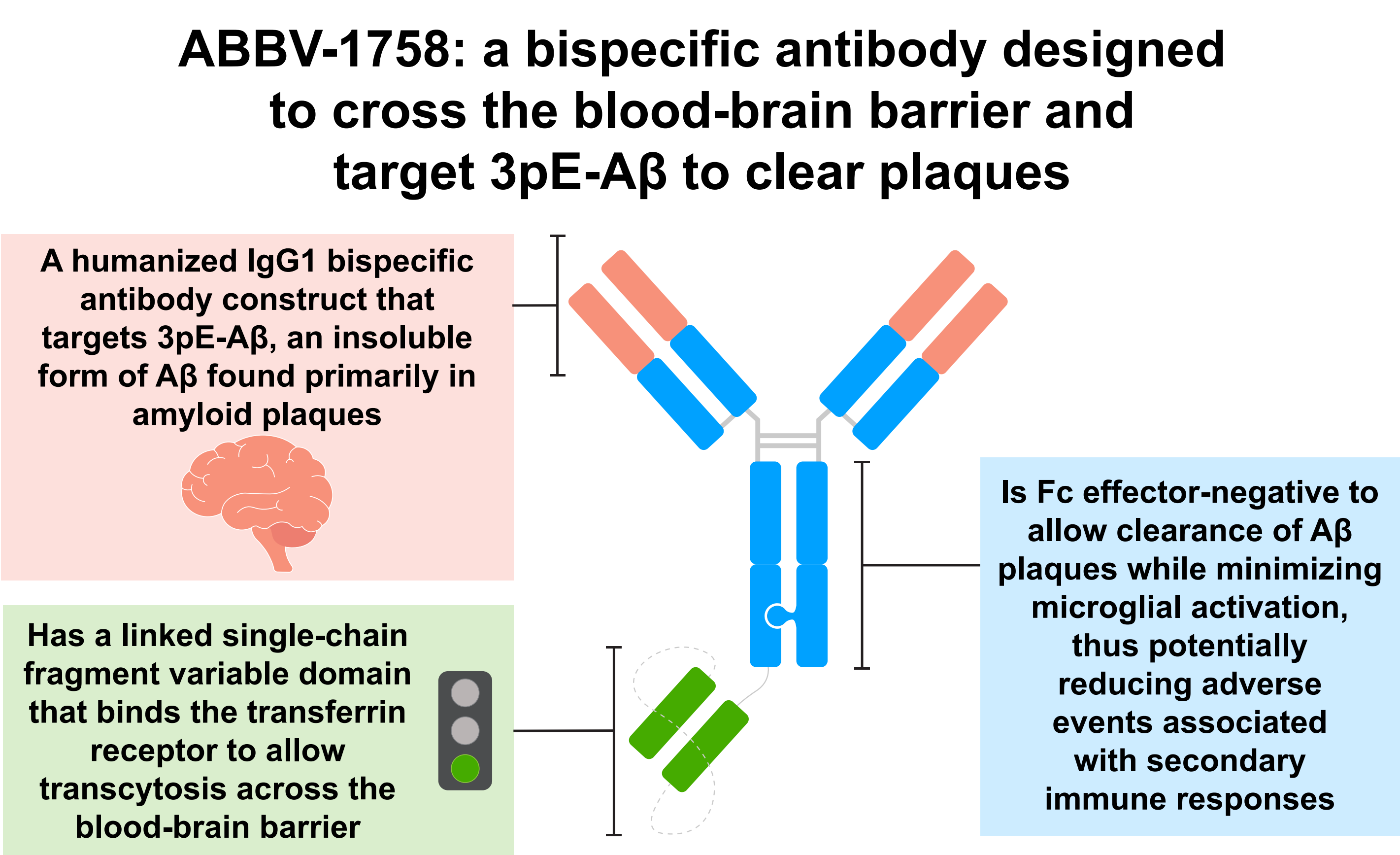
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INTRODUCTION

- Alzheimer’s disease (AD) is the most common cause of dementia in older adults¹
- Disease modifiers that slow AD progression include various amyloid beta (Aβ)-directed therapies with mechanisms that improve the clearance of amyloid plaques²
- However, due to the restrictive nature of the blood-brain barrier and the large molecular weight of anti-Aβ immunotherapies, achieving an optimal dose that is both safe and effective is challenging
- ABBV-1758, a bispecific antibody construct targeting N-terminal truncated Aβ pyroglutamated at position 3 (3pE-Aβ), was found to be generally safe and well-tolerated in a recent Phase 1 single ascending dose study in healthy volunteers
- The aim of the present study (NCT07599670)³ is to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics—including amyloid removal—associated with ABBV-1758 in approximately 200 patients with AD



STUDY DESIGN

Phase 1b/2 multicenter, multi-country, randomized, placebo-controlled, double-blind, dose-finding study

Hypothesis

ABBV-1758 will lead to rapid and robust removal of amyloid plaques from the brains of patients with AD, while maintaining acceptable safety, tolerability, and convenient dosing

Study stages

	Screening period ≤6 months	Double-blind treatment 28 weeks	Safety follow-up 12 weeks	Optional extension
Stage A Multiple ascending dose	✓	✓	✓	✓
Stage B Dose expansion	✓	✓	✓	✓
Stage C Asian populations	✓	✓	✓	✓

Eligibility

- 50-90 years of age
- Mini-Mental State Examination score ≥20
- Blood-plasma biomarkers predictive of elevated brain amyloid burden
- Amyloid PET scan ≥50 CL

Key evaluations

- Safety evaluations include adverse events reports, clinical laboratory tests, MRI imaging, vital signs, and electrocardiograms
- Change from baseline in brain amyloid plaque deposition as measured by amyloid PET scan in **Stage A** will guide the doses to be studied in **Stage B** and **Stage C**

ABBV-1758 or placebo administered subcutaneously or intravenously once every 4 weeks

Aβ, amyloid beta; AD, Alzheimer’s disease; CL, Centiloid; MRI, magnetic resonance imaging; PET, positron emission tomography.