Investigational Development of Mim8

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Mim8 (denecimig) is a Factor VIIIa mimetic bispecific antibody that is currently being investigated as a subcutaneous prophylactic treatment for hemophilia A with or without inhibitors.[1-8] An overview of the FRONTIER clinical development program can be found below. Mim8 is not yet approved by the Food and Drug Administration (FDA). Determination of safety and efficacy by the FDA has not yet been made, and the date of product approval is not known at this time.

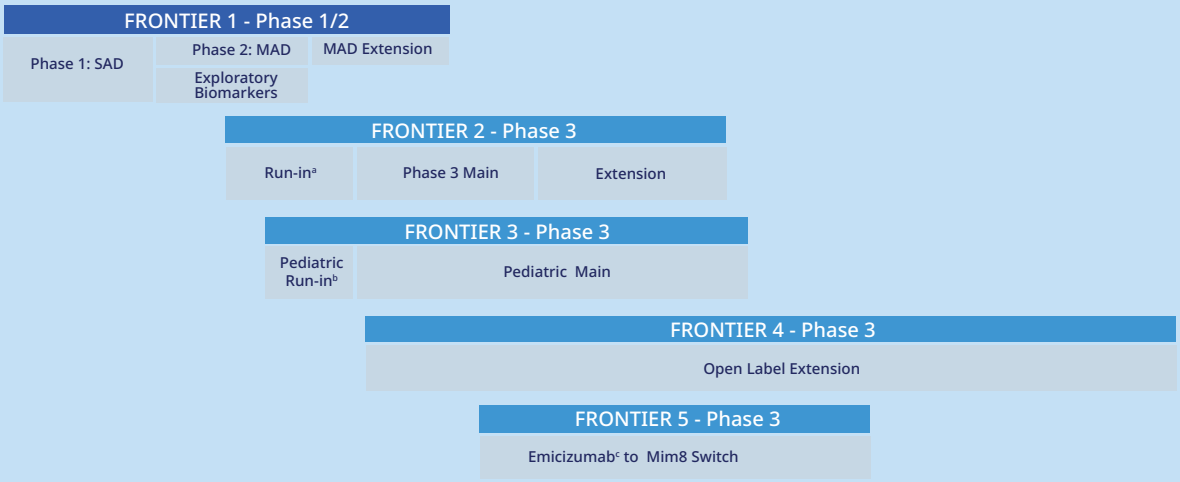

Figure 1. FRONTIER Clinical Development Program[8,9]

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a. For patients who are on a previous prophylactic treatment, there was a run-in observational period (minimum 26 weeks) before patients receive their first dose of Mim8.[10]
b. Depending on current treatment, patients may join a run-in observational period (minimum 26 weeks) which documents their current prophylaxis prior to their first Mim8 dose.[10]
c. Hemlibra® (emicizumab-kxwh) injection, for subcutaneous use, Genentech, Inc.[11]

Study Name NCT Number	Phase	Study Population	Eligibility Criteria	Study Design & Description
FRONTIER 1[1-4] NCT04204408	Phase 1/2	Healthy patients	Male patients aged 18-45 years	SAD phase: Single-center, double-blind, randomized, placebo-controlled trial evaluating the safety, tolerability, PK, and PD of Mim8[1] ⊕
		PwHA with or without inhibitors	Male patients aged 12-64 years and severe HA (FVIII activity <1%)	MAD phase: Multinational, open-label, partly randomized trial evaluating the safety, tolerability, PK, and PD of Mim8[2] ⊕
FRONTIER 2[5,10] NCT05053139	Phase 3	PwHA with or without inhibitors (adults and adolescents ≥12 years old)	All genders and patients with HA of any severity	Multinational, open-label, randomized, controlled study to evaluate efficacy and safety of weekly or monthly Mim8 prophylaxis[a] ⊕
FRONTIER 3[6,10] NCT05306418	Phase 3	PwHA with or without inhibitors (pediatric patients aged 1 to 11 years)	All genders and patients with HA of any severity	Multinational, open-label, non-randomized, uncontrolled study to evaluate safety, efficacy and exposure of weekly or monthly Mim8 prophylaxis[b] ⊕
FRONTIER 4[7,10] NCT05685238	Phase 3	Patients from FRONTIER 1, 2, 3	Refer to FRONTIER 1, 2, 3	Open-label, non-randomized, parallel, long-term extension trial to further evaluate safety and efficacy of Mim8 ⊕
FRONTIER 5[8] NCT05878938	Phase 3	Adults and adolescents with HA with or without inhibitors	All genders and patients with HA of any severity and aged ≥12 years	Open-label safety study switching directly from emicizumab[c] prophylaxis to Mim8 prophylaxis ⊕

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Abbreviations: HA: hemophilia A; MAD: multiple ascending dose; PD: pharmacodynamic; PK: pharmacokinetic; PwHA: patients with Hemophilia A; SAD: single ascending dose.

References are on the next page.

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