


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.

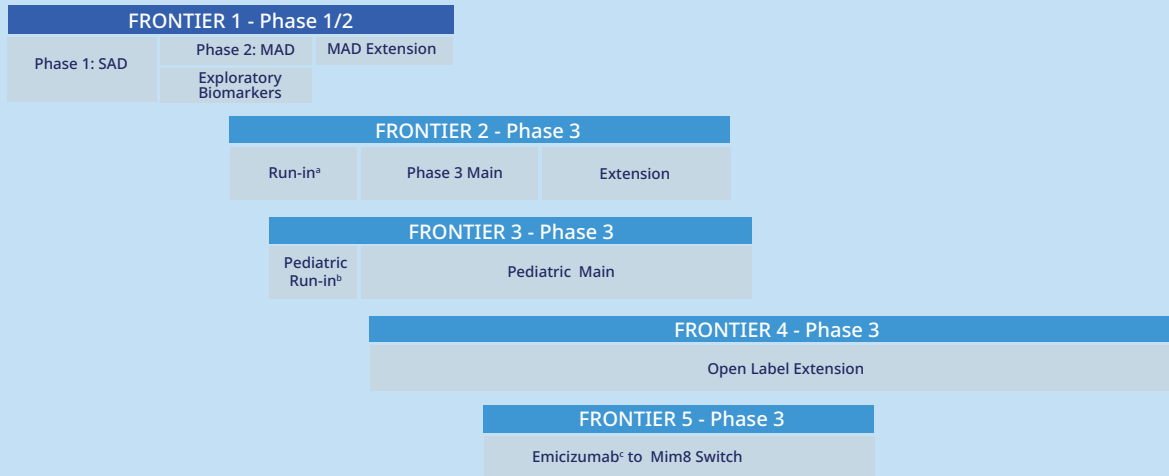


Figure 1. FRONTIER Clinical Development Program^{8,9}

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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 |
|--------------------------|-----------|---|---|--|
| | 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 |
| | 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 ³ |
| | 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 ⁵ |
| | 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 |
| | 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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