Garadacimab provides early onset of protection against HAE attacks from Week 1 after first administration

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BACKGROUND

- Early onset of efficacy and durable attack protection are critical to optimize disease control and establish treatment confidence
- Garadacimab is a first-in-class, fully human mAb targeting FXIIa under evaluation for HAE in pediatric, adolescent, and adult patients[1–3]

STUDY DESIGN AND KEY OUTCOMES OF THE PIVOTAL PHASE 3 AND OLE STUDIES

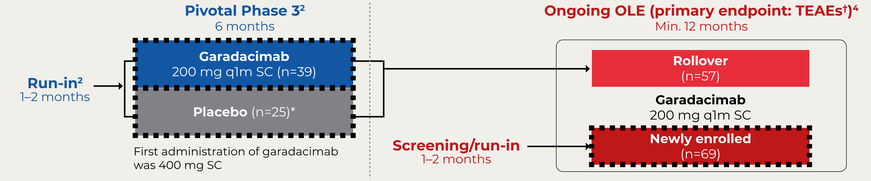
87% **Reduction** in mean monthly number of HAE attacks vs placebo in pivotal **Phase 3 (VANGUARD) study**, P<0.0001 (median reduction **100%**; exposure 6 months)[2]

95% **Reduction** in mean monthly number of HAE attacks vs run-in in **Phase 3 OLE** (median reduction **100%**; exposure 13.8 months)[4]

Favorable long-term safety and tolerability profiles in both Phase 3 studies[2,4]

Eligibility[2,4]

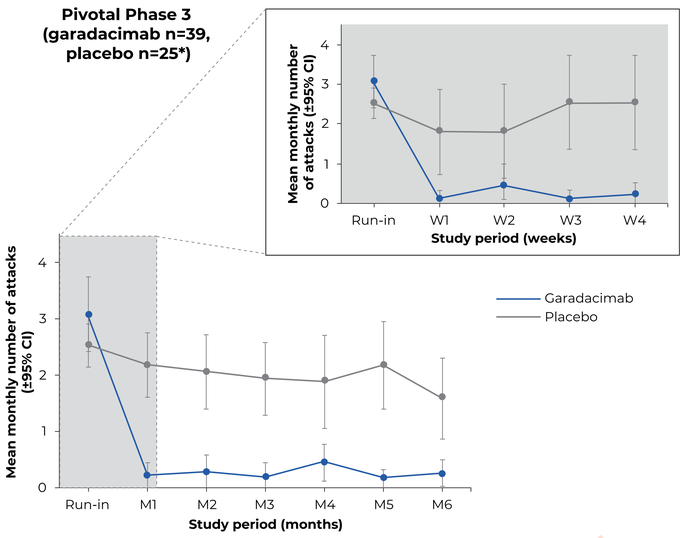
- **HAE diagnosis**
- **Aged ≥12 years**
- **Baseline ≥1 attack/month**



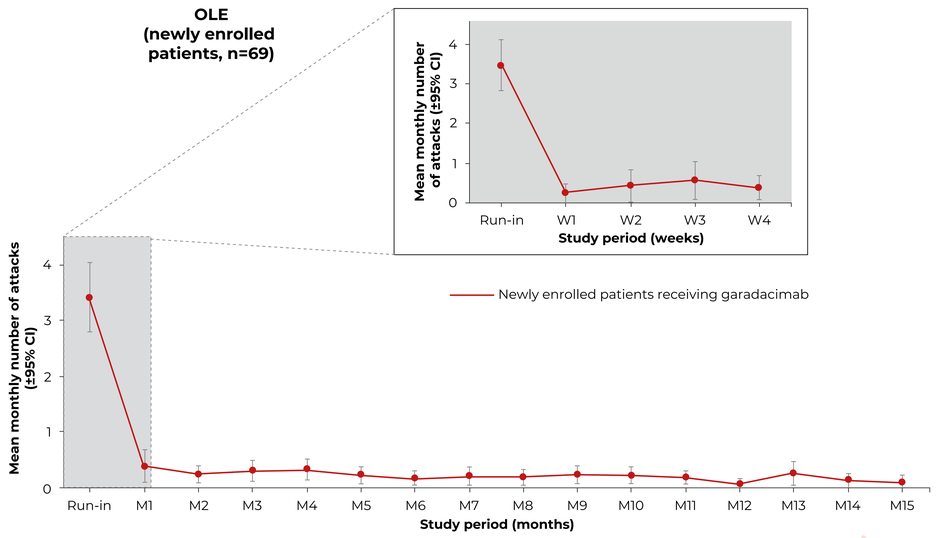
***Post hoc* analysis from the pivotal and OLE Phase 3 studies**

Early onset of efficacy and durable protection from HAE attacks demonstrated by garadacimab

GARADACIMAB SHOWS EARLY ONSET AND DURABLE PROTECTION FROM HAE ATTACKS

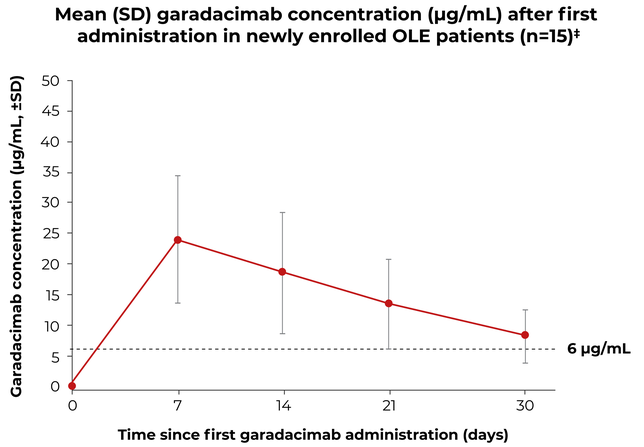


Garadacimab reduced mean monthly attack number as early as Week 1 vs run-in, compared to placebo



Garadacimab reduced mean monthly attack number as early as Week 1 vs run-in

GARADACIMAB CONCENTRATION EXCEEDS THERAPEUTIC THRESHOLD AFTER FIRST ADMINISTRATION



- $C_{min,ss}$ of 6 µg/mL identified as target threshold corresponding to ≥90% relative risk reduction in HAE attacks as determined by exposure-response analysis[5]

Garadacimab exposure exceeded target therapeutic threshold of 6 µg/mL after the first administration and remained over threshold through to Day 30‡

CONCLUSIONS

- Early onset of protection from HAE attacks with garadacimab as early as Week 1 after first administration in both pivotal and OLE Phase 3 studies
- Durable protection from HAE attacks with garadacimab across 15 months in the Phase 3 OLE study
- Garadacimab exposure exceeded target therapeutic threshold from Week 1 after first administration

*One patient in the placebo arm was excluded from efficacy analysis as they received treatment for <30 days; †TEAEs in patients with HAE-C1-INH; ‡Pharmacokinetic parameters were evaluated after the initial loading dose in a representative subset of newly enrolled patients (n=15).
CI, confidence interval; $C_{min,ss}$, minimum concentration in the dosing interval at steady state; FXIIa, activated factor XII; HAE, hereditary angioedema; HAE-C1-INH, hereditary angioedema with C1-inhibitor deficiency or dysfunction; M, month; mAb, monoclonal antibody; OLE, open-label extension; q1m, once-monthly; SC, subcutaneous; SD, standard deviation; TEAE, treatment-emergent adverse event; W, week.

References

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Disclosures

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