

# Rationale and Design of the ALPHA-SOLAR Clinical Trial of STAR-0215 for the Treatment of Hereditary Angioedema (HAE)

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## INTRODUCTION

- Hereditary angioedema (HAE), a rare genetic disorder, causes episodic attacks of localized swelling which can be disabling and potentially fatal.
- In patients with HAE due to C1-inhibitor deficiency or dysfunction, normal regulation of plasma kallikrein activity is lacking leading to increases in plasma kallikrein activity and release of bradykinin resulting in angioedema attacks.
- STAR-0215 is an investigational monoclonal antibody inhibitor of plasma kallikrein with long-lasting activity enabled by a YTE-modified Fc domain.
- Results from the single ascending dose Phase 1a trial (NCT05477160) demonstrated that STAR-0215 was well tolerated at all doses administered and achieved clinically relevant kallikrein inhibition after single doses > 100 mg.<sup>1</sup>
- These results support the ongoing Phase 1b/2 ALPHA-STAR trial (NCT05695248); initial results demonstrate a rapid reduction in monthly attack rates (90-96%) after 3 and 6 months of follow up, coupled with a favorable safety profile.
- There were no reports of injection site pain with administration of STAR-0215 in HAE patients in ALPHA-STAR.
- Here, we describe the design of the ongoing Phase 2 extension study (NCT06007677) that is investigating the long-term safety of STAR-0215 in patients with HAE.

## METHODOLOGY

ALPHA-SOLAR is an open-label, phase 2 clinical trial (NCT06007677) open to participants in the ongoing Phase 1b/2 ALPHA-STAR trial (adults, HAE type I or II) who meet eligibility requirements. This trial will enroll up to 56 participants globally. Enrolled participants will receive a subcutaneous (SC) loading dose (600 mg) and either 300mg SC Q3 Months (Q3M) or 600mg SC Q6 Months (Q6M) of STAR-0215. ALPHA-SOLAR participants who continue from ALPHA-STAR Cohorts 1 and 2 will receive SC loading dose and Q3M; participants from ALPHA-STAR Cohort 3 will receive SC loading dose and Q6M. The assessments occur every 3 and 6 months. The trial is expected to continue for 5 years (Figure 1).

## OBJECTIVE

The goal of the ALPHA-SOLAR clinical trial is to enable the collection of information about long-term safety and efficacy of STAR-0215 in participants with HAE.

Figure 1. ALPHA-STAR and ALPHA-SOLAR clinical trial design

