A single on-demand treatment with orally administered KVD900 significantly slows progression and accelerates resolution of attacks in patients with hereditary angioedema (HAE): Results of a phase 2, placebo-controlled, double-blind cross-over trial


On-demand treatment of HAE attacks is recommended to prevent attack progression and the development of potentially life-threatening angioedema episodes.

In a previous study1, the oral, small-molecule plasma kallikrein inhibitor KVD900 was shown to suppress plasma kallikrein activity by >90% within the first 30 minutes of administration to healthy volunteers. Background

Almost all events were single, mild or moderate cases; no serious or severe events were observed.

KVD900 significantly accelerated time to complete attack resolution.

KVD900 significantly slowed attack progression to use of rescue medication.

Primary endpoint: KVD900 significantly slowed attack progression to use of rescue medication.

KVD900 significantly accelerated time to improvement of rescue or PGI-S worsening.

Use of conventional attack treatment

Standard, well-accepted outcome measures

Study design

Initial PK Phase

Randomized cross-over study

Treatment-related adverse events* **P=0.001; Gehan's Generalized Wilcoxon Test. †P<0.05; Prescott's Test. Full analysis set. Censoring occurs where a subject did not use conventional attack treatment within 12h post-study drug dosing.

Data on File.

KalVista Pharmaceuticals, Inc.

Conclusions

Early use of KVD900 halts attack progression

Use of KVD900 at attack onset significantly increases time without rescue medication

KVD900 is efficacious within the first hours of the attack

Use of KVD900 significantly shortens the time to improvement of attack symptoms

KVD900 accelerates attack resolution

Use of KVD900 significantly shortens the time to attack resolution

KVD900 is generally safe and well tolerated

Conflicts: # Paid Scientific Advisors, * Employees of and § Consultants to KalVista Pharmaceuticals.

Inclusion/exclusion criteria

Inclusion criteria

• Confirmed type I or II HAE
• >3 documented HAE attacks in past 93 days
• Access to conventional attack treatment

Clinically relevant patient population

Exclusion criteria

Treatment with:

• HAE prophylaxis
• ACE inhibitors
• Estrogen-containing medications
• Androgens or fibrinolytics
• Strong CYP3A4 or CYP2C9 inhibitors and inducers

Representative distribution of attacks by location

Use of rescue or PGI-S worsening

Safety

Almost all events were single, mild or moderate cases; no serious or severe events were observed.

Data on File.

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