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KVD900 Phase 2 Topline Results

February 9, 2021

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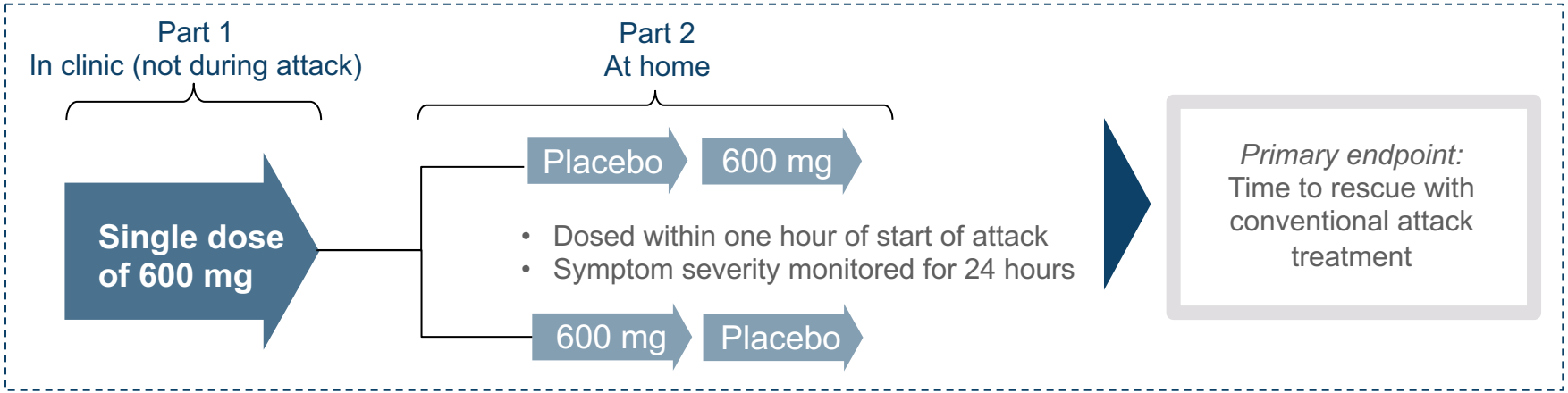
KVD900: Phase 2 Clinical Trial Design

- 53 Type I and II HAE patients at 25 sites in the United States and Europe
- Part 1: All patients receive a single dose of KVD900 in clinic for PK/PD assessment
- Part 2: All patients randomized to treat the first attack with either KVD900 or placebo and then treat a second attack with the alternative treatment



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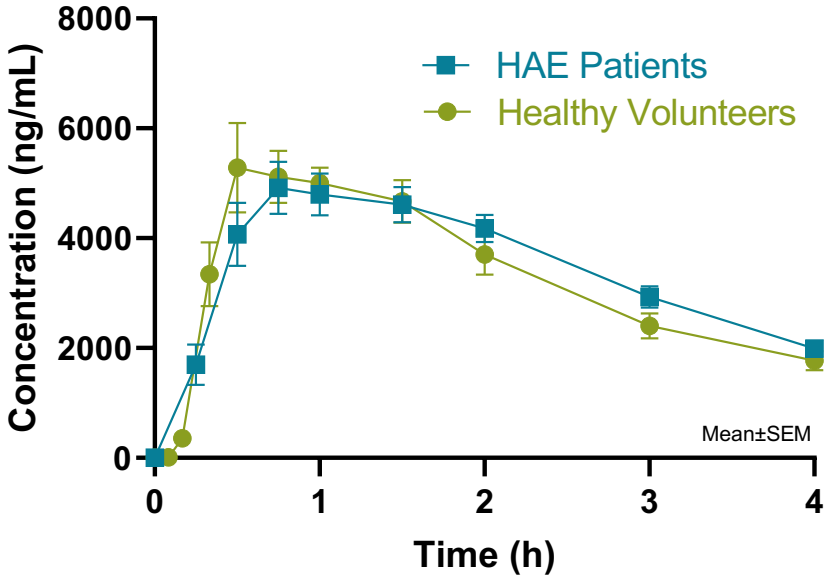
PK Profile in HAE Patients is Similar to Healthy Volunteers

- Part 1, open label dose of KVD900 in HAE patients
  - No food restriction prior to dosing
- Pharmacokinetic profile similar to profile obtained in fasted, healthy volunteers



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KVD900: Phase 2 Clinical Trial Endpoints

- Primary endpoint
  - Time to use of conventional attack treatment (rescue) within 12 hours
- Secondary endpoints
  - Time to symptom relief within 12 hours of study drug on the Patient Global Impression of Change (PGI-C)
  - Time to symptom relief within 12 hours of study drug on the Visual Analogue Scale (VAS)
  - Time to worsening on the Patient Global Impression of Severity (PGI-S) or use of rescue within 12 hours of study drug

Patient Disposition & Demographics

- 68 randomized
  - 53 completed
  - 1 withdrew consent
  - 14 did not treat 2 attacks due to completion of trial
  - No AE withdrawals
- Exposure to Study Drug
  - 126 doses of 600 mg KVD900
    - 68 in Part 1
    - 58 in Part 2
  - 55 doses of Placebo
  - Median time to trial drug administration from start of attack: 30 min

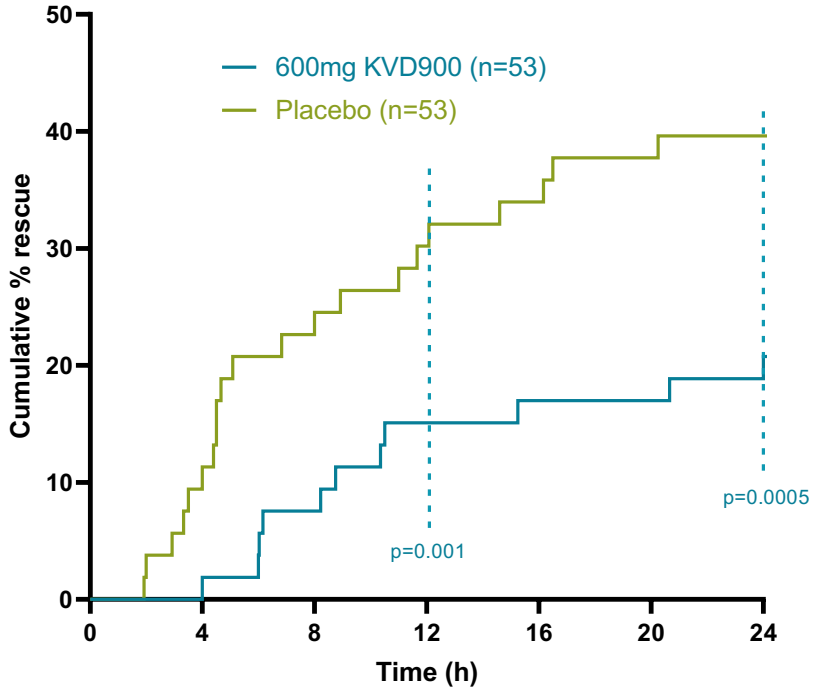
Demographic Characteristics
n = 68

Age mean (SD) Range	 38.3 (13.23) 19 – 68
Gender (m/f) n (%)	 31/37 (45.6/54.4)
BMI (kg/m2) mean (SD) range	 27.3 (5.47) 18.8 – 40.9
Type I / II n (%)	 68 (100%)

Trial Meets its Primary Endpoint

- KVD900 significantly reduced use of rescue within 12 hours: p=0.001*
  - Placebo 30.2%
  - KVD900 15.1%

- Efficacy maintained at 24 hours
  - p=0.0005*



*Gehan's Generalized Wilcoxon Test

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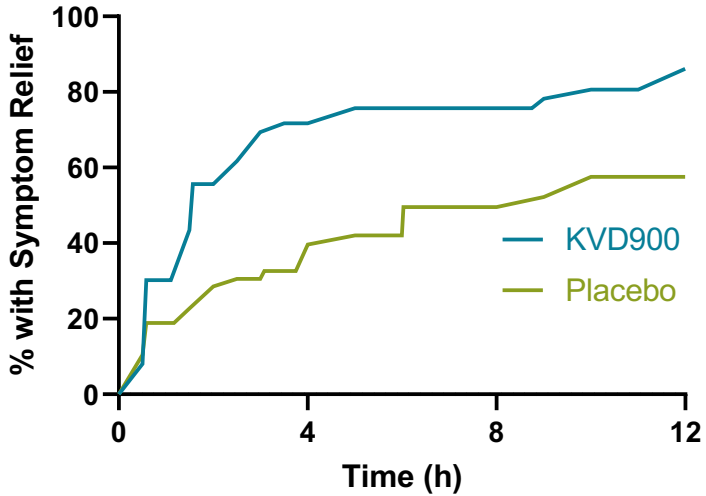
KVD900 Speeds Symptom Relief: Impression of Change

- KVD900 treated attacks achieved symptom relief more quickly: p<0.0001*
  - Patient Global Impression of Change (PGI-C)
  - Primary endpoint Ruconest phase 3
- Median time to symptom relief
  - KVD900 1.6 hours
  - Placebo 9 hours

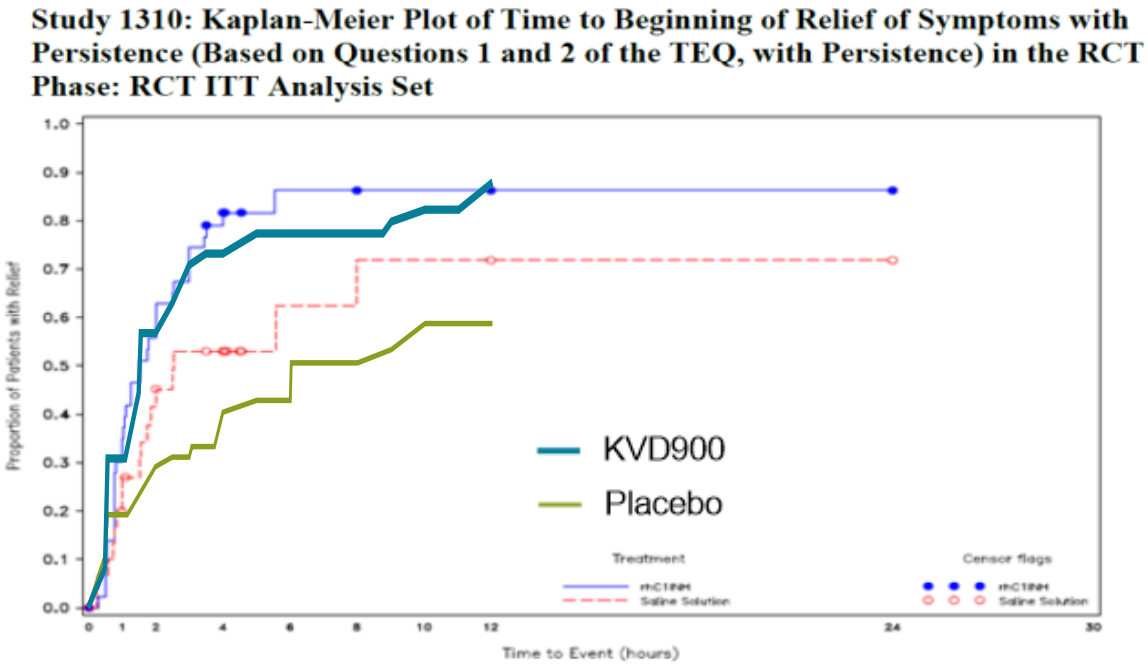


Symptom relief defined as attack rated a little better or higher for 2 consecutive time points

*Gehan's Generalized Wilcoxon Test

Symptom Relief Compared to Ruconest (rC1-INH)

- Time to symptom relief
  - KVD900 1.6 hours
  - Ruconest 1.5 hours
- Ruconest is administered by intravenous injection



Ruconest data from Charles M. Maplethorpe, MD, PhD. Clinical Reviewer. Summary Basis of Approval, Recombinant C1 Esterase Inhibitor, STN: 125495/0.
The results of the trials for KVD900 and Ruconest may not be directly comparable, as they are not from a single head-to-head clinical trial.

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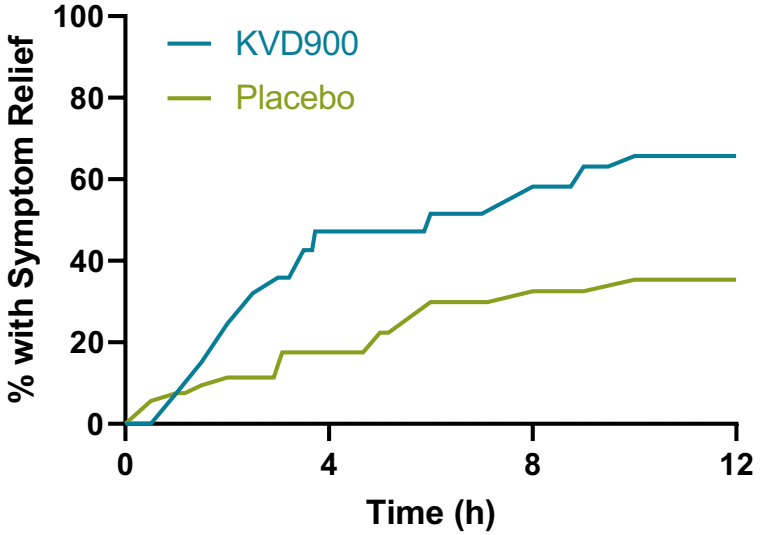
KVD900 Speeds Symptom Relief: Composite VAS

- KVD900 treated attacks achieved symptom relief more quickly: p<0.0001*
  - Composite VAS (abdominal pain, skin pain and skin swelling)
- Median time to onset of symptom relief
  - KVD900 6 hours
  - Placebo >12 hours**



Symptom relief defined as 50% reduction in composite VAS score for three consecutive time points

*Gehan's Generalized Wilcoxon Test; **Data censored at 12 hours

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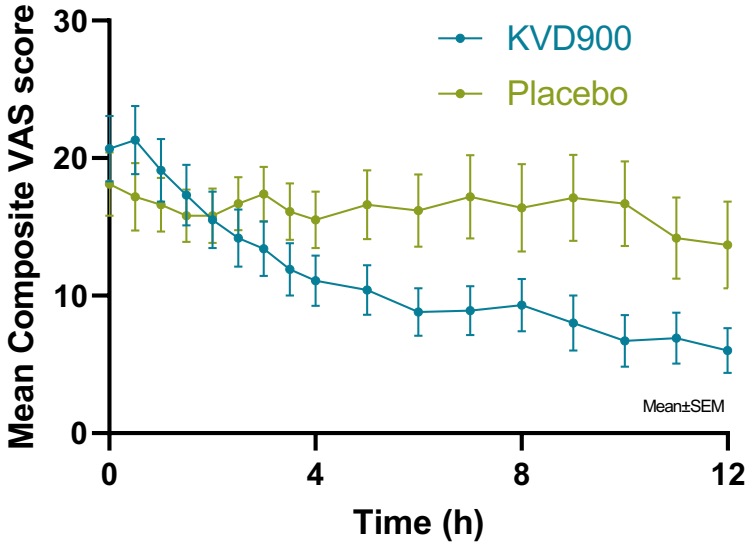
KVD900 Improves Cumulative Severity by Composite VAS

- Reduced cumulative severity by composite VAS over 12 hours (p=0.0008*) and 24 hours (p=0.0005*)
  - Time- and baseline-adjusted AUC
  - Excludes assessments Post-Rescue



*ANOVA with fixed effects of treatment, sequence and HAE Attack (1st or 2nd) and subject nested within sequence as a random effect.

KVD900 Compared to Firazyr (icatibant)

- KVD900 mean baseline VAS 20.7mm
- Icatibant baseline VAS ~40mm
- Early intervention with KVD900 leads to lower severity
  - Key benefit of oral therapy
  - Consistent with modern HAE treatment recommendations

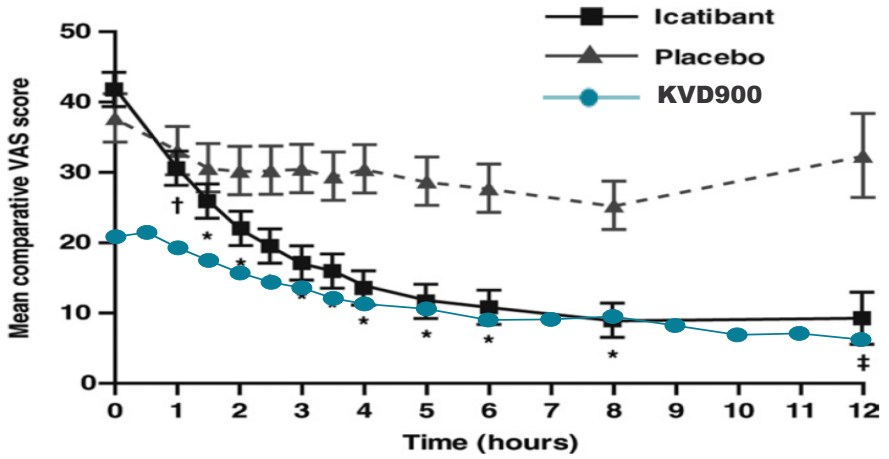


Figure 3. Mean composite VAS-3 score for the first 12 hours after treatment (*nonlaryngeal ITT population*). $^{*}P \leq .001$; $^{\dagger}P = .003$; $^{\ddagger}P = .041$, vs placebo. Sixteen subjects (icatibant $n = 5$; placebo $n = 11$) who had not achieved relief by hour 8 had nonmissing data for hour 12.

Firazyr data from Lumry et al., Ann Allergy Asthma Immunol. 2011;107:529 –537. The results of the trials for KVD900 and Firazyr may not be directly comparable, as they are not from a single head-to-head clinical trial.

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Summary of Topline Outcomes

	KVD900	Placebo	p value
Rescue			
Use of rescue within 12h*	15.1%	30.2%	0.001
Use of rescue within 24h*	20.8%	39.6%	0.0005
PGI-S			
Time to Worsening or rescue within 12h*	>12h***	3.0h	<0.0001
Cumulative Symptom Relief over 12h**			0.0024
Cumulative Symptom Relief over 24h**			0.0036
PGI-C			
Time to Symptom Relief within 12h*	1.6h	9.0h	<0.0001
Cumulative Symptom Relief over 12h**			0.005
Cumulative Symptom Relief over 24h**			0.0036
VAS			
Time to Symptom Relief within 12h*	6.0h	>12h***	<0.0001
Cumulative Symptom Relief over 12h**			0.0008
Cumulative Symptom Relief over 24h**			0.0005

**Gehan's Generalized Wilcoxon Test; **ANOVA with fixed effects of treatment, sequence and HAE Attack (1st or 2nd) and subject nested within sequence as a random effect; ***Data censored at 12 hours*

Related Treatment Emergent Adverse Events*

	Part 1 KVD900 N=68	Part 2 KVD900 N=58	Part 2 Placebo N=55
Total (events/patients)	8 / 5 (7.4%)	3 / 3 (5.2%)	2 / 2 (3.6%)
Gastrointestinal Disorders	1 / 1 (1.5%)	1 / 1 (1.7%)	1 / 1 (1.8%)
Abdominal Pain Upper	-	1 / 1 (1.7%)	-
Anal Incontinence	-	-	1 / 1 (1.8%)
Nausea	1 / 1 (1.5%)	-	-
General Disorders	1 / 1 (1.5%)	-	-
Malaise	1 / 1 (1.5%)	-	-
Musculoskeletal Disorders	1 / 1 (1.5%)	1 / 1 (1.7%)	-
Back Pain	1 / 1 (1.5%)	1 / 1 (1.7%)	-
Nervous System Disorders	3 / 3 (4.4%)	1 / 1 (1.7%)	1 / 1 (1.8%)
Dizziness	1 / 1 (1.5%)	-	-
Headache	2 / 2 (2.9%)	1 / 1 (1.7%)	1 / 1 (1.8%)
Vascular Disorders	2 / 2 (2.9%)	-	-
Flushing	2 / 2 (2.9%)	-	-

*Within 48 hours of trial drug administration

KVD900 Phase 2 Clinical Trial Conclusions

- All trial endpoints were statistically significant
  - Primary endpoint p=0.001
  - Secondary endpoints all p<0.0001
- KVD900 rapidly suppresses circulating plasma kallikrein, halts attack progression, reduces symptoms and improves patient well-being
- KVD900 enables early intervention and improved treatment outcomes
  - Efficacy profile is fast and comparable with current injectable products
  - Patients feel better and symptoms resolve quickly with KVD900
- KVD900 is generally safe and well tolerated
- Next step is FDA end of Phase 2 meeting followed quickly by Phase 3 trial initiation

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