



KalVista Pharmaceuticals Reports Positive Results for KVD900 Phase 2 Demonstrating Statistically and Clinically Significant Responses Across All Endpoints as an Oral On-Demand Treatment for HAE Attacks

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– Oral KVD900 Primary Endpoint Shows Only 15% Use of Rescue Medication in Patients with Hereditary Angioedema (HAE) –

– KVD900 Generally Safe and Well-Tolerated –

– Conference Call to Discuss Trial Results Today at 8:30 a.m. ET –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Feb. 9, 2021-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, today announced positive topline data from a Phase 2 clinical trial demonstrating statistically and clinically significant efficacy of KVD900 as an oral on-demand treatment for hereditary angioedema (HAE) attacks.

"We are very excited to share this positive data which shows that KVD900 is the first oral therapy to achieve clinical efficacy results comparable to current injectable therapies, while also demonstrating a promising safety and tolerability profile. The rapid onset of symptom relief and significant reduction in the use of rescue medication show that patients can confidently take KVD900 at the earliest signs of an attack and avoid the burden and discomfort of injections," said Andrew Crockett, Chief Executive Officer of KalVista. "We look forward to working with regulatory agencies to bring the many advantages of KVD900 to patients as quickly as possible. In parallel, we remain committed to advancing our oral HAE franchise, with submission of an IND this quarter for KVD824 as a prophylactic treatment and ongoing preclinical work on our oral Factor XIIa program."

The KVD900 Phase 2 was a randomized, double-blind, placebo-controlled, crossover clinical trial evaluating the efficacy and safety of KVD900 as an on-demand treatment for hereditary angioedema (HAE) attacks. The trial completed 53 adult HAE patients from 25 clinical sites in the United States and Europe. The trial included type 1 and type 2 HAE patients who had three attacks in 90 days prior to enrollment. During the first part of the two-part trial, patients received a single, open label 600 mg dose of KVD900 to evaluate pharmacokinetic and pharmacodynamic properties. All patients then entered part two of the trial, which was a double-blind investigation to assess the efficacy of KVD900 compared to placebo in a two-attack, crossover design. During part two of the trial, patients took a single dose of 600 mg of KVD900 or placebo within one hour of the start of the first attack. The second attack was dosed with the alternative crossover treatment. Patients were able to use their conventional rescue treatment, as required.

Topline Phase 2 Results

- Attacks treated with KVD900 significantly reduced use of rescue ($p=0.001$), with 15% of KVD900 treated attacks rescued compared to 30% on placebo at 12 hours.
 - This efficacy benefit of KVD900 was maintained at 24 hours ($p=0.0005$).
- KVD900 significantly reduced time to onset of symptom relief ($p<0.0001$) on a Patient Global Impression of Change scale (PGI-C), with a median time of 1.6 hours versus 9 hours for attacks treated with placebo.
- KVD900 treated attacks achieved symptom relief more quickly than placebo treated attacks ($p<0.0001$) when assessed using a composite Visual Analogue Scale (VAS) score.
- Within 12 hours of oral administration, KVD900 significantly increased the number of stabilized or improved attacks when assessed by a Patient Global Impression of Severity scale (PGI-S) or use of rescue ($p<0.0001$).
- Additional exploratory endpoints were also statistically significant and favored KVD900 treatment over placebo.
- There were no serious adverse events reported in the trial and no patients withdrew due to adverse events. In the open-label phase, 8 on-treatment drug-related treatment emergent adverse event (TEAE) were experienced by 5 patients. In the crossover phase of the trial, 3 on-treatment drug-related TEAEs were experienced by 3 patients (5.2%) following administration of KVD900, and 2 on-treatment drug-related TEAEs were experienced by 2 patients (3.6%) following administration of placebo.

"Today's data show that KVD900 halts HAE attack progression and also provides rapid relief by shortening the time to symptom resolution," said Dr. Emel Aygören-Pürsün, Principal Investigator for the KVD900 Phase 2 Clinical Trial and Head of the HAE Center at the University Hospital Frankfurt. "The results are highly encouraging. For patients, easy and efficacious oral on-demand treatment of attacks is now within reach."

The Company will post a presentation with data from the Phase 2 clinical trial of KVD900 on the investors section of the company website at www.kalvista.com. The Company plans to present the full data for the KVD900 Phase 2 study at a future medical meeting.

Conference Call

KalVista will be holding a Conference Call today at 8:30 a.m. ET to discuss the KVD900 Phase 2 clinical results. The webcast can be accessed on www.kalvista.com or by dialing (833) 714-2255 (US) or (207) 823-1864 (International) and referencing ID 2429345.

About KVD900

Discovered by KalVista, KVD900 is a novel, potent, oral plasma kallikrein inhibitor and the most advanced compound in our portfolio of candidates for the treatment of hereditary angioedema (HAE). KVD900 has received a Fast Track designation from the U.S. Food and Drug Administration and an approved Pediatric Investigational Plan (PIP) from the European Medicines Agency (EMA).

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors for diseases with significant unmet need. KalVista has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). KalVista is developing KVD900 as an oral on-demand therapy for acute HAE attacks. KVD824 is in development for prophylactic treatment of HAE with an IND filing for a Phase 2 clinical trial expected in the first quarter of 2021. In addition, KalVista's oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment of HAE for patients. In DME, an intravitreally administered plasma kallikrein inhibitor, called KVD001, has completed a Phase 2 clinical trial.

For more information, please visit www.kalvista.com and follow us on Twitter [@KalVista](https://twitter.com/KalVista) and on [LinkedIn](https://www.linkedin.com/company/kalvista-pharmaceuticals).

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