UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 13, 2024

KALVISTA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	001-36830	20-0915291
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

55 Cambridge Parkway
Suite 901E
Cambridge, Massachusetts 02142
(Address of Principal Executive Offices) (Zip Code)

(857) 999-0075
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value Per Share	KALV	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On February 13, 2024, KalVista Pharmaceuticals, Inc. ("the Company") issued a corporate presentation slide deck with information including clinical data from the Company's Phase 3 KONFIDENT clinical trial (the "KONFIDENT trial").

Additionally, on February 13, 2024, the Company issued a press release announcing clinical data from the KONFIDENT trial.

A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K.

The information furnished in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On February 13, 2024, the Company announced clinical data from the KONFIDENT trial. Program updates and updated data are summarized as follows:

The KONFIDENT trial met all primary and key secondary endpoints and demonstrated a favorable safety profile. Hereditary Angioedema ("HAE") attacks treated with both 300 mg and 600 mg of sebetralstat achieved the primary endpoint of beginning of symptom relief significantly faster than placebo ($p<0.0001$ for 300 mg, $p=0.0013$ for 600 mg). The median time to beginning of symptom relief was 1.61 hours with sebetralstat 300 mg (CI 1.28, 2.27), 1.79 hours with sebetralstat 600 mg (CI 1.33, 2.27) and 6.72 hours with placebo (CI 2.33, >12).

Consistent with previous trials, sebetralstat was well-tolerated, with a safety profile similar to placebo. The KONFIDENT trial had no patient withdrawals due to any adverse event and no treatment-related serious adverse events.

Primary and key secondary endpoints were analyzed in a fixed, hierarchical sequence and adjusted for multiplicity. Key secondary endpoints showed:

- HAE attacks treated with sebetralstat 300 mg or 600 mg achieved a significantly faster time to a reduction in attack severity from baseline, compared to placebo ($p=0.0036$ for 300 mg and $p=0.0032$ for 600 mg)
- HAE attacks treated with sebetralstat 300 mg or 600 mg demonstrated a significantly faster time to complete attack resolution, compared to placebo ($p=0.0022$ for 300 mg and $p<0.0001$ for 600 mg)

The Company plans to present Phase 3 data for the KONFIDENT trial at the annual meeting of the American Academy of Allergy Asthma and Immunology on February 25, 2024.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation
99.2	Press Release, dated February 13, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein that do not describe historical facts, including, but not limited to, statements we make regarding our business plans and objectives, timing and success of our planned nonclinical and clinical development activities, timing and results of nonclinical studies and clinical trials, efficacy and safety profiles of our product candidates, any expectations about safety, efficacy of sebetralstat and our ability to obtain regulatory approvals for sebetralstat and other candidates in development, the ability of sebetralstat to treat hereditary angioedema (HAE), the potential therapeutic benefits and economic value of our product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, our ability to protect intellectual property and the impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, and geopolitical conflicts, including the conflicts in Ukraine and the Middle East, on our business and operations . Such risks and uncertainties include, among others, the risks identified in the Company's filings with the Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K for the year ended April 30, 2023, filed with the SEC on July 10, 2023, and other reports as filed with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made or to reflect the occurrence of unanticipated events.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KALVISTA PHARMACEUTICALS, INC.

By: /s/ Benjamin L. Palleiko
Benjamin L. Palleiko
President, Chief Business Officer and Chief Financial Officer

Date: February 13, 2024

Exhibit 99.1

KalVista Pharmaceuticals

Corporate Overview

February 2024

Forward-Looking Statements

This presentation and the accompanying oral commentary contain forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or other comparable terminology. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information business plans and objectives, timing and success of our planned nonclinical and clinical development activities, timing and results of nonclinical studies and clinical trials, efficacy and safety profiles of our product candidates, any expectations about safety, efficacy of sebetralstat and our ability to obtain regulatory approvals for sebetralstat and other candidates in development, the ability of sebetralstat to treat hereditary angioedema (HAE), the potential therapeutic benefits and economic value of our product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, our ability to protect intellectual property and the impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, and geopolitical conflicts, including the conflicts in Ukraine and the Middle East, on our business and operations.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that are described under the heading "Risk Factors" contained in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") and other documents we file from time to time with the SEC, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Company Highlights

- Discovery, development, and commercialization of oral, small molecule protease inhibitors
- Lead program Sebetralstat for on-demand treatment of rare disease hereditary angioedema (HAE)
- Data from Phase 3 KONFIDENT trial announced February 2024; met all primary and secondary endpoints, with favorable safety profile; NDA expected H1 2024
- Sebetralstat would be first oral option in $900 million on-demand HAE market and has potential to transform treatment of the disease and the entire $2.7 billion market
- Preclinical oral Factor XIIa program focused on HAE and additional indications
- All programs internally developed, with full rights and IP protection into the 2040's
- Funded into 2025 with $103 million at October 31, 2023

Program Portfolio

Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Status
Sebetralstat	On-Demand HAE	KONFIDENT (trial completed)				Data reported; NDA mid-2024
		KONFIDENT-S (Open-Label Extension)				Trial ongoing
		Orally Disintegrating Tablets				Advancing to sNDA as lifecycle extension
Oral Factor XIIa	HAE Prophylaxis					Discovery and Optimization
Oral Factor XIIa	Thrombosis, inflammation					Future opportunities under evaluation

KalVista Pharmaceuticals

Hereditary Angioedema (HAE)

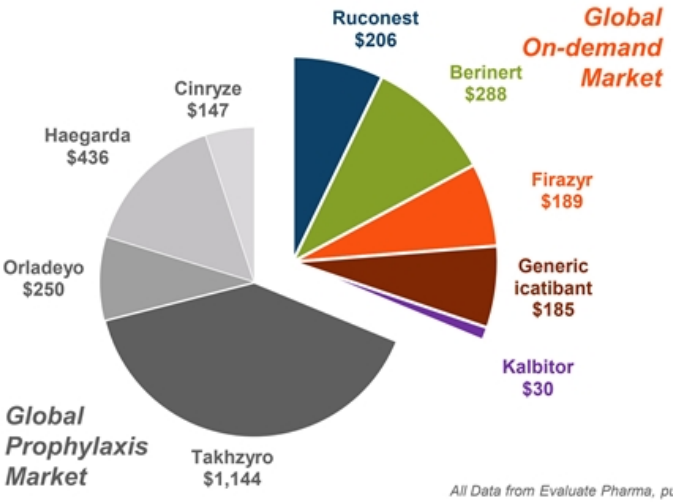
Hereditary Angioedema (HAE)

- Genetic condition causing painful and pronounced swelling in various parts of the body
  - Primarily caused by defect in C1 inhibitor activity, which leads to uncontrolled plasma kallikrein activation and bradykinin release
- Orphan disease: incidence 1 in 10,000 to 1 in 50,000[1]
  - 6,500 – 8,000 patients in US; similar in EU
  - Incidence consistent worldwide; patients have average of ~2 attacks per month
- Approved on-demand therapies are injected or infused - high unmet need for efficacious and safe oral administration
  - On-demand + prophylaxis is majority share in US, although burden of treatment remains high
  - On-demand only is majority share ex-US

[1] *www.haei.org*

On-Demand is $900 Million Market, With Growth Potential

On-demand was $900 Million revenue market in 2022



At branded prices, US on-demand market alone would be $1+ billion

US units 2022

Ruconest	29,200
Berinert	35,400
Firayzr	10,500
Gx icatibant	49,300
Total units	124,400

Firazyr WAC/dose: $10,800

All Data from Evaluate Pharma, public filings and certain Company estimates.

KalVista Pharmaceuticals

Sebetralstat: HAE On-Demand Therapy

Welcome to the New Era of HAE

KONFIDENT™

Positive topline results from the largest clinical trial conducted in HAE

We believe SEBETRALSTAT offers the promise to be the foundational HAE treatment

- **On-demand with or without prophylaxis**
- **Any attack location or severity**
- **Adults and adolescents**

Unmet Need In HAE Is Underappreciated

The goal of treatment is to minimize compromises in lifestyle, but attacks still cause anxiety and impact quality of life

Anxiety and depression are common in people living with HAE

~50% of people taking prophylaxis continue to experience HAE attacks

96% of people on prophylaxis feel they must change their plans for the day when an attack occurs[3]

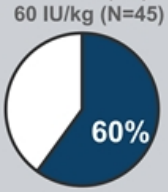
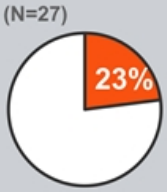
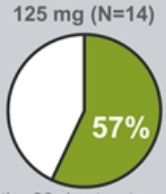
People living with HAE prefer to treat at home to avoid treating attacks in public

People typically delay injectable treatment for hours and studies show more than 40% of attacks aren't treated at all[1,2,4]

[1]Maurer M, et al. Hereditary Angioedema Attacks Resolve Faster and Are Shorter after Early Icatibant Treatment. PLoS ONE. 2013;8(2):e53773. [2]Longhurst H J et al. Real-world outcomes in hereditary angioedema: first experience from the Icatibant Outcome Survey in the United Kingdom Allergy Asthma Clin Immunol. 2018;14: 28. [3]Remaining Burden of Hereditary Angioedema (HAE) Attacks Despite Modern Long-term Prophylaxis Stephen Betschel, Sally van Kooten, Markus Heckmann, Sherry Danese, Ledia Goga,Teresa Caballero; EAACI 2023 Hybrid Congress. [4]Banerji A, et al. Allergy Asthma Proc. 2015;36(3):213-7. doi: 10.2500/aap.2015.36.3824

Patients on LTP Still Have Attacks

Proportion of patients that experienced attacks on approved LTP in placebo-controlled trials

Treatment	C1-INH (SC) 60 IU/kg[1]	Lanadelumab 300 mg Q2W[2]		Berotralstat 125 mg[3]
Trial design	Randomized, placebo-controlled crossover phase 3 trial (16 weeks)	Randomized, double-blind, parallel-group, placebo-controlled phase 3 trial (26 weeks)		Randomized, double-blind, parallel-group, dose-response phase 2 trial[4] (28 days)
Proportion of patients experiencing attacks during observed period	**C1-INH (SC) 60 IU/kg (N=45)**	**Lanadelumab 300 mg Q2W (N=27)**		**Berotralstat 125 mg (N=14)**
	 Entire 16-day treatment period	 Entire 26-week treatment period	 Steady state (days 70-182)	 Entire 28-day treatment period

Although LTP reduces attack frequency, many patients continue to have attacks and require ready access to effective on-demand treatment

References: 1. Longhurst H, et al. *N Engl J Med*. 2017;376(12):1131-1140. 2. Banerji A, et al. *JAMA*. 2018;320(20): 2108-2121. 3. Aygören-Pürsün E, et al. *N Engl J Med*. 2018;379:352-362. 4.Not reported in phase 3 trial.

The Sebetralstat Treatment Vision

EARLY

- Patients empowered to **treat early** - at **first recognition** of attack
- Halt progression of swelling at **earliest stages**

ALL ATTACKS

- Patients **able to treat all attacks**, since it is impossible to predict which ones will escalate in severity or migrate to other anatomic locations, including the larynx
- Current **barriers to treatment are removed** including pain and inconvenience associated with parenteral therapies

EASE OF USE

- Sebetralstat dosing is **simple** with easy-to-take **tablets**
- Patients can **easily carry, store and access** anytime, anywhere
- **Quick-dissolving oral disintegrating tablet** (ODT), a potential future advancement


KalVista
Pharmaceuticals
Topline Data from
Phase 3 KONFIDENT Trial

Sebetralstat Phase 3 Trial Design

KONFIDENT™
SEBETRALSTAT CLINICAL TRIAL

- Double blind crossover trial assessing 300 mg and 600 mg sebetralstat versus placebo
- Primary endpoint: Time to beginning of symptom relief using PGI-C
- At least 90% powered to detect treatment differences vs placebo
- Each patient treats up to 3 attacks anytime, anywhere
  - One with each treatment in a randomized, blinded sequence
  - Patients take up to two doses per attack

Primary endpoint:
- Time to beginning of symptom relief (PGI-C)

Key secondary endpoints:
- Time to improvement (PGI-S)
- Time to resolution (PGI-S)

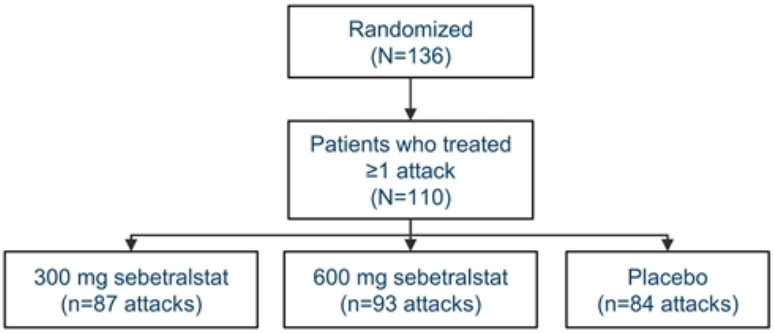
Key Differences in Design Between the Sebetralstat Phase 2 and Phase 3 KONFIDENT Trials

	Phase 2 Trial	Phase 3 KONFIDENT Trial
Primary endpoint	Time to use of conventional attack treatment within 12 hours after study drug administration	PGI-C: TOSR defined as at least “a little better” (≥2 time points in a row) within 12 hours after study drug administration
Population	Adults (≥18 years of age) with HAE type 1 or 2	Adolescents and adults (≥12 years of age) with HAE type 1 or 2
LTP	No LTP allowed	Stable LTP eligible to participate (excluding androgens and tranexamic acid)
Attack locations	Peripheral, abdominal	All attack locations
Attack severity	Mild to moderate	Mild to very severe
Attack eligibility	Patient required to notify trial physician to confirm attack eligibility before dosing	Patient not required to call physician to confirm attack eligibility before dosing
Treatment	Single dose of study drug with minimum 48-hour washout between attacks	Up to 2 doses of study drug permitted as treatment for a single attack

Enrollment and Demographics

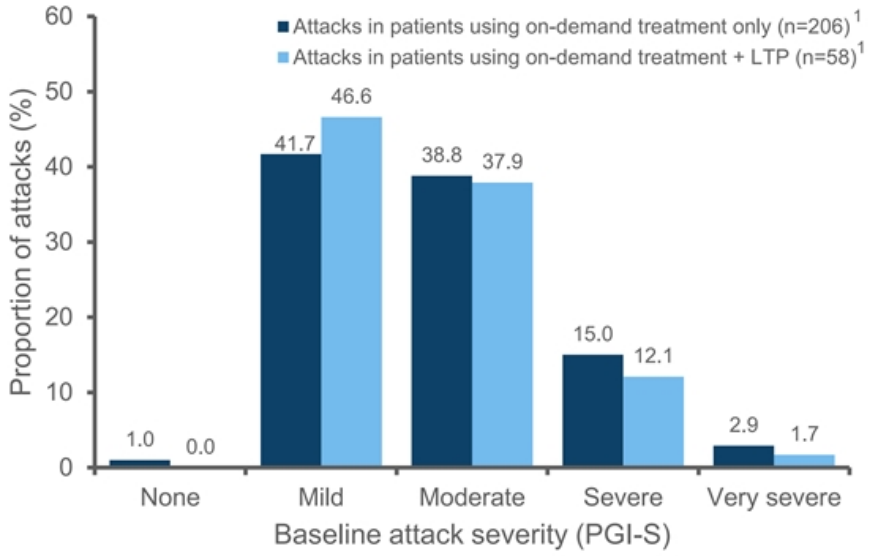
	Total (N=110)
Age (years)	
Mean (SD)	37.7 (15.0)
Median (min, max)	39.5 (13, 74)
Age (category), n (%)	
18+	97 (88.2)
12-17	13 (11.8)
Sex, n (%)	
Female	66 (60.0)
Male	44 (40.0)
BMI (kg/m^2)	
Mean (SD)	27.4 (6.3)
Median (min, max)	26.2 (18.2, 45.6)
Geography, n (%)	
Europe	58 (52.7)
US	34 (30.9)
Asia/Pacific[a]	18 (16.4)

Data on file



- 10 patients discontinued from the trial
- No patients withdrew due to an AE

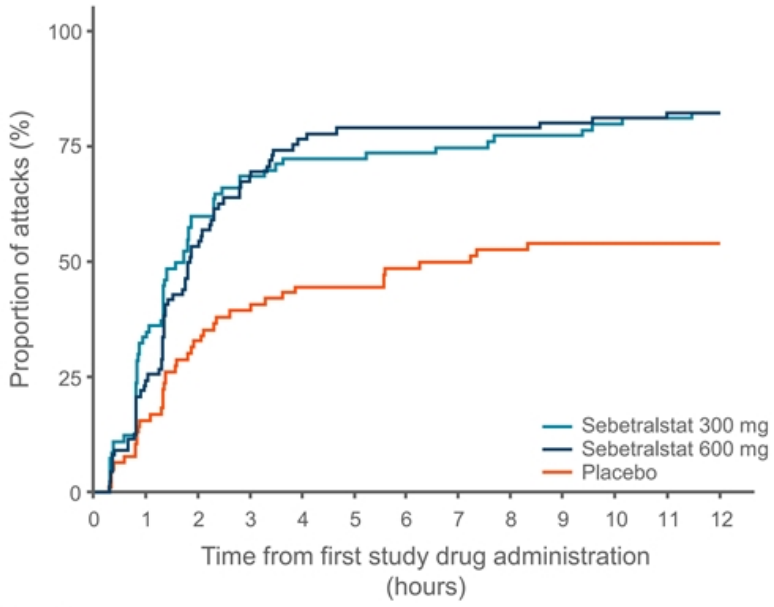
Comparable Attack Severity in Patients Using LTP



	Total (N=110)
Current treatment regimen, n (%)	
On-demand only	86 (78.2)
On-demand + LTP	24 (21.8)
Berotralstat	11 (10.0)
Lanadelumab	8 (7.3)
C1INH	5 (4.5)

1. Baseline severity for 1 attack in each group not reported. Data on file.

Primary Endpoint: Time to Beginning of Symptom Relief



Data on file

- Time to beginning of symptom relief was statistically significantly faster vs placebo for
  - 300 mg (p<0.0001)
  - 600 mg (p=0.0013)
- Median time (95% CI) to beginning of symptom relief was
  - 1.61 h (1.28, 2.27) for 300 mg
  - 1.79 h (1.33, 2.27) for 600 mg
  - 6.72 h (2.33, >12) for placebo

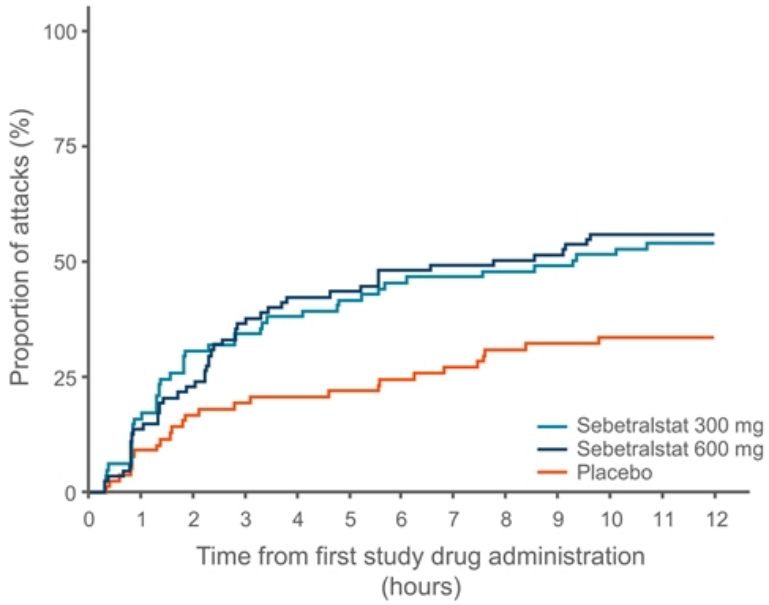
Primary Endpoint: Consistent Treatment Effect Across Subgroups

- Trial was not powered to statistically test treatment effect within subgroups
- Treatment effect with sebetralstat was consistent across subgroups including
  - Sex, race, age, geographic region, HAE subtype, time to treatment, attack location, attack severity
- Importantly, consistent treatment effect was also observed in subgroups not previously studied with sebetralstat

Time to beginning of symptom relief	Sebetralstat 300 mg		Sebetralstat 600 mg	
Subgroup	**n**	**Median (95% CI)**	**n**	**Median (95% CI)**
On-demand with LTP	19	1.85 (0.79, 3.47)	21	2.03 (0.78, 3.41)
Adolescent	10	2.27 (0.28, 9.36)	11	2.16 (0.33, 9.53)
Severe/very severe	14	1.40 (0.78, 2.78)	18	1.50 (0.79, 2.27)

Data on file

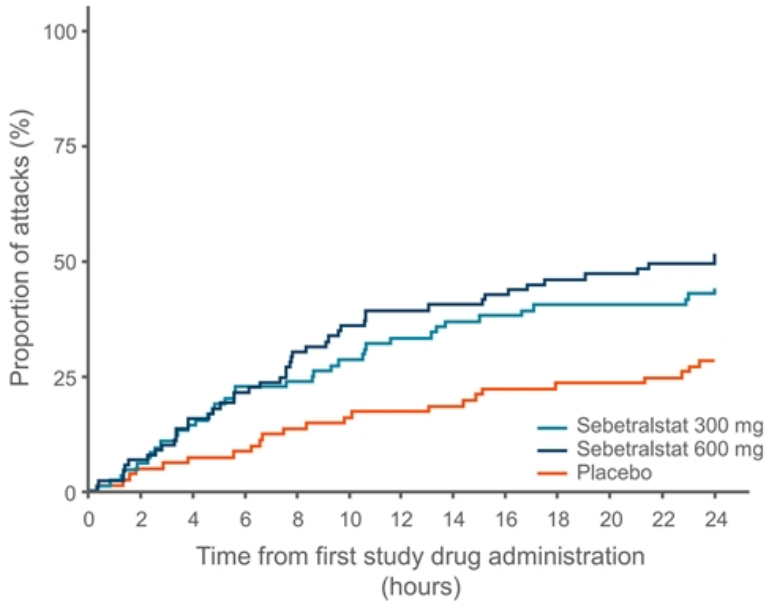
Key Secondary: Time to Reduction in Attack Severity



Data on file

- Time to reduction in attack severity was statistically significantly faster vs placebo for
  - 300 mg (p=0.0036)
  - 600 mg (p=0.0032)
- Median time (95% CI) to reduction in attack severity was:
  - 9.27 h (4.08, >12) for 300 mg
  - 7.75 h (3.27, >12) for 600 mg
  - >12 h (>12, >12) for placebo

Key Secondary: Time to Complete Attack Resolution



Data on file

- Time to complete attack resolution was statistically significantly faster vs placebo for
  - 300 mg (p=0.0022)
  - 600 mg (p<0.0001)
- Proportion achieving complete attack resolution within 24 hours was:
  - 44.0% for 300 mg
  - 51.7% for 600 mg
  - 28.4% for placebo

On-treatment Related Adverse Events

System organ class preferred term, n (%) E	Sebetralstat 300 mg (n=86)	Sebetralstat 600 mg (n=93)	Placebo (n=83)
Gastrointestinal disorders	1 (1.2) 1	1 (1.1) 1	1 (1.2) 1
Dyspepsia	1 (1.2) 1	0	0
Nausea	0	1 (1.1) 1	1 (1.2) 1
General disorders and administration site conditions	1 (1.2) 1	0	0
Fatigue	1 (1.2) 1	0	0
Nervous system disorders	0	1 (1.1) 1	2 (2.4) 2
Headache	0	1 (1.1) 1	1 (1.2) 1
Dysgeusia	0	0	1 (1.2) 1
Reproductive system and breast disorders	0	0	1 (1.2) 1
Menstruation irregular	0	0	1 (1.2) 1
Skin and subcutaneous tissue disorders	0	0	1 (1.2) 1
Rash	0	0	1 (1.2) 1

E, number of events; TEAE, treatment-emergent adverse events. On-treatment AEs were defined as TEAEs that start within 3 days of administering the final dose of study drug for an attack. At each level of patient summarization, a patient is counted once if the patient reported one or more events. Adverse events were coded using MedDRA, Version 26.0.
See Table 14.3.1.3.2 – Safety Set. Data on file.

Results in the Sebetralstat Phase 2 Trial and the Phase 3 KONFIDENT Trial

		Phase 2 Trial		Phase 3 KONFIDENT Trial		
Population		Adults 100% | adolescents 0%		Adults 88.2% | adolescents 11.8%		
LTP		On-demand only: 100% On-demand + LTP: Not allowed		On-demand only: 78.2% On-demand + LTP: 21.8%		
Attack locations	**Peripheral** **Abdominal**	68.1% 26.5%		56.1% 43.2%		
Attack severity	**Mild** **Moderate** **Severe** **Very severe**	50.4% 45.1% Not allowed Not allowed		42.8% 38.6% 14.4% 2.7%		
Dose		Sebetralstat 600 mg	Placebo	Sebetralstat 300 mg	Sebetralstat 600 mg	Placebo
Time to administration		30 minutes		41 minutes		
Median time to beginning of symptom relief		1.6 h	9.0 h	1.61 h	1.79 h	6.72 h
Second dose		Not allowed	Not allowed	38.4%	41.1%	55.4%
Use of conventional treatment within 12 h		15.1%	30.2%	13.8%	8.6%	25.0%

Data on file

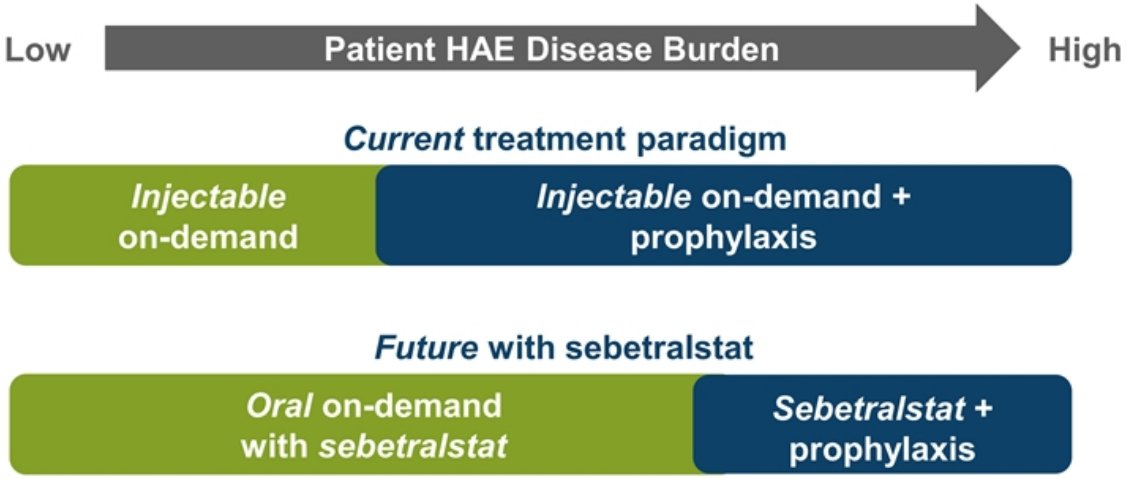
Update: KONFIDENT-S Open-Label Extension

- Trial to evaluate the long-term safety of sebetralstat
- As of February 2, 2024
  - More than 110 patients enrolled
  - More than 640 attacks treated
- Median time to treatment: 10 minutes
- All attack locations well represented, including 14 laryngeal attacks treated to date

Sebetralstat Halts the Attack When Today's Patients are Still Deciding Whether to Treat

1. Firazyr (icatibant). Package insert. Lexington, MA: Shire Orphan Therapies, Inc; 2011. 2. Data on file.

Sebetralstat Can Become the Foundational HAE Therapy



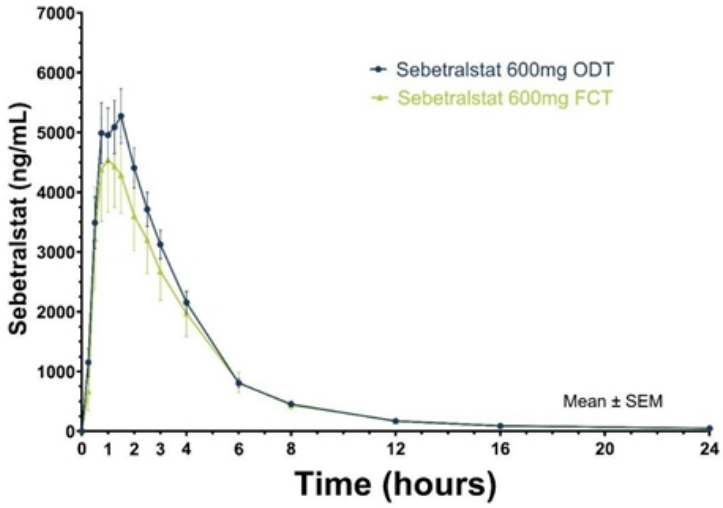
Sebetralstat Can Become the Foundational HAE Therapy

Market Share	Increased Treatment	Prophy ⟶ On-Demand	Future Indications
			
✓ Convert current on-demand market, including prophylaxis patients, who still experience attacks ✓ Branded pricing	✓ ~40% of attacks are untreated, including for prophylaxis patients[1] ✓ More attacks will ultimately be treated for both prophylaxis and on-demand patients	✓ Patients may switch from prophylaxis to on-demand, seeking an efficacious and safe oral option ✓ More cost effective for many prophylaxis patients	✓ Plasma kallikrein mediated normal C1-INH angioedema ✓ Short-term prophylaxis ✓ Pediatrics 2-11

[1]*Banerji A, et al. Allergy Asthma Proc. 2015;36(3):213-7. doi: 10.2500/aap.2015.36.3824*

Orally Disintegrating Tablet (ODT): A Future Enhancement

- ODT increases ease of dosing for patients - in particular, pediatrics and those with difficulty swallowing
- Phase 1 data shows similar pharmacokinetics to current film-coated tablets (FCT)
- Regulatory plan agreed with FDA for sNDA filing



KalVista Pharmaceuticals

Factor XIIa

Factor XIIa is an Attractive Drug Target

- Factor XIIa (FXIIa) activates the kallikrein kinin system
  - Generates plasma kallikrein, leading to uncontrolled bradykinin release in HAE
  - FXIIa and plasma kallikrein inhibitors selectively block bradykinin generated by the plasma kallikrein kinin system, unlike bradykinin receptor antagonists
- FXIIa inhibitory antibody has been shown clinically to reduce HAE attack frequency[1]
  - At least as efficacious as approved therapies against other targets
  - No known chronic safety implications
- KalVista is developing oral Factor XIIa inhibitors
  - Initially for HAE, but also implicated in other inflammatory and thrombotic conditions

1. Banerji et al JAMA 2018, 2Craig et al Lancet 2023

KalVista Value Proposition

- Data from Phase 3 KONFIDENT trial announced February 2024; met all primary and secondary endpoints, with favorable safety profile; NDA expected H1 2024
- Sebetralstat would be first oral option in $900 million on-demand HAE market and has potential to transform treatment of the disease and the entire $2.7 billion market
- Oral FXIIa inhibitor program future development opportunity in both HAE prophylaxis and other indications
- All programs internally developed, with full rights and IP protection into the 2040's
- Funded into 2025

KalVista Pharmaceuticals

NASDAQ: KALV

KalVista Pharmaceuticals Reports Phase 3 KONFIDENT Trial Meets All Endpoints for Sebetralstat as First Oral On-demand Therapy for Hereditary Angioedema

– Sebetralstat 300 mg achieved beginning of symptom relief in 1.6 hours –

– Safety profile comparable to placebo –

– On track for submission of new drug application to U.S. FDA in the first half of 2024 –

– Conference call to discuss trial results today at 8:30 a.m. ET –

CAMBRIDGE, Mass. & SALISBURY, England – February 13, 2024 – 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 results from the phase 3 KONFIDENT clinical trial demonstrating statistically and clinically significant efficacy of sebetralstat as oral on-demand therapy for hereditary angioedema (HAE). KONFIDENT was the largest and most representative trial ever conducted in HAE, and included adolescents, patients using long-term prophylaxis, and all attack severities and locations.

The clinical trial met all primary and key secondary endpoints and demonstrated a favorable safety profile. HAE attacks treated with both 300 mg and 600 mg of sebetralstat achieved the primary endpoint of beginning of symptom relief significantly faster than placebo ($p<0.0001$ for 300 mg, $p=0.0013$ for 600 mg). The median time to beginning of symptom relief was 1.61 hours with sebetralstat 300 mg (CI 1.28, 2.27), 1.79 hours with sebetralstat 600 mg (CI 1.33, 2.27) and 6.72 hours with placebo (CI 2.33, >12).

Consistent with previous studies, sebetralstat was well-tolerated, with a safety profile similar to placebo. There were no patient withdrawals due to any adverse event and no treatment-related serious adverse events (SAEs) were observed. Treatment-related adverse event rates were 2.3% for 300 mg sebetralstat, 2.2% for 600 mg sebetralstat, and 4.8% for placebo.

“We are thrilled to announce positive phase 3 results for the KONFIDENT trial, which we believe position sebetralstat to become the first oral, on-demand therapy for the treatment of HAE. These clinically meaningful results represent a potentially significant advance for people living with HAE. If approved, sebetralstat may offer a compelling treatment option for patients and their caregivers given the long-standing preference for an effective and safe oral therapy that provides rapid symptom relief for HAE attacks,” said Andrew Crockett, Chief Executive Officer of KalVista.

Mr. Crockett added, “Most importantly, we want to thank the people living with HAE, their families, and the investigator teams around the world who supported KONFIDENT and made it the largest clinical trial ever conducted in HAE. We look forward to submitting a new drug application for sebetralstat to the U.S. FDA in the first half of 2024 and in the EU and Japan later this year.”

Primary and key secondary endpoints were analyzed in a fixed, hierarchical sequence and adjusted for multiplicity. Key secondary endpoints showed:

- Attacks treated with sebetralstat 300 mg or 600 mg achieved a significantly faster time to a reduction in attack severity from baseline, compared to placebo ($p=0.0036$ for 300 mg and $p=0.0032$ for 600 mg)
- Attacks treated with sebetralstat 300 mg or 600 mg demonstrated a significantly faster time to complete attack resolution, compared to placebo ($p=0.0022$ for 300 mg and $p<0.0001$ for 600 mg)

“These highly encouraging phase 3 results show that sebetralstat provided rapid symptom relief in a broad HAE population that reflects my clinical practice,” said Danny Cohn, MD, PhD, Department of Vascular Medicine, University of Amsterdam, and principal investigator for the KONFIDENT phase 3 trial. “If approved, sebetralstat could transform the management of HAE.”

“With no new on-demand therapies for HAE approved for nearly a decade, having a safe and effective oral, on-demand treatment for HAE attacks could be immensely valuable in addressing unmet needs and reducing the treatment burden associated with current injectable treatments,” said Marc A. Riedl, MD, professor of medicine and clinical director, U.S. Hereditary Angioedema Association Center at the University of California, San Diego, and an investigator for the KONFIDENT phase 3 trial. “Against the backdrop of patient needs and opportunities, the results of this trial with sebetralstat are extremely encouraging for the HAE community.”

The Company plans to present phase 3 data for the KONFIDENT trial at the annual meeting of the American Academy of Allergy Asthma and Immunology (AAAAI) on February 25, 2024.

Webcast Details

KalVista will host a webcast today at 8:30am ET. In conjunction, the Company will post a presentation with data from the phase 3 KONFIDENT trial of sebetralstat on the investors section of the company website. Stockholders and other interested parties may participate in the call by following the instructions below. The live webcast can be accessed on the Event Calendar portion of the KalVista investor page. A replay will be available on the KalVista website shortly after completion of the event and will be archived for up to 30 days.

Webcast Link: https://edge.media-server.com/mmc/p/mzfxtn9e

Participant Call Link: https://register.vevent.com/register/BI9a15a8c461b94eca9b3f649b83cdec60

About the KONFIDENT Phase 3 Trial

The KONFIDENT phase 3 trial was a randomized, double blind, event-driven, crossover clinical trial evaluating the efficacy and safety of sebetralstat 300 mg and 600 mg versus placebo for the on-demand treatment of HAE. The trial enrolled a total of 136 adult and adolescent HAE patients from 66 clinical sites across 20 countries, making it the largest clinical trial ever conducted in HAE. In the trial, patients treated each eligible attack with up to two doses of study drug, and each patient could treat up to three attacks over the course of the study. The trial included type 1 and type 2 HAE patients who had at least two attacks in 90 days prior to enrollment.

About Sebetralstat

Discovered by KalVista, sebetralstat is an investigational novel, oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). Sebetralstat received Fast Track and Orphan Drug designations from the U.S. FDA, as well as Orphan Drug Designation and an approved Pediatric Investigational Plan from the European Medicines Agency (EMA).

About Hereditary Angioedema

Hereditary angioedema (HAE) is a rare genetic disease resulting in deficiency or dysfunction in the C1 esterase inhibitor (C1INH) protein and subsequent uncontrolled activation of the kallikrein-kinin system. People living with HAE experience painful and debilitating attacks of tissue swelling in various locations of the body that can be life-threatening depending on the location affected. All currently approved on-demand treatment options require either intravenous or subcutaneous administration.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors for diseases with significant unmet need. KalVista disclosed positive phase 3 data for the KONFIDENT trial for its oral, on-demand therapy sebetralstat in February 2024. The Company anticipates submitting a new drug application to the U.S. FDA for sebetralstat in the first half of 2024 and expects to file for approval in Europe and Japan later in 2024. In addition, KalVista's oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment for people living with HAE and other diseases.

For more information about KalVista, please visit www.kalvista.com.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, timing or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our Phase 3 KONFIDENT trial, and to obtain regulatory approvals for sebetralstat and other candidates in development, the success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in development to treat HAE or other diseases, and the future progress and potential success of our oral Factor XIIa program. Further information on potential risk factors that could affect our business and financial results are detailed in our filings with the Securities and Exchange Commission, including in our annual report on Form 10-K for the year ended April 30, 2023, our quarterly reports on Form 10-Q, and our other reports that we may make from time to time with the Securities and Exchange Commission. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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