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): December 18, 2024

Corvus Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37719**	**46-4670809**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

863 Mitten Road, Suite 102 Burlingame, CA	**94010**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 900-4520
Former name or former address, if changed since last report: Not applicable

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, Par Value $0.0001 per share	CRVS	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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.

On December 18, 2024, Corvus Pharmaceuticals, Inc. (the "Company") issued the press release furnished as Exhibit 99.1 hereto.

Item 8.01. Other Events.

On December 18, 2024, the Company announced interim data from the randomized, double-blind, placebo-controlled Phase 1 clinical trial evaluating soquelitinib in patients with moderate to severe atopic dermatitis. The Company also announced that Samlyn Capital, a holder of warrants to purchase 3,633,978 shares of common stock of the Company, has delivered exercise notices with respect to all of its warrants in advance of the June 30, 2025 expiration date, which is expected to result in cash proceeds to the Company of approximately $12.7 million.

Soquelitinib Interim Data from the Atopic Dermatitis Phase 1 Clinical Trial

The Company reported complete results from Cohort 1 of the trial, which includes 16 patients (12 that received soquelitinib 100 mg oral twice per day and four that received placebo) with follow up at 28 days and at 58 days. At 58 days, two patients in the soquelitinib group were not available for follow up. See Table 1 below for patient characteristics.

Table 1: Cohort 1 Patient Characteristics

	Soquelitinib (N=12)	**Placebo (N=4)**
Age, mean (range), yrs	46.3 (30–66)	50.5 (32–62)
Gender, male n (%)	7 (58.3)	4 (100)
Race/ethnicity, n (%)		
Asian	2 (16.7)	0 (0)
Black or African American	6 (50)	4 (100)
White	3 (25)	0 (0)
Hispanic or Latino	1 (8.3)	0 (0)
Baseline EASI, mean (range)	20.4 (15.0–46.6)	18.5 (14.9–24.8)
Baseline IGA, mean (range)	3.0 (2–4)	3.3 (3–4)
Prior AD therapies, n (%)		
Topical Corticosteroids	11 (91.7)	4 (100)
Systemic therapies	3 (25)	2 (50)
Concomitant topical steroids	0 (0)	1 (25)

- The mean baseline EASI and IGA scores for soquelitinib patients were 20.4 and 3.0, respectively, compared to an EASI score of 18.5 and an IGA score of 3.3 for placebo patients.
- All soquelitinib patients discontinued topical corticosteroids prior to enrollment, while one placebo patient continued topical corticosteroid treatment. All patients, except the one placebo, discontinued topical corticosteroids for at least 27 days prior to enrolling in the study.
- Cohort 1 included a high proportion of African American patients: 50% of the soquelitinib group and 100% of the placebo group. African Americans with atopic dermatitis are known to have a less favorable prognosis compared to other patient populations.

Cohort 1 Efficacy Data

The cohort 1 EASI and IGA scores are shown in Table 2 below.

- EASI scores at 28-day and 58-day follow-up demonstrate a favorable effect of soquelitinib treatment compared to placebo.
- The soquelitinib mean EASI score reduction was 55.9% at 28 days (n=12) compared to mean EASI reduction of 27.0% in placebo. At day 58, continued improvement in the soquelitinib group was seen with mean EASI reduction of 69.1% (n=10) compared to mean EASI reduction of 19.1% for the placebo group.
- At day 28, in the soquelitinib group, nine of 12 patients achieved EASI 50; three of 12 achieved EASI 75 and one of 12 achieved EASI 90. Three of 12 patients achieved IGA 0 or 1. In the placebo group, two of four patients achieved EASI 50 and no patients achieved EASI 75, EASI 90 or IGA 0 or 1.
- At day 58, in the soquelitinib group, nine of 10 patients achieved EASI 50, four of 10 achieved EASI 75 and one of 10 achieved EASI 90. Three of 10 patients achieved IGA 0 or 1. In the placebo group, one in four patients achieved EASI 50 and no patients achieved EASI 75, EASI 90 or IGA 0 or 1.
- The timing of EASI improvement in the soquelitinib group indicates that a treatment effect begins early, at eight days, and continues for the remainder of the study. (See Figures 1 and 2 below). All soquelitinib treated patients showed improvement in EASI scores.
- The small number of placebo patients demonstrates a variable course over the treatment period with no substantial change over the 58-day period.

Table 2: Cohort 1 Efficacy Results

	4 week (Day 28)		**8 week (Day 58)**	
	Placebo (N=4)	**Soquelitinib (N=12)**	**Placebo (N=4)**	**Soquelitinib (N=10)**
Change EASI Mean % Reduction	27.0	55.9	19.1	69.1
EASI 50 (%pts)	50	75	25	90
EASI 75 (%pts)	0	25	0	40
EASI 90 (%pts)	0	8	0	10
IGA 0 or 1 (%pts)	0	25	0	30

Figure 1: Mean EASI Score Change from Baseline (%) for Soquelitinib Treatment Group (N=12 at day 28 and N=10 at day 58)

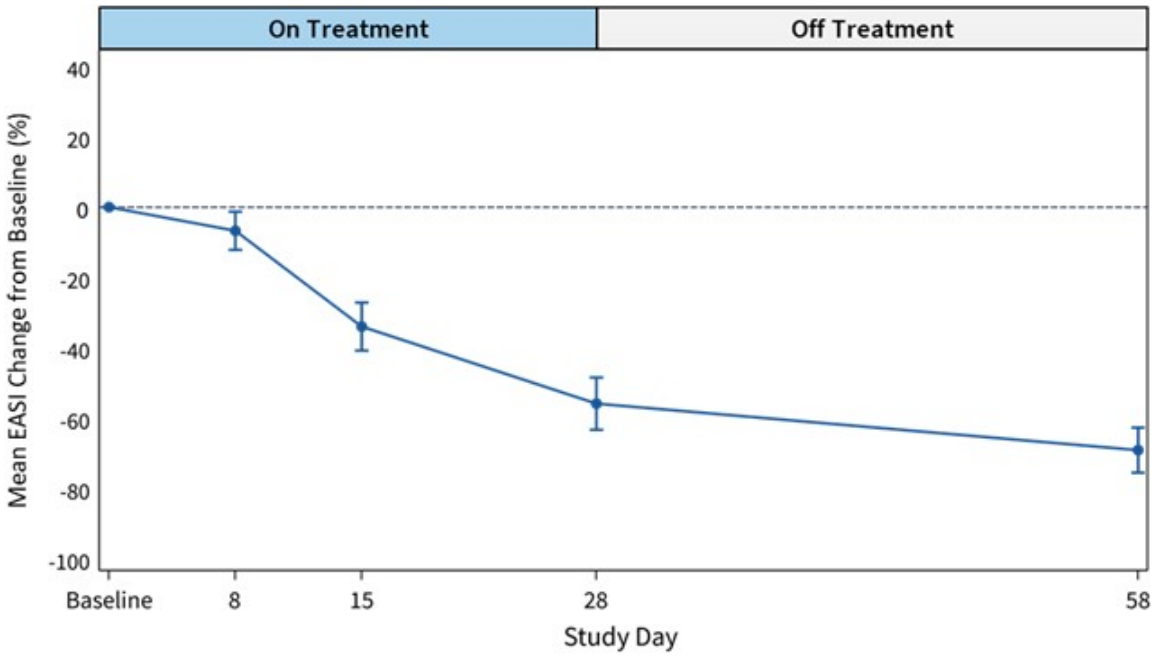
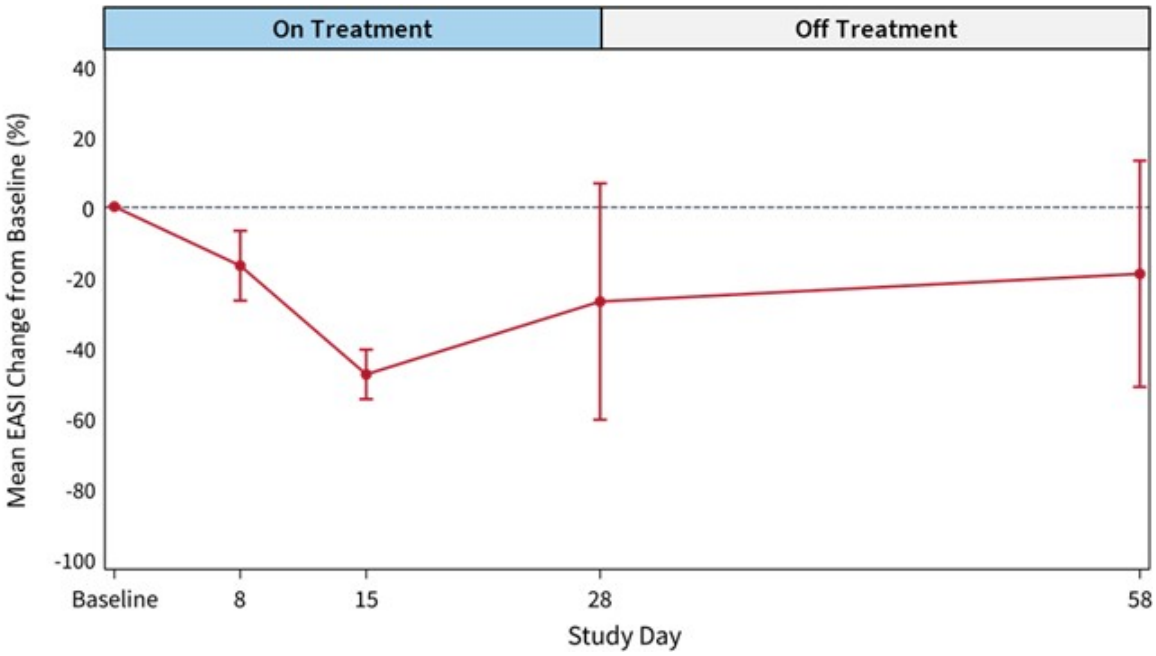


Figure 2: Mean EASI Score Change from Baseline (%) for Placebo Group (N=4)



Cohort 1 Safety Data

No significant safety issues were observed. All the patients completed 28 days of dosing. One patient reported Grade 1 nausea that did not interfere with the subject receiving the full treatment course, and one patient developed COVID-19 on day 28 of treatment; that patient had an uneventful recovery. No clinically significant laboratory abnormalities were seen. See Table 3 below.

Table 3: Cohort 1 Safety

	Soquelitinib (N=12)	Placebo (N=4)
Subjects with adverse events	2*	0
Serious adverse events	0	0
Adverse events leading to study drug discontinuation	0	0
Adverse events leading to death	0	0
Treatment-related adverse events:		
Nausea (Grade 1)	1	0

* Reported adverse events: Nausea (N=1) and Covid-19 (N=1); both resolved without any dose modification.

Serum Cytokine Changes

Relationships between reductions in certain cytokines with improvement in EASI scores were observed. Significant cytokines changes were seen for IL-5, IL-17, IL-31, IL-33, TSLP and a trend for TARC in EASI 50 responders (N=9) compared to non-responders (N=3). No such relationships were seen in the placebo group.

Cohort 2 Initial Efficacy and Safety Data

As of December 16, the Company has enrolled 12 patients in Cohort 2 of the trial (soquelitinib 200 mg oral once per day). As of December 7, Day 28 follow up data is available for three patients with efficacy results consistent with that seen in Cohort 1. No clinically significant laboratory abnormalities or treatment related adverse events have been reported in any of the patients enrolled in Cohort 2.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements related to the potential safety and efficacy of soquelitinib; expected cash proceeds from the exercise of warrants; and the Company's conduct of, enrollment in and timing of clinical trials. All statements other than statements of historical fact contained in this Current Report on Form 8-K are forward-looking statements. These statements often include words such as "believe," "expect," "anticipate," "intend," "plan," "estimate," "seek," "will," "may" or similar expressions. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond the Company's control. The Company's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to, risks detailed in the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, filed with the Securities and Exchange Commission on November 12, 2024, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: the Company's ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials of its product candidates; the accuracy of the Company's estimates relating to its ability to initiate and/or complete preclinical studies and clinical trials and release data from such studies and clinical trials; the results of preclinical studies and interim data from clinical trials not being predictive of future results; the Company's ability to enroll sufficient numbers of patients in its clinical trials; the unpredictability of the regulatory process; regulatory developments in the United States and other foreign countries; the costs of clinical trials may exceed expectations; and the Company's ability to raise additional capital. Although the

Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Corvus Pharmaceuticals, Inc. dated December 18, 2024.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL Document).

The information furnished in Exhibit 99.1 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.

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 hereunto duly authorized.

CORVUS PHARMACEUTICALS, INC.

Date: December 18, 2024

By: /s/ Leiv Lea
Leiv Lea
Chief Financial Officer

Corvus Pharmaceuticals Announces Interim Data from Placebo-Controlled Phase 1 Clinical Trial of Soquelitinib for Atopic Dermatitis

Data from lowest dose level cohorts demonstrate a favorable safety and efficacy profile

Data includes complete results from cohort 1 and initial results from cohort 2

Early exercise of common stock warrants from stockholder generates cash proceeds of approximately $12.7 million

Company to host conference call and webcast today at 8:00 a.m. ET / 5:00 a.m. PT

BURLINGAME, Calif., December 18, 2024 - Corvus Pharmaceuticals, Inc. (NASDAQ: CRVS), a clinical-stage biopharmaceutical company, today announced interim data from the randomized, double-blind, placebo-controlled Phase 1 clinical trial evaluating soquelitinib in patients with moderate to severe atopic dermatitis. The data demonstrated a favorable safety profile and efficacy profile, supporting the ongoing development of soquelitinib for atopic dermatitis and the potential of ITK inhibition as a novel mechanism of action for other immune diseases.

“We are pleased with the early results of our soquelitinib Phase 1 atopic dermatitis clinical trial, which show an attractive potential product profile at the lowest dose we are studying,” said Richard A. Miller, M.D., co-founder, president and chief executive officer of Corvus. “The data show consistent signs of efficacy, combined with a novel mechanism of action, a convenient oral route of administration and a favorable safety profile. This is also supported by an analysis of serum cytokine levels, which show a possible relationship between clinical response and reductions in IL-5, IL-17, IL-31, IL-33 and TSLP, along with a trend for TARC. We believe the data highlights soquelitinib’s potential as a new treatment option for atopic dermatitis and the broader opportunity for ITK inhibition for other immune related diseases. In addition to blocking the production of multiple inflammatory cytokines, soquelitinib may have persistent direct effects on immune cell function that act to regulate aberrant immune responses. We look forward to completing the Phase 1 trial and initiating other trials with soquelitinib for immune diseases.”

Soquelitinib Atopic Dermatitis Phase 1 Clinical Trial Design

The randomized, double-blind, placebo-controlled Phase 1 clinical trial is planned to enroll 64 patients with moderate to severe atopic dermatitis that previously failed one prior topical or systemic therapy. Patients are enrolled into one of four dosing cohorts in a 3:1 ratio (12 active and 4 placebo) to receive either soquelitinib or placebo. The cohorts are sequentially enrolled and will examine 100 mg oral twice per day, 200 mg oral once per day, 200 mg oral twice per day and 400 mg oral once per day. Patients are treated for 28 days and are then followed for an additional 30 days with no therapy.

These doses were selected based on the Company’s prior experience evaluating soquelitinib in T cell lymphoma patients. The doses in the atopic dermatitis trial bracket the 200 mg oral twice a day dosing regimen, which is the level that has been shown to provide complete ITK occupancy and that is being evaluated in the Company’s ongoing registrational Phase 3 clinical trial of soquelitinib in peripheral T cell lymphoma.

The primary endpoints include safety and tolerability, and efficacy, measured by improvement in Eczema Area and Severity Index (EASI) score, Investigator Global Assessment (IGA), reduction in itch and various cytokine biomarkers. EASI scores are also evaluated by the percent of patients that achieve a specified percent reduction in EASI score – EASI 50 for patients that achieved a 50% reduction; EASI 75 for a 75% reduction; and EASI 90 for a 90% reduction. Corvus and a data monitoring committee will be able to monitor the data from the trial as the trial progresses.

Soquelitinib Interim Data from the Atopic Dermatitis Phase 1 Clinical Trial

The Company is reporting complete results from Cohort 1 of the trial, which includes 16 patients (12 that received soquelitinib 100 mg oral twice per day and four that received placebo) with follow up at 28 days and at 58 days. At 58 days, two patients in the soquelitinib group were not available for follow up. The soquelitinib and placebo patients were well matched; see Table 1 below for patient characteristics.

Table 1: Cohort 1 Patient Characteristics

	Soquelitinib (N=12)	Placebo (N=4)
Age, mean (range), yrs	46.3 (30–66)	50.5 (32–62)
Gender, male n (%)	7 (58.3)	4 (100)
Race/ethnicity, n (%)		
Asian	2 (16.7)	0 (0)
Black or African American	6 (50)	4 (100)
White	3 (25)	0 (0)
Hispanic or Latino	1 (8.3)	0 (0)
Baseline EASI, mean (range)	20.4 (15.0–46.6)	18.5 (14.9–24.8)
Baseline IGA, mean (range)	3.0 (2–4)	3.3 (3–4)
Prior AD therapies, n (%)		
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- The mean baseline EASI and IGA scores for soquelitinib patients were 20.4 and 3.0, respectively, compared to an EASI score of 18.5 and an IGA score of 3.3 for placebo patients.
- All soquelitinib patients discontinued topical corticosteroids prior to enrollment, while one placebo patient continued topical corticosteroid treatment. All patients, except the one placebo, discontinued topical corticosteroids for at least 27 days prior to enrolling in the study.
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- EASI scores at 28-day and 58-day follow-up demonstrate a favorable effect of soquelitinib treatment compared to placebo.
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- At day 28, in the soquelitinib group, nine of 12 patients achieved EASI 50; three of 12 achieved EASI 75 and one of 12 achieved EASI 90. Three of 12 patients achieved IGA 0 or 1. In the placebo group, two of four patients achieved EASI 50 and no patients achieved EASI 75, EASI 90 or IGA 0 or 1.
- At day 58, in the soquelitinib group, nine of 10 patients achieved EASI 50, four of 10 achieved EASI 75 and one of 10 achieved EASI 90. Three of 10 patients achieved IGA 0 or 1. In the placebo group, one in four patients achieved EASI 50 and no patients achieved EASI 75, EASI 90 or IGA 0 or 1.
- The timing of EASI improvement in the soquelitinib group indicates that a treatment effect begins early, at eight days, and continues for the remainder of the study. (See Figures 1 and 2 below). All soquelitinib treated patients showed improvement in EASI scores.
- The small number of placebo patients demonstrates a variable course over the treatment period with no substantial change over the 58-day period.

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	4 week (Day 28)		8 week (Day 58)	
	Placebo (N=4)	Soquelitinib (N=12)	Placebo (N=4)	Soquelitinib (N=10)
Change EASI Mean % Reduction	27.0	55.9	19.1	69.1
EASI 50 (%pts)	50	75	25	90
EASI 75 (%pts)	0	25	0	40
EASI 90 (%pts)	0	8	0	10
IGA 0 or 1 (%pts)	0	25	0	30

Figure 1: Mean EASI Score Change from Baseline (%) for Soquelitinib Treatment Group (N=12 at day 28 and N=10 at day 58)

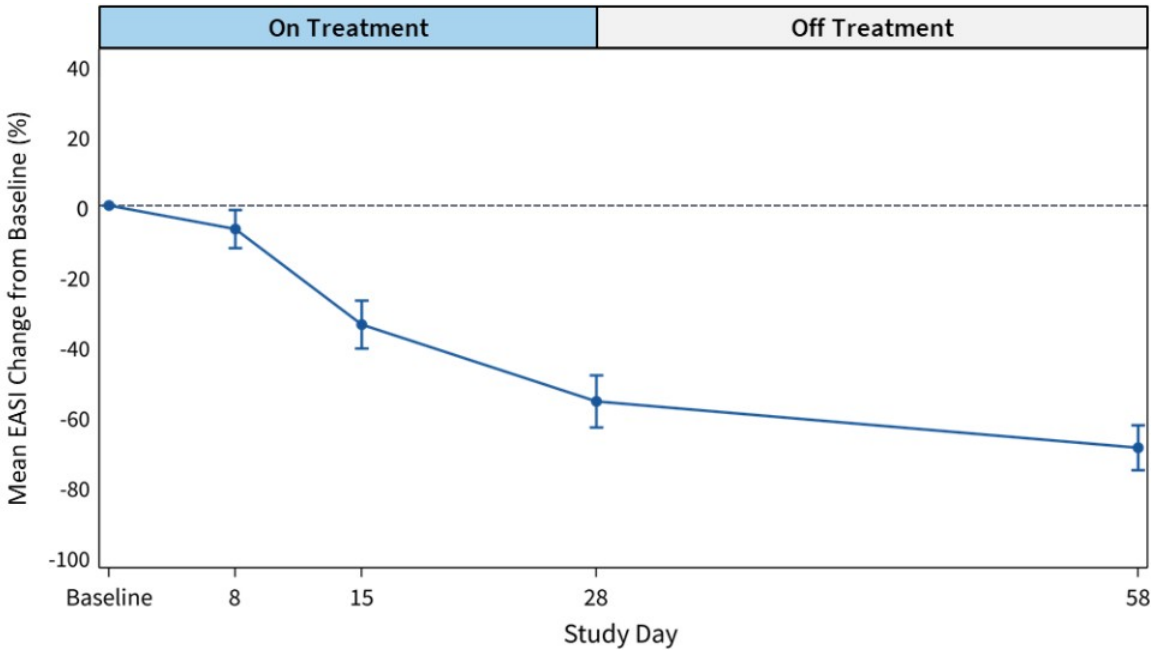
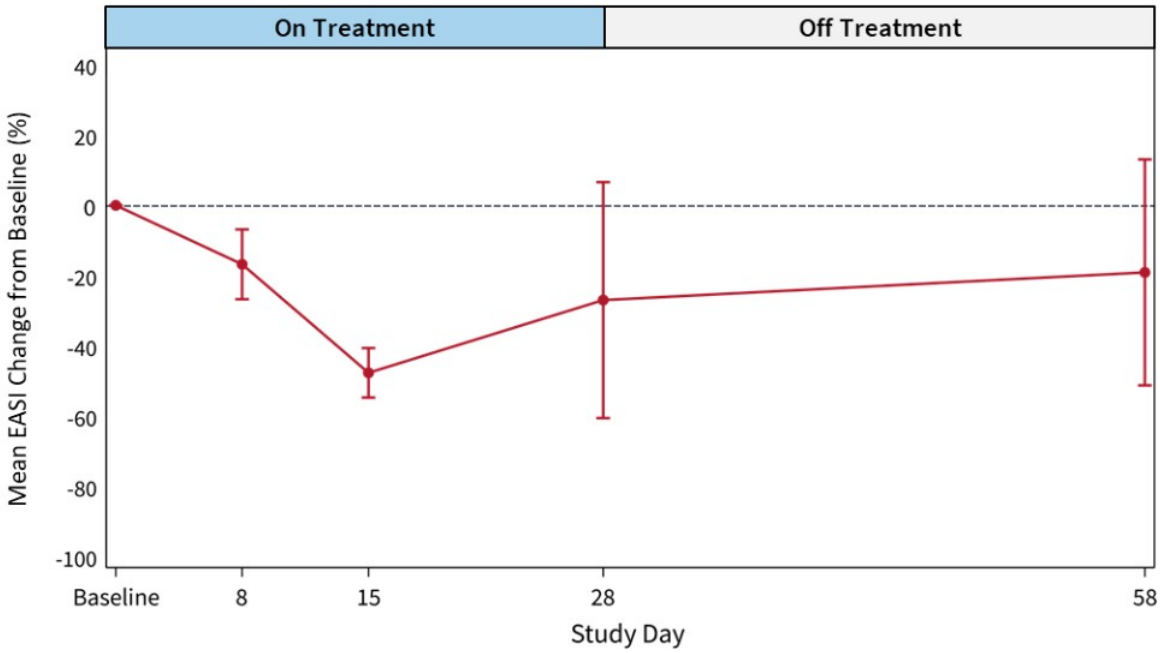


Figure 2: Mean EASI Score Change from Baseline (%) for Placebo Group (N=4)



Cohort 1 Safety Data

No significant safety issues were observed. All the patients completed 28 days of dosing. One patient reported Grade 1 nausea that did not interfere with the subject receiving the full treatment course, and one patient developed COVID-19 on day 28 of treatment; that patient had an uneventful recovery. No clinically significant laboratory abnormalities were seen. See Table 3 below.

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Adverse events leading to death	0	0
Treatment-related adverse events:		
Nausea (Grade 1)	1	0

* Reported adverse events: Nausea (N=1) and Covid-19 (N=1); both resolved without any dose modification.

Serum Cytokine Changes

Relationships between reductions in certain cytokines with improvement in EASI scores were observed. Significant cytokines changes were seen for IL-5, IL-17, IL-31, IL-33, TSLP and a trend for TARC in EASI 50 responders (N=9) compared to non-responders (N=3). No such relationships were seen in the placebo group.

Cohort 2 Initial Efficacy and Safety Data

As of December 16, the Company has enrolled 12 patients in Cohort 2 of the trial (soquelitinib 200 mg oral once per day). As of December 7, Day 28 follow up data is available for three patients with efficacy results consistent with that seen in Cohort 1. No clinically significant laboratory abnormalities or treatment related adverse events have been reported in any of the patients enrolled in Cohort 2.

Early Exercise of Common Stock Warrants
The Company also announced that Samlyn Capital, a holder of warrants to purchase 3,633,978 shares of common stock, has delivered exercise notices with respect to all of its warrants in advance of the June 30, 2025 expiration date, which will result in cash proceeds to the Company of approximately $12.7 million.

Conference Call, Webcast and Presentation Slides
Corvus will host a conference call and webcast today, Wednesday, December 18, 2024 from 8:00 – 9:00 a.m. ET to provide an overview of the soquelitinib atopic dermatitis Phase 1 clinical data. The conference call can be accessed by dialing 1-800-717-1738 (toll-free domestic) or 1-646-307-1865 (international) or by clicking on this link for instant telephone access to the event. The live webcast, which will include presentation slides, may be accessed via the investor relations section of the Corvus website. A replay of the webcast will be available on Corvus' website for 60 days.

About Atopic Dermatitis
Atopic dermatitis, also called eczema, is a chronic disease that can cause inflammation, redness, scaly patches, blisters and irritation of the skin. It affects up to 20% of children and up to 10% of adults, and treatments include topical therapies, oral therapies and systemic injectable biologic therapies. It is frequently associated with other allergic disorders such as food allergies and asthma. Atopic dermatitis, like asthma and allergy, involves the participation of Th2 lymphocytes which secrete cytokines that result in inflammation. Soquelitinib has been shown in preclinical studies to inhibit cytokine production from Th2 lymphocytes.

About Soquelitinib
Soquelitinib (formerly CPI-818) is an investigational small molecule drug given orally designed to selectively inhibit ITK (interleukin-2-inducible T cell kinase), an enzyme that is expressed predominantly in T cells and plays a role in T cell and natural killer (NK) cell immune function. Soquelitinib has been shown to affect T cell differentiation and induce the generation of Th1 helper cells while blocking the development of both Th2 and Th17 cells and production of their secreted cytokines. Th1 T cells are required for immunity to tumors, viral infections and other infectious diseases. Th2 and Th17 helper T cells are involved in the pathogenesis of many autoimmune and allergic diseases. The Company believes the inhibition of specific molecular targets in T cells may be of therapeutic benefit for patients with cancers, including solid tumors, and in patients with autoimmune and allergic diseases. Recent studies have demonstrated that ITK controls a switch between the differentiation of Th17 proinflammatory cells and T regulatory suppressor cells. Inhibition of ITK leads to a shift toward T regulatory cell differentiation which has the potential to suppress autoimmune and inflammatory reactions. Based on interim results from a Phase 1/1b clinical trial in patients with refractory T cell lymphomas, which demonstrated tumor responses in very advanced, refractory, difficult to treat T cell malignancies, the Company has initiated a registrational Phase 3 clinical trial (NCT06561048) of soquelitinib in patients with relapsed PTCL. Soquelitinib is also now being investigated in a randomized placebo-controlled phase 1 clinical trial in patients with atopic dermatitis. A recent publication describing the chemistry, enzymology and biology of soquelitinib appeared in npj Drug Discovery in December 2024 and is available online at the Nature website and on the Publications and Presentations page of the Corvus website.

About Corvus Pharmaceuticals
Corvus Pharmaceuticals is a clinical-stage biopharmaceutical company pioneering the development of ITK inhibition as a new approach to immunotherapy for a broad range of cancer and immune diseases. The Company's lead product candidate is soquelitinib, an investigational, oral, small molecule drug that selectively inhibits ITK. Its other clinical-stage candidates are being developed for a variety of cancer indications. For more information, visit www.corvuspharma.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements related to the potential safety and efficacy of the Company's product candidates including soquelitinib; the potential use of soquelitinib to treat atopic dermatitis and the potential of ITK inhibition as a novel mechanism of action for other immune diseases; and the Company's conduct of, enrollment in and timing of clinical trials, including the Company's Phase 3 clinical trial in PTCL and Phase 1 clinical trial in atopic dermatitis. All statements other than statements of historical fact contained in this press release are forward-looking statements. These statements often include words such as "believe," "expect," "anticipate," "intend," "plan," "estimate," "seek," "will," "may" or similar expressions. Forward-looking statements are subject to a

number of risks and uncertainties, many of which involve factors or circumstances that are beyond the Company's control. The Company's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to, risks detailed in the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, filed with the Securities and Exchange Commission on November 12, 2024, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: the Company's ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials of its product candidates; the accuracy of the Company's estimates relating to its ability to initiate and/or complete preclinical studies and clinical trials and release data from such studies and clinical trials; the results of preclinical studies and interim data from clinical trials not being predictive of future results; the Company's ability to enroll sufficient numbers of patients in its clinical trials; the unpredictability of the regulatory process; regulatory developments in the United States and other foreign countries; the costs of clinical trials may exceed expectations; and the Company's ability to raise additional capital. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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