

# **PRESS RELEASE**

# ASLAN PHARMACEUTICALS ANNOUNCES POSITIVE INTERIM RESULTS FROM PHASE 2 STUDY OF EBLASAKIMAB IN DUPILUMAB-EXPERIENCED ATOPIC DERMATITIS PATIENTS

- Interim readout of 22 patients shows unprecedented efficacy data compared to prior atopic dermatitis (AD) studies with biologics: 60.0% of *dupilumab*-experienced AD patients treated with 400mg *eblasakimab* weekly achieved EASI-90 (at least a 90% reduction in their Eczema Area Severity Index (EASI) score) and 66.7% achieved a vIGA score of 0 or 1 (clear or almost clear skin) after 16 weeks, versus 14.3% of patients on placebo.
- 20% of patients treated with *eblasakimab* achieved EASI-100 (100% reduction in their EASI score) versus 0% on placebo.
- Of the six patients treated with *eblasakimab* that previously had an inadequate response to *dupilumab*, 66.7% achieved EASI-90 and a vIGA score of 0 or 1 after 16 weeks.
- *Eblasakimab* produced rapid and clinically meaningful itch relief versus placebo. The mean reduction in peak pruritus numerical rating scale (PP-NRS) score for *eblasakimab*-treated patients was 58.9% compared to a 12.9% reduction for placebo.
- Data from this unique study of *dupilumab*-experienced AD patients shows *eblasakimab* has the potential to be highly effective in AD patients even if *dupilumab* has not been.

San Mateo, California, and Singapore, April 22, 2024 – ASLAN Pharmaceuticals (Nasdaq: ASLN), a clinical-stage, immunology-focused biopharmaceutical company developing innovative treatments to transform the lives of patients, today announced positive interim results from the Phase 2 study of *eblasakimab* in moderate-to-severe atopic dermatitis (AD) adult patients previously treated with *dupilumab*, TREK-DX. The primary endpoint, which is the percent change in Eczema Area Severity Index (EASI) score from baseline to week 16, was statistically significant when compared to placebo (p=0.0059), even though the interim analysis was not powered for statistical significance due to the sample size. 73.3% (11/15) of *eblasakimab*-treated patients achieved a reduction in EASI score of at least 75% from baseline (EASI-75) compared to 14.3% (1/7) on placebo (p=0.0431).

"We are extremely pleased to see *eblasakimab* delivering these spectacular results using a dosing regimen higher than we have tested previously. Most patients on *eblasakimab* achieved EASI-90 and vIGA of 0 or 1 after just 16 weeks of treatment, with numbers unprecedented in other biologics AD studies. Notably, in patients that previously had an inadequate response to *dupilumab*, two-thirds achieved EASI-90 and vIGA 0 or 1 when treated with *eblasakimab*," said Dr Carl Firth, Chief Executive Officer of ASLAN Pharmaceuticals.

"We know that over 60% of *dupilumab*-treated patients fail to achieve an IGA score of 0 or 1 after 16 weeks<sup>1</sup>, and, of those patients that do achieve it, still half do not maintain it after the subsequent 36 weeks<sup>2</sup>. The data we have announced today provide compelling evidence that *eblasakimab*, with its unique mechanism of action, has the potential to be an important new therapy for this emerging patient population. We look forward to announcing the topline readout from the full dataset of the TREK-DX study at the end of this year, the first and only placebo-controlled study of *dupilumab*-experienced AD patients, and to optimizing the dose regimen for patients in the planned Phase 3 studies of *eblasakimab*."

# Summary of the interim data

The TREK-DX trial is enrolling moderate-to-severe adult AD patients who have discontinued *dupilumab* treatment for any reason, including inadequate control of AD, loss of access or an adverse event, after at least 16 weeks of *dupilumab* treatment. In an interim analysis of data from 22 patients, comprising the intent-to-treat (ITT) population, that were randomized 2:1 active to placebo, 17 patients completed the 16-week treatment period and five patients



(two in the active arm and three in the placebo arm) discontinued before the completion of the 16-week treatment period<sup>3</sup>.

Patients treated with *eblasakimab* 400mg once weekly (n=15) saw a rapid onset of action in the first few weeks of treatment, with a statistically significant improvement in EASI score by Week 4 (p=0.0169) compared to placebo (n=7). By Week 16, a 86.9% mean reduction<sup>4</sup> in EASI score from baseline was observed for *eblasakimab*-treated patients compared to a 51.2% reduction for placebo (p=0.0059). Clinically meaningful improvements were achieved in other key efficacy measures compared to placebo at Week 16, including:

- 73.3% (11/15) of *eblasakimab*-treated patients achieved EASI-75, versus 14.3% (1/7) on placebo (p=0.0431).
- 60.0% (9/15) of *eblasakimab*-treated patients achieved EASI-90, versus 14.3% (1/7) on placebo (p=0.1278).
- 20.0% (3/15) of *eblasakimab*-treated patients achieved EASI-100, versus 0% (0/7) on placebo (EASI-100 was not a pre-specified endpoint).
- 66.7% (10/15) of *eblasakimab*-treated patients achieved a vIGA score of 0 or 1, versus 14.3% (1/7) with placebo (p=0.0750).
- 58.9% mean reduction in peak pruritus numerical rating scale (PP-NRS) score for *eblasakimab*-treated patients, versus a 12.9% reduction for placebo (p=0.0015). 53.8% (7/13) of *eblasakimab*-treated patients, with a baseline score of at least 4, achieved a 4-point reduction in PP-NRS score, versus 14.3% (1/7) on placebo (p=0.2460).

Of the six patients treated with *eblasakimab* who previously had an inadequate response to *dupilumab*, 66.7% (4/6) achieved EASI-90 and 66.7% (4/6) achieved a vIGA score of 0 or 1.

Treatment was well-tolerated and no new safety signals were identified. There were no reports of conjunctivitis or injection site reactions in the active or placebo arm.

# Summary of data from subgroup with baseline EASI score of 18 or above

As previously announced, the TREK-DX recruitment criteria were tightened in October 2023 to enroll only patients with a baseline EASI score of 18 or above. These more stringent criteria will be the basis of analysis in the topline readout, expected at the end of 2024. Of the 22 patients in this interim analysis, 15 meet these amended enrollment criteria, and have the following efficacy findings at Week 16:

- 89.2% mean reduction in EASI score from baseline for *eblasakimab*-treated patients, versus a 45.7% reduction for placebo (p=0.0045).
- 83.3% (10/12) of *eblasakimab*-treated patients achieved EASI-75, versus 0% (0/3) on placebo (p=0.0556).
- 66.7% (8/12) of *eblasakimab*-treated patients achieved EASI-90, versus 0% (0/3) on placebo (p=0.1667).
- 25% (3/12) of *eblasakimab*-treated patients achieved EASI-100, versus 0% (0/3) on placebo (EASI-100 was not a pre-specified endpoint).
- 75.0% (9/12) of *eblasakimab*-treated patients achieved a vIGA score of 0 or 1, versus 0% (0/3) with placebo (p=0.1111).
- 61.2% mean reduction in PP-NRS score for *eblasakimab*-treated patients, versus a 1.5% increase for placebo (p=0.0004). 60% (6/10) of *eblasakimab*-treated patients, with a baseline score of least 4, achieved a 4-point reduction in PP-NRS score, versus 0% (0/3) on placebo (p=0.2000).

The interim data will be submitted for presentation at an upcoming scientific conference.



## About the TREK-DX study

TREK-DX (TRials in EblasaKimab in Dupilumab eXperienced AD patients) is the first randomized, double-blind, placebo-controlled trial to be conducted in AD patients who have been previously treated with *dupilumab*. The trial is expected to enroll 75 patients across sites in North America and Europe to evaluate the efficacy and safety of *eblasakimab* in patients with moderate-to-severe AD previously treated with *dupilumab*. The trial is enrolling patients who have discontinued *dupilumab* treatment for any reason, including inadequate control of AD, loss of access or an adverse event, after at least 16 weeks of *dupilumab* treatment. The trial consists of a 16-week treatment period and an 8-week safety follow-up period. Patients in the active arm receive a loading dose of 600mg of *eblasakimab* at weeks 0 and 1, followed by 400mg *eblasakimab* dosed every week. Patients in the placebo arm are dosed at weeks 0 and 1 and every week thereafter. The primary efficacy endpoint is percentage change in EASI score from baseline to week 16. Key secondary efficacy endpoints include the proportion of patients achieving validated Investigator Global Assessment (vIGA) score of 0 (clear) or 1 (almost clear), proportion of patients with a 75% or greater reduction in EASI (EASI-75), proportion of patients achieving EASI-50 and EASI-90, and changes in peak pruritus.

#### References

- 1. Thaci et al (2019) J Dermatol Sci 94(2):266-275
- 2. Worm et al (2020) JAMA Derm 156(2):131-143
- 3. One patient in each treatment arm took a rescue medication during the treatment period. Their efficacy data was set to missing (continuous endpoints) or failure (binary endpoints) after initiation of the rescue medication for the purpose of efficacy analyses. Missing data were analysed using Last Observation Carried Forward imputation.
- 4. Least squares (LS) mean

#### About eblasakimab

*Eblasakimab* is a potential first-in-class monoclonal antibody targeting the IL-13 receptor subunit of the Type 2 receptor, a key pathway driving several allergic inflammatory diseases. *Eblasakimab's* unique mechanism of action enables specific blockade of the Type 2 receptor and has the potential to improve upon current biologics used to treat allergic disease. By blocking the Type 2 receptor, *eblasakimab* prevents signaling through both interleukin 4 (IL-4) and interleukin 13 (IL-13) – the key drivers of inflammation in AD and Type 2-driven COPD. ASLAN announced positive results from the Phase 2b TREK-AD study of *eblasakimab* in moderate-to-severe biologic-naïve AD patients in July 2023, and is currently investigating *eblasakimab* in *dupilumab*-experienced, moderate-to-severe AD patients in the Phase 2 trial, TREK-DX.

## **About ASLAN Pharmaceuticals**

ASLAN Pharmaceuticals (Nasdaq: ASLN) is a clinical-stage, immunology-focused biopharmaceutical company developing innovative treatments to transform the lives of patients. ASLAN is developing *eblasakimab*, a potential first-in-class antibody targeting the IL-13 receptor in moderate-to-severe atopic dermatitis (AD) with the potential to improve upon current biologics used to treat allergic disease, and has reported positive topline data from a Phase 2b dose-ranging study in moderate-to-severe AD patients. ASLAN is currently investigating *eblasakimab* in *dupilumab*-experienced, moderate-to-severe AD patients in the TREK-DX Phase 2 trial, with topline data expected at the end of 2024. ASLAN is also developing *farudodstat*, a potent oral inhibitor of the enzyme dihydroorotate dehydrogenase (DHODH) as a potential first-in-class treatment for alopecia areata (AA) in a Phase 2a, proof-of-concept trial with an interim readout expected in Q3 2024. ASLAN has teams in San Mateo, California, and in Singapore. For additional information please visit the <u>ASLAN website</u> or follow ASLAN on <u>LinkedIn</u>.

## Forward looking statements

This release contains forward-looking statements. These statements are based on the current beliefs and expectations of the management of the Company. These forward-looking statements may include, but are not



limited to statements regarding the Company's business strategy and clinical development plans; statements related to the safety and efficacy of eblasakimab, including interim results; the Company's plans and expected timing with respect to clinical trials, clinical trial enrollment and clinical trial results for eblasakimab; the potential of eblasakimab as a first-in-class treatment for atopic dermatitis; and expectations regarding the terms of patents and ability to obtain and maintain intellectual property protection for product candidates. The Company's estimates, projections and other forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations, or financial performance, and inherently involve significant known and unknown risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of many risks and uncertainties, which include, unexpected safety or efficacy data observed during preclinical or clinical studies; risks that future clinical trial results may not be consistent with interim, initial or preliminary results or results from prior preclinical studies or clinical trials; clinical site activation rates or clinical trial enrollment rates that are lower than expected; the impact of health epidemics or pandemics, or geopolitical conflicts on the Company's operations, research and development and clinical trials and potential disruption in the operations and business of third-party manufacturers, contract research organizations, other service providers and collaborators with whom the Company conducts business; general market conditions; changes in the competitive landscape; and the Company's ability to obtain sufficient financing to fund its strategic and clinical development plans. Other factors that may cause actual results to differ from those expressed or implied in such forward-looking statements are described in the Company's US Securities and Exchange Commission filings and reports (Commission File No. 001- 38475), including the Company's Annual Report on Form 20-F filed with the US Securities and Exchange Commission on April 12, 2024. All statements other than statements of historical fact are forward-looking statements. The words "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan," or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes are intended to identify estimates, projections, and other forward-looking statements. Estimates, projections, and other forward-looking statements speak only as of the date they were made, and, except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement.

## Ends

## **ASLAN Media and IR contacts**

**Emma Thompson** Spurwing Communications Tel: +65 6206 7350 Email: <u>ASLAN@spurwingcomms.com</u> Ashley R. Robinson LifeSci Advisors, LLC Tel: +1 (617) 430-7577 Email: <u>arr@lifesciadvisors.com</u>