#### 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

September 9, 2024 Date of Report (Date of earliest event reported)

#### **Zura Bio Limited**

(Exact name of registrant as specified in its charter)

98-1725736 Cayman Islands 001-40598 (State or other jurisdiction of (I.R.S. Employer (Commission incorporation) File Number) Identification No.)

> 1489 W. Warm Springs Rd. #110 Henderson, NV 89014 (Address of principal executive offices, including zip code)

(702) 825-9872 (Registrant's telephone number, including area code)

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

Ch	eck 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 communication 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)

 $\begin{tabular}{ll} \hline \begin{tabular}{ll} \hline \end{tabular} & \begin{tabular}{$  $\ \square$  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 Class A Ordinary Shares, par value \$0.0001 per share The Nasdaq Stock Market ZURA Warrants, each whole warrant exercisable for one Class A Ordinary Share at an exercise price of \$11.50 per share ZURAW The Nasdaq Stock Market

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.  $\square$ 

#### Item 7.01 Regulation FD Disclosure.

On September 9, 2024, Zura Bio Limited ("ZURA", the "Company") provided an updated corporate presentation that may be used in connection with presentations at conferences and investor meetings. The full text of the Company's corporate presentation is filed as Exhibit 99.1 hereto, and incorporated herein by reference, and may also be accessed through the "News & Events" section of the Company's website at investors.zurabio.com.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Financial Statements and Exhibits

(d) Exhibits.

Exhibit No. Description

99.1 104

Corporate presentation, dated September 9, 2024
Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### SIGNATURES

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

#### ZURA BIO LIMITED

Date: September 9, 2024

By: /s/ Kim Davis
Kim Davis
Chief Legal Officer



# Three Unique Dual-Pathway Biologics, Clinically Validated for Therapeutic Areas with Unmet Needs

September 2024

Nasdag Ticker: ZURA

## Forward Looking Statements Disclaimer

This communication includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Words such a "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believe," "predict," "potential," "continue," "strategy," "future," "opportunity," "would," "seem," "seek,' such terms and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are predictions, projections and other statements about current expectations and assumptions and, as a result, are subject to risks and uncertainties that could cause the actual results to differ materially from the expected results. These finclude, but are not limited to: expectations with respect to development and regulatory plans, trial designs, and the costs, timing and results thereof; expectations with respect including the timing of study initiation and completion; expectations with respect to Zura Bio's development program, including clinical trials and the timing thereof, and expectation programs, data readouts and product candidates of other parties; Zura Bio's cash resources and projected cash runway, the potential to raise additional capital to support the companying in assets to offer broader and improved clinical responses; expectations with respect to addressable markets, projected CAGRs and patient populations; and expectations with from any financing transactions. These statements are based on various assumptions, whether or not identified in this communication. These forward-looking statements are provided to serve as, and must not be relied on by an investor as, a guarantee, an assurance, a prediction or a definitive statement of fact or probability.

Actual events are difficult or impossible to predict and could differ materially from those expressed or implied in such forward-looking statements, as a result of these risks and uncertaintied to: the potential of Zura Bio's product candidates and their related benefits, competing product candidates and products both in development and approved; Zura Bio's of key events and initiation of Zura Bio's studies and release of clinical data may take longer than anticipated or may not be achieved at all; the potential general acceptability product candidates by regulatory authorities, payors, physicians, and patients may not be achieved; Zura Bio's ability to attract and retain key personnel; Zura Bio's future operating and needs for additional financing may not be achieved; Zura Bio has not completed any clinical trials, and has no products approved for commercial sale; Zura Bio has incurred si and expects to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future; Zura Bio requires substantial additional capital t is unable to raise such capital when needed or on acceptable terms, Zura Bio may be forced to delay, reduce, and/or eliminate one or more of its development programs or future Bio may be unable to renew existing contracts or enter into new contracts; Zura Bio relies on third-party contract development manufacturing organizations for the manufacture of on contract research organizations, clinical trial sites, and other third parties to conduct of its preclinical studies and clinical trials; Zura Bio may be unable to obtain regulatory app and there may be related restrictions or limitations of any approved products; Zura Bio may be unable to successfully respond to general economic and geopolitical conditic effectively manage growth; Zura Bio faces competitive pressures from other companies worldwide; Zura Bio may be unable to adequately protect its intellectual property right documents filled, or to be filled by Zura Bio, with the SEC, inclu

Zura Bio does not undertake or accept any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future should circumstances change, except as otherwise required by securities and other applicable laws.

This presentation discusses product candidates that are under clinical study, and which have not yet been approved for marketing by the US Food and Drug Administration. No resafety or effectiveness of these product candidates for the use for which such product candidates are being studied. Caution should be exercised when comparing data across product candidates. Differences existing between trial designs and patient populations and characteristics. The results across such trials may not have interpretative value on Zura Statements included herein concerning clinical trials for the product candidates have not been reviewed or endorsed by Eli Lilly ("Lilly") or Pfizer.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy securities, nor shall there be any sale of securities in any state or jurisdiction in which such or unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

### **Company Summary**



High-Potential Biologics: Three novel, clinically validated dual-pathway biologics, each targeting mult

markets, advancing towards Phase 2 trials

Lead Asset Development: Tibulizumab Phase 2 study for SSc expected to commence in 4Q 2024, with

for HS anticipated in 2Q 2025

Strategic Milestones: Anticipating 2 key internal catalysts and up to 11 external readouts over the n

with potential to significantly drive value creation

Proven Leadership: An experienced team with a demonstrated history of driving over \$8 billion is

acquisitions within the last three years, showcasing their ability to execute st

and value creation

Financial Strength: Cash runway to support operations as currently planned through 2027

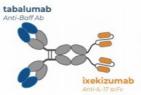


# Pipeline of Novel Dual-Pathway Biology Designed to Meaningfully Advance Outcomes in I&I Diseases



tibulizumab

Pipeline-in a-product



Only bispecific antibody targeting IL-17A and BAFF

Phase 1

Tibulizumab has been studied in three Phase 1/1b clinical studies to date \*

- √ 78 participants dosed across 3 studies
  - n=57 single dose
  - n=21 multiple doses up to 12 weeks

Planning to initia tibulizumab for S HS in 2Q 2025.

crebankitug

Potential best-in-class



IL-7R and TSLP Inhibition with potential best in class TSLP inhibition Crebankitug has been studied in three Phase 1/1b clinical studies to date \*\*

- √ 93 participants dosed
  - n=60 single dose
  - n=33 multiple doses up to 12 weeks

Actively assessing landscape and ex therapeutic indic future developm

torudokimab

Potential best-in-class



Best in class in inhibiting GM-CSF production by human mast cells Torudokimab has been studied in three Phase 1/2 clinical studies to date \*\*\*

- √ 244 participants dosed
  - n= 81 single dose
  - n=163 multiple doses up to 52

Actively assessing landscape and ex therapeutic indic future developm

(\*) Phase 1/b studies conducted by Eli Lilly & Co. (Phase 1 SAD in participants with rheumatoid arthritis, Phase 1b MAD in participants with Sjogren's syndrome, Phase 1 SAD in healthy Japanese and Caucasian participants)

(\*\*) Phase 1/b studies conducted by Pfizer. (Phase 1a SAD in healthy adult volunteers, Phase 1b MAD in participants with type-1 diabetes, Phase 1b MAD in participants with multiple sclerosis)

(\*\*\*) Phase 1/2 studies conducted by Eli Lilly & Co. (Phase 1 SAD, MAD and Safety / PK in in healthy participants, Phase 2 in participants with atopic dermatitis)

Clinical Study Reports

Acronyms: BAFF, B cell-activating factor; GM-CSF, granulocyte-macrophage colony-stimulating factor; HS, hidradenitis suppurativa; I&I, inflammation and immunology; IL, interleukin; Q, quarter; SSc, systemic sclerosis; TSLP, thymic stromal lymphopoietin

# **Dual-Biology Pathways Present Opportunities for High-Impact Therapeutic Targets with Attractive Market Potential**

Prevalence <sup>1</sup> U.S., EU5* and Japan	Potential Therapeutic Area	TAM (\$USD) U.S., EU5* and Japan
270 k	<b>SSc</b> systemic sclerosis	\$2,500 M
700 k	<b>HS</b> hidradenitis suppurativa	\$3,200 M
7 M	<b>AA</b> alopecia areata	\$5,200 M
32 M	<b>COPD</b> chronic obstructive pulmonary disease	\$23,692 M
25 M	<b>AD</b> atopic dermatitis	\$31,000 M
47 M	Asthma	\$25,247 M
~112 M		\$90,839 M

(\*) Germany, France, Italy, Spain, and United Kingdom

Sources: 

<sup>1</sup> Clarivate/DRG. Accessed 19 August 2024. Projected Prevalence and TAM 2032; "Alopecia Areata - National Alopecia Areata Foundation." NAAF, <a href="www.naaf.org/alopecia-areata">www.naaf.org/alopecia-areata</a>; Internal Analysis; Evaluate Pharma

Acronyms: k, kilo-thousand; M, million; TAM, total addressable market

### Zura is Led by a Strong Leadership Team with a Proven Track Record in Drug and Business Development





ROBERT LISICKI Chief Executive Officer and Director



VERENDER BADIAL Chief Financial Officer



KIRAN NISTALA MBBS, PhD
Chief Medical Officer and
Head of Development





GARY WHALE PhD Chief Technology Officer



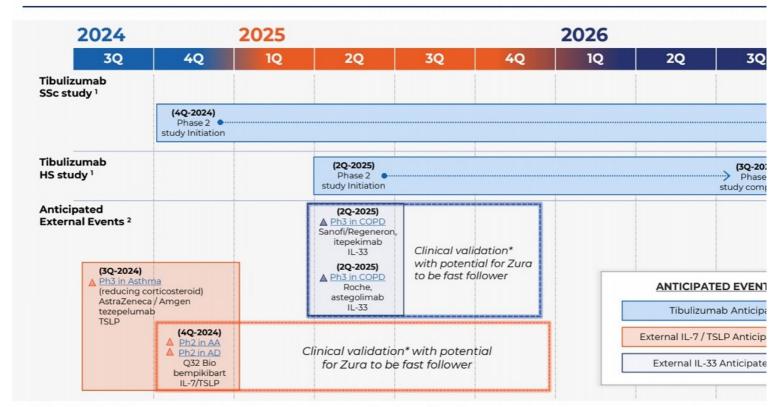
KIM DAVIS JD Chief Legal Officer and Corporate Secretary



MICHAEL HOWELL PhD

Chief Scientific Officer and
Head of Translational Medicine

## **Key Anticipated Events Through 2026**



(\*) Other IL-7Rα clinical data sources that may be available include a Phase 2 trial of lusvertikimab in ulcerative colitis.

Sources: <sup>1</sup>Zura Planning Assumptions; <sup>2</sup>clinicaltrials.gov, Company Presentations
Acronyms: AA, alopecia areata; AD, atopic dermatitis; COPD, chronic obstructive pulmonary disease; HS, hidradenitis suppurativa; IL, interleukin; Q, quarter; SSc, systemic sclerosis;
TSLP, thymic stromal lymphopoietin









# Increased Probability of Success Through Scientific and Clinical Validation

- IL-17 and BAFF are both validated as key contributors to SSc progression
- Multiple clinical studies demonstrate that inhibiting IL-17 and targeting B cells benefits SSc treatment
- Simultaneously inhibiting these validated targets may improve outcomes



### **High Unmet Need and Significant Value**

- Rare and life-threatening condition with a 40%-60% mortality rate within 10 years
- Limited treatment options available, with no advanced-line agents approved specifically for SSc
- 96% of rheumatologists identify SSc as the highest area of patient need 1

Sources: <sup>1</sup> Spherix Global Insights: Market Dynamix: Systemic Sclerosis (US) 2024
Acronyms: B, billion; BAFF, B cell-activating factor; IL, interleukin; SSc, systemic sclerosis; TAM, total addressable market

# Systemic Sclerosis is a Multi-Organ Disease with No Effective Treatments



# Systemic sclerosis is a rare & life-threatening disease

~300,000

people with SSc in US, EU and Japan <sup>1</sup>

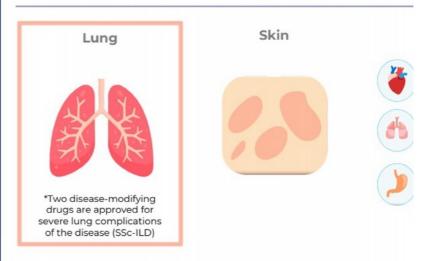
### Zero

SSc-specific \* drugs approved

(\*) no effective treatment exists that combats the disease across organ systems

Sources: <sup>1</sup>Clarivate/DRG. Accessed 19 August 2024. Projected Prevalence 2032.

#### Systemic sclerosis is characterized by tissue inflamm



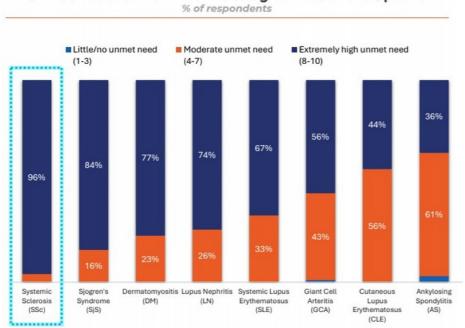
#### Multiple areas for evaluation and improveme

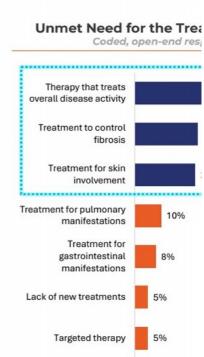


### Rheumatologists Rank SSc as the Highest Area of Need, with Significant Opportunity for Greater and Broader Clinical Benefit









96% of respondents highlight a pressing need for new pharmacological treatment

Source: Spherix Global Insights: Market Dynamix: Systemic Sclerosis (US) 2024

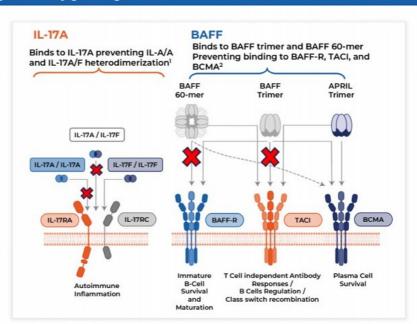
# Both IL-17A and BAFF-Mediated Inflammation Contribute to SSc Progression



#### Selective antibody therapy may be insufficient to address the heterogeneity

IL-17A is a pro-inflammatory cytokine that has been identified as a key contributor to SSc progression.

- IL-17A is increased in skin lesions and peripheral blood<sup>1,2</sup>
- Neutralization of IL-17A protected against bleomycin induced fibrosis<sup>3</sup>



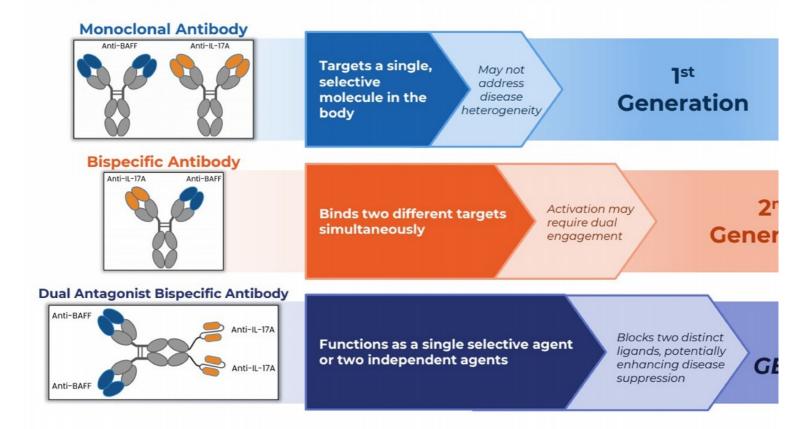
B cell activation a potent B-cell promotes the differentiation

- BAFF is i blood an fibrosis a pulmona
- In pre-cli blockade & autoan

### Inhibiting both IL-17A and BAFF may lead to better clinical outcomes in

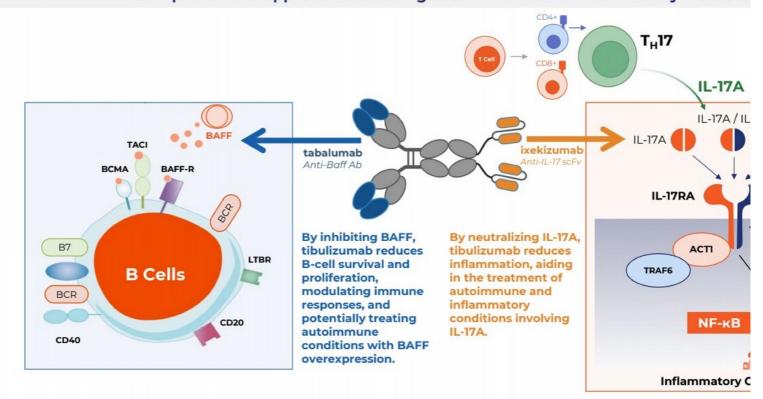
Sources: <sup>1</sup> Zhou, Q., et al. The Journal of Immunology, doi:10.4049/jimmunol.1500956; <sup>2</sup> Yang, X., et al. Arthritis Research & Therapy, doi:10.1186/ar4430; <sup>3</sup> Cipolla, E., et al. The FASEB Journal, doi:10.1096/fj.201700289r; <sup>4</sup> Matsushita, T. Arthritis & Rheumatism, doi:10.1002/art.21526; <sup>5</sup> Matsushita et al. J Rheum 2007; <sup>6</sup> Matsushita et al. J Invest Dermatol 2007; <sup>7</sup> François, A., et al. Journal of Autoimmunity, doi:10.1016/j.jaut.2014.08.003.

# Tibulizumab Was 'designed and engineered' to Enable Engagement with IL-17A, BAFF, or *Both Simultaneously*



### Tibulizumab Targets IL-17A, BAFF, or Both Simultaneously

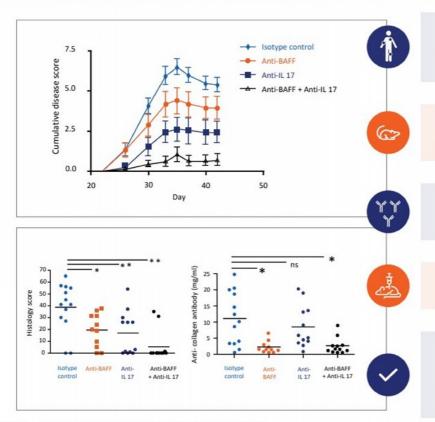
Tibulizumab uniquely targets BAFF for B cell regulation and IL-17A for inflammation contr comprehensive approach to treating autoimmune and inflammatory diseases





# Pre-Clinical Evidence of Additive Benefit from Inhibiting IL-17A and Neutralizing BAFF





Rheumatoid arthritis is a prototypic autoimm disease where individually targeting IL-17A-n inflammation or depleting B cells has been validated

The collagen-induced arthritis (CIA) murine r similarly characterized by **increased IL-17A p** and B cells that drive disease pathogenesis

Surrogate murine antibodies were used to even whether **neutralization of IL-17A and BAFF** to targeting individual pathways

Mice were injected with anti-IL-17A and/or a on days 22, 29, and 36

Blockade of both IL-17A and BAFF was associ reduced:

- Disease severity
- Anti-collagen antibodies
- Inflammation in the hind paw (histology

Sources: Zura Internal Data, Investigational New Drug (IND) Briefing Acronyms: BAFF, B cell-activating factor; IL, interleukin

# Separately Inhibiting IL-17A or BAFF Has Demonstrated Efficacy in SSc Placebo-Controlled Studies



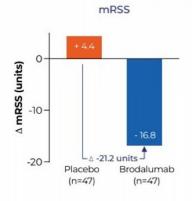
#### **IL-17 receptor antagonist - Phase 3**

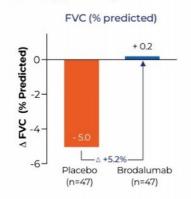
#### **Brodalumab**

- Achieved primary and endpoints for skin (reduced mRSS) and lung (improved FVC), respectively.
- Demonstrated therapeutic effects on lung/respiratory functions, digital ulcers, symptoms of gastroesophageal reflux disease, and QOL without noteworthy safety concerns

#### **CLINICAL PRECEDENT**

Phase 3 brodalumab study (24 weeks)





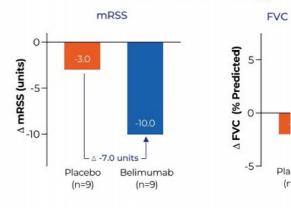
#### BAFF antagonist - II

#### **Belimumab**

- A 52-week, investigator-initiated, single-center, dou controlled pilot study in 20 participants with dcSSc
- Both treatment groups experienced improvements belimumab (-10 vs. -3; p = NS)
- Secondary endpoints were met with statistical sign endpoints: SHAQ-DI and VAS Raynaud's phenomer

#### **CLINICAL PRECEDENT**

Phase 2 belimumab IIT study (52 w



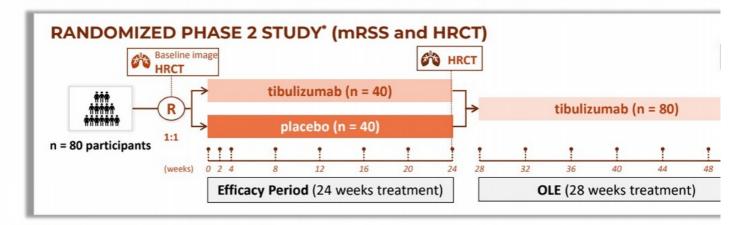
Sources: <sup>1</sup> Fukasawa, T., et al. Annals of the Rheumatic Diseases, doi:10.1136/annrheumdis-2022-eular.2519. <sup>2</sup> Gordon, Jessica K., et al. Arthritis Rheumatology, doi:10.1002/art.40358.

Acronyms: BAFF, B cell-activating factor; dcSSc, diffuse cutaneous systemic sclerosis; FVC, forced vital capacity, IIT, investigator-initiated trial; MMF, mycophenolate mofetil; mRSS, modified Rodnan Skin Score; QOL, quality of life; SHAQ-DI, scleroderma health assessment questionnaire – disability index; SSc, systemic sclerosis; VAS, visual analogue scale

### Planned Phase 2 SSc Study\* is Focused on **Demonstrating Benefit in Skin and Lung Endpoints**

#### **KEY INCLUSION CRITERIA**

- Early diffuse cutaneous SSc, enriched for SSc-ILD
- Stable background therapy
- Anti-centromere antibody negative
- Disease duration ≤2 years: mRSS 15-45
- Disease duration 2-5 years:
  - mRSS 20-45
  - RNA Pol III negative, or evidence of recei



#### **KEY EFFICACY ENDPOINTS**

mRSS (primary)

qHRCT / FVC

**HAQ-DI** (Function)

revised CR

(\*) Study design is subject to change.

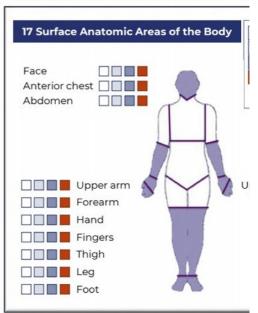
Zura Internal Planning
CRISS, Composite Response Index in Systemic Sclerosis; FVC, forced vital capacity, HAQ-DI, health assessment questionnaire – disability index; ILD, interstitial lung disease; mRSS, modified Rodnan skin scot OLE, open-label extension; qHRCT, quantitative high-resolution computed tomography; SSc, systemic sclerosis

### modified Rodnan Skin Score (mRSS): Endpoint for Assessing Skin Thickness and Fibrosis



Severe skin thickening and tightening restricts movement and causes painful ulcers on the hands and fingers, significantly impairing daily activities and quality of life. The mRSS assesses skin thickness in syspatients by evaluating 17 body sites (e.g. abdomen, arms, legs). Each site is scored

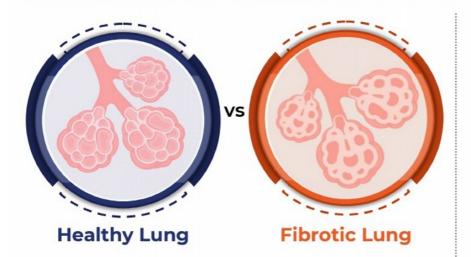
The total score ranges from 0 to 51, with hindicating greater skin involvement.



Sources: 1 Khanna, D., et al. Journal of Scleroderma and Related Disorders, doi:10.5301/jsrd.5000231; 2 Ferreli, C., et al. Clinical Reviews in Allergy & Immunology, doi:10.1007/s12016-017-8625-4.

# In Phase 2, Lung Involvement using qHRCT will be a Key Secondary Endpoint



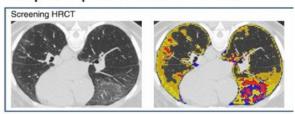


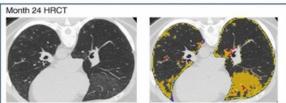
ILD includes various pulmonary disorders marked by inflammation and progressive lung fibrosis, resulting in restrictive lung function and impaired gas exchange.

SSc often leads to ILD due to immune system dysregulation and subsequent lung interstitial fibrosis.

QILD by HRCT provides a sensitive measu involvement, detecting changes as small as

#### Example of improvement after 24 months of MMF in t

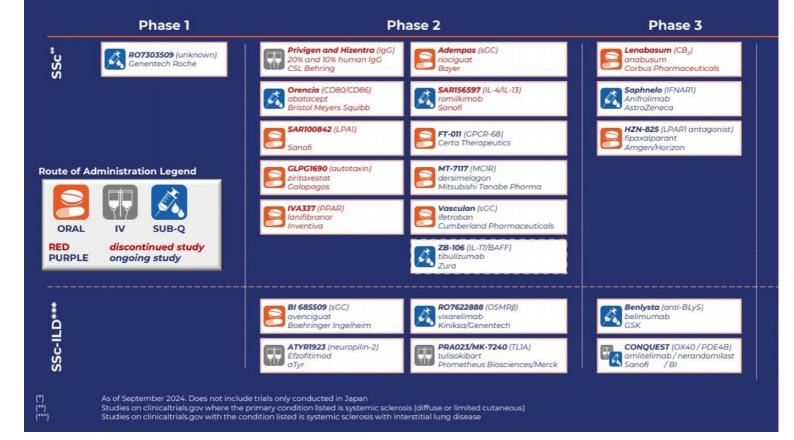




The blue and red areas show QLF, while the yel quantitative ground glass. The entire colored area represents QLF areas decreased (*arrow in B*).

Sources: Goldin, J., et al. Annals of the American Thoracic Society, doi:10.1513/annalsats.201802-079oc; Zura Bio internal planning
Acronyms: ILD, interstitial lung disease; MMF, mycophenolate mofetil; qHRCT, quantitative high-resolution computed tomography; QILD, quantitative interstitial lung disease;
QLF, Quantitative Lung Fibrosis; SSc, systemic sclerosis

# External Development Programs\*: Key Studies and Marketed SSc-ILD Specific Products for Systemic Sclerosis

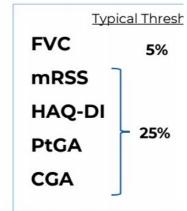


# **Revised CRISS Endpoint in SSc Assessment**

**STEP 1:** Assess for significant SSc-related events:

If no significant SSc-related event, proceed to Step 2 **STEP 2:** Assess each measure for improve worsening:

- New scleroderma renal crisis
- New decline in percent predicted FVC≥15% in established ILD or new percent predicted FVC below 80% predicted
- New onset of left ventricular failure requiring treatment
- New onset of pulmonary arterial hypertension requiring treatment
- Gastrointestinal dysmotility requiring enteral or parenteral nutrition
- Digital ischemia with gangrene, amputation, or hospitalization requiring treatment



RESPONDER: Improvem
≥2 core measures w
worsening in ≤1 core me

Sources: Zura Internal Planning
Acronyms: CGA, clinical global assessment; CRISS: composite response index in systemic sclerosis; FVC, forced vital capacity; HAQ-DI, health assessment questionnaire – disability index; ILD, interstitial lung disease; mRSS, modified Rodnan skin score; PtGA, patient global assessment

### Phase 2 SSc Development Aims to Reduce Historical Risks in Therapeutic Area Development





### **Historic Drivers of SSc Study Failures:**

- Novel and unvalidated mechanisms
- Inclusion/exclusion criteria oversights
- Challenges in balancing sample sizes for mRSS and ILD participants



### **Increasing Probability of Success:**

- Larger study sample size increases the probability of success (mRSS)
- High-resolution CT highly correlates with FVC, improving ILD readthrough
- Sufficient sample size for ILD readouts to understand potential Phase 3 effects

Acronyms: CT, computed tomography, FVC, forced vital capacity; IL, interleukin; ILD, interstitial lung disease; mRSS, modified Rodnan Skin Score



# Rationale for Phase 2 Study in Hidradenitis Suppurativa Patients





# Increased Probability of Success Through Scientific and Clinical Validation

- IL-17A and BAFF are clinically validated as key contributors to HS pathology
- Inhibiting IL-17A or disrupting B cells individually shows strong clinical support
- Ixekizumab shows high affinity for IL-17A and IL-17A/F
- Dual inhibition of these targets could improve patient outcomes



#### Unmet Need and Growth Potential

- 50% to 70% of HS patients do not achieve HiSCR75 with current treatments
- In the chronic phase, BAFF may play a more significant role, highlighting an unmet need that tibulizumab can address
- The TAM is projected to grow to \$3.5B \$4B by 2030

Acronyms: BAFF, B cell-activating factor; HiSCR, Hidradenitis Suppurativa Clinical Response; HS, hidradenitis suppurativa; IL, interleukin; TAM, total addressable market

### **An Overview of Hidradenitis Suppurativa**



#### **DISEASE OVERVIEW**

Hidradenitis suppurativa is an inflammatory follicular skin disease

Skin lesions form in the armpits, groin, and under the breasts due to inflammation and infection of the sweat glands

- ✓ Recurrent nodules and abscesses resulting in pus-like discharge
- ✓ Difficult-to-heal open wounds and scarring
- ✓ Increased Th1/Th17 and B cell mediated inflammation 1-3
- ✓ Disproportionately affects women between adolescent age to 55 years of age <sup>4,5</sup>





#### **CLINICAL OPPORTUNITY 6**

**~300K people** living with HS in the U.S.

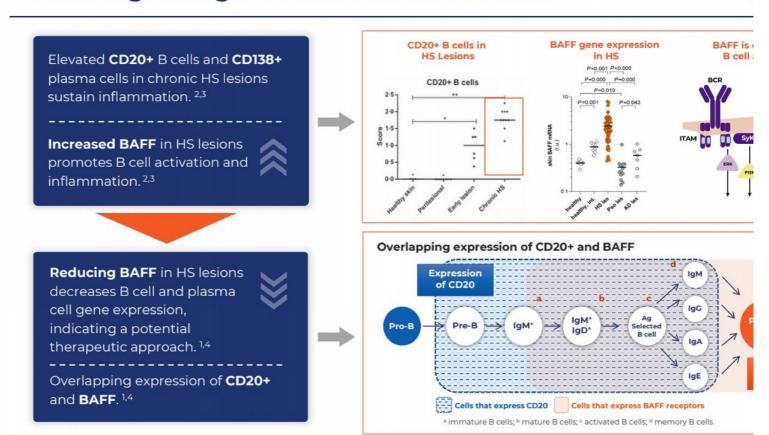
Average time to diagnosis is **7 years** 

~>50% patie inadequate

Sources:

<sup>1</sup>Moran, Barry, et al. Journal of Investigative Dermatology, doi:10.1016/j.jid.2017.05.033. <sup>2</sup>Banerjee, Anirban, et al. Immunological Investigations, doi:10.1080/08820139.2016.1230867. <sup>3</sup> Sabat, Robert, et al. Journal of Allergy and Clinical Immunology, doi:10.1016/j.jaci.2022.10.034. <sup>4</sup> Garg, Amit, et al. JAMA Dermatology, doi:10.1001/jamadermatol.2017.0201. <sup>5</sup> Ingram, John R. British Journal of Dermatology, doi:10.1111/bjd.19435. <sup>6</sup> Medical Literature, MEDACorp KOL Discussions

### **B Cell Signaling Potentiates HS Disease**



Sources: <sup>1</sup>Van der Zee, H.H., et al. British Journal of Dermatology, doi:10.1111/j.1365-2133.2011.10698.x. <sup>2</sup> Rumberger, Beth E., et al. Inflammation Research, doi:10.1007/s00011-020-01381-7.

<sup>3</sup> Sabat, Robert, et al. Journal of Allergy and Clinical Immunology, doi:10.1016/j.jaci.2022.10.034. <sup>4</sup> Gudjonsson, Johann E., et al. JCI Insight, doi:10.1172/jci.insight.139930

### Role of IL-17A and B Cells Is Clinically Validated; However, Clinical Effect Remains Modest with Single-Pathway Inhibition



			VARTIS		<b>○</b> MoonLal
comp	oany and drug INN >>	secukinumab	remibrutinib*	bimekizumab	sonelokimab
Med	hanism	IL-17 A	BTKi	IL-17 A/F	IL-17 A/F
Administration Phase		SC/IV	PO	SC	SC
		Phase 3	Phase 2b	Phase 2	Phase 2
D	osing	30mg Q2W for 16W	100 mg or 25 mg BID	320mg Q2W for 12W	120mg Q2W for 12W
Total Patients		n = 360	n = 77	n = 88	n = 234
Efficacy	Non-Placebo Adjusted	42% - 45%	48.5% - 72.7%	63%	66%
(HiSCR50)	Placebo Adjusted	11% +	38%	35%	38%
Efficacy	Non-Placebo Adjusted	N/A	27.3% - 42.4%	50%	43%
(HiSCR75)	Placebo Adjusted	N/A	24%	29%	29%
Safety	Candidiasis	0% - 3%1	0	9%	10.5%

<sup>(\*)</sup> There have been no head-to-head clinical trials between the product candidates listed above. Study designs and protocols for each product candidate were different, and as a result, resumply not be comparable between product candidates.

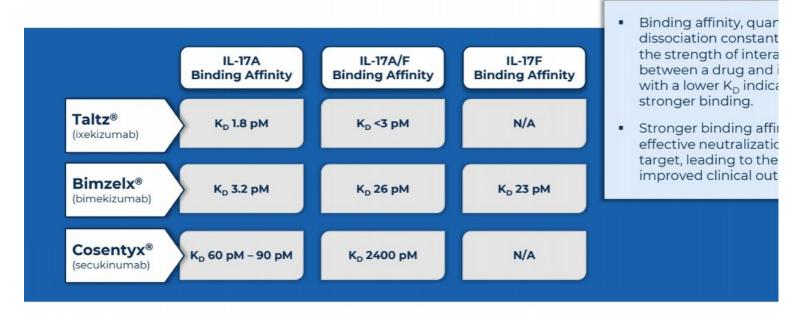
Sources: Company Presentations, Publications and Research.

1 Represents data from psoriaiss trial. 2 Represents afety data from psoriaist strial remibrutinib, 2024 AAD S026.

Acronyms: BID, twice a day, BTKi, Bruton tyrosine kinase inhibitors; HiSCR, Hidradenitis Suppurativa Clinical Response; HS, hidradenitis suppurativa; IL, interleukin; INN, international non-proprietary IV, intravenous; PO, per os or by mouth; Q2W, every two weeks; Q4W, every four weeks; SC, subcutaneous

# Tibulizumab\* IL-17A Component Has Class-Leading Binding Affinity Against IL-17A and IL-17A/F

Ixekizumab is a humanized IgG4 monoclonal antibody

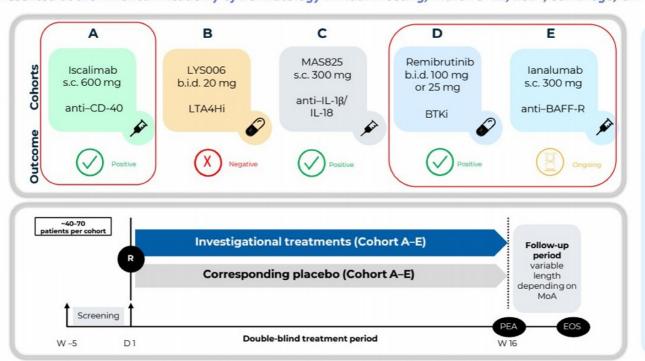


(\*) Tibulizumab was engineered from Taltz® (ixekizumab)

Sources:  $^{1}$ Taltz $^{0}$ . Prescribing Information. Lilly USA, LLC,  $\frac{1}{1}$  LtC,  $\frac{1}{1}$  LtC,  $\frac{1}{1}$  LtC,  $\frac{1}{1}$  Lilly com/hcp/moa-il7a-igq4. Acronyms:  $^{1}$  IgG4, immunoglobulin G4;  $^{1}$  K $_{D}$ , dissociation constant; pM, picomolar

# Ongoing Novartis Phase 2b Multicenter Platform Study Offers Additional Clinical Evidence of B Cell Targeting Benefit in HS

Presented at the American Academy of Dermatology Annual Meeting; March 8–12, 2024; San Diego, CA.



#### **Patients**

- Adult paraged 18-
- Moderat for ≥12 m anatomi ≤15 tunn
- Cohorts
   ≥5 inflam
- Cohorts inflamm

\*Study started in February 2019 and is currently ongoing.

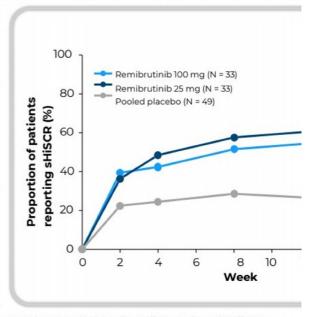
BAFF-R, B-cell activating factor of the tumor necrosis alpha family receptor; b.i.d., twice daily; BTKi, Bruton's tyrosine kinase inhibitor; CD, cluster of differentiation; D, day; EOS, end of study; HS, hidradenitis suppurativa; IL, interleukin; LTA4H, leukotriene A4 hydrolase; MoA, mechanism of action; PEA, primary endpoint analysis; R, randomization; s.c., subcutaneous; W, week. Clinicaltrials.gov NCT03827798. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT03827798 (Accessed 6 Mar 2024).

# Novartis' Interim Results Presented at '24 AAD: BTKi PBO-Adjusted Delta Aligns with Approved and In-Development Agents

Presented at the American Academy of Dermatology Annual Meeting; March 8-12, 2024; San Diego, CA.

 The primary endpoint of this study was met for both doses of remibrutinib; patients treated remibrutinib reported a greater rate of sHiSCR\* at Week 16 compared with placebo

	Coh	Cohort A-D	
	Remibrutinib 25 mg (N = 33)	Remibrutinib 100 mg (N = 33)	Pooled Placebo (N = 49)
Proportion of patie	nts with sHiSCR*:		
Observed with NRI (%)	72.7	48.5	34.7
Difference <sup>†</sup> (%) (95% CI)	38.0 (21.1 to 55.0)	13.8 (-4.4 to 32.0)	
Bayesian estimated (%)	72.3	48.5	34.9
Difference† (%) (95% CI)	37.2 (19.7 to 53.0)	13.9 (-4.2 to 31.9)	
Probability of difference‡	99.9	89.6	



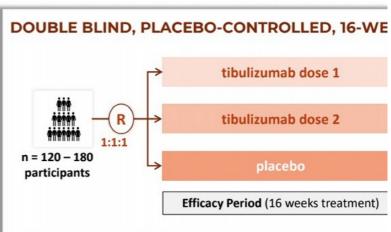
<sup>\*</sup>The sHiSCR is defined as a ≥50% reduction in the abscess and inflammatory nodule count and no increase in draining tunnels compared with baseline. †Difference refers to the difference between remibrutinib (either dose) and pooled placebo at Week 16. ‡Bayesian posterior probability of remibrutinib (either dose) being better than pooled placebo. CI, confidence interval; HiSCR, hidradenitis suppurativa clinical response; n, total number of patients with response; N, total number of patients in each treatment arm; NRI, non-responder imputation; sHiSCR, simplified hidradenitis suppurativa clinical response.

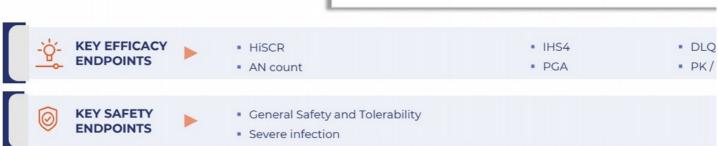
### Planned Phase 2 HS Study Design\*



#### **KEY INCLUSION CRITERIA**

- Moderate to Severe HS
- Hurley Stage II/III
- Total abscess and inflammatory nodule count (AN) ≥ 5
- Up to 30% TNF inadequate responders





(\*) Study design is subject to change.

Sources: Zura Internal Planning
Acronyms: DLQI, dermatology life quality index; HiSCR, Hidradenitis Suppurativa Clinical Response; HS, hidradenitis suppurativa; IHS4, international hidradenitis suppurativa severity score system; PD, pharmacodynamic; PGA, physician's global assessment; PK, pharmacokinetic; R, randomization



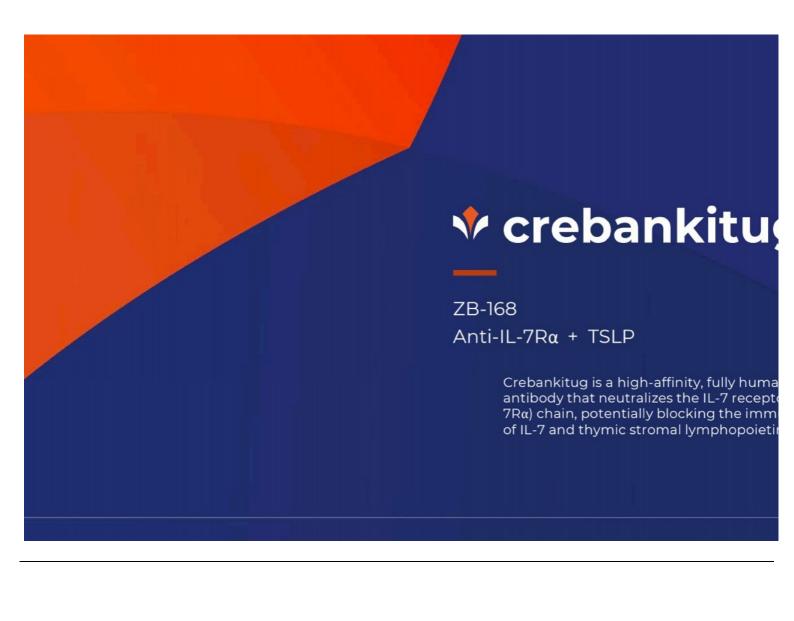
# **Tibulizumab Summary**

The Phase 2 development programs for systemic sclerosis and hidradenitis suppurativa are progressing

The strategy follows validated pathways with the potential for improved outcomes, supported by related mechanism-of-action data from IL-17 and BAFF/B-cell depletion therapies

We believe tibulizumab is positioned as a potential first-in-class dual-pathway biologic

The next 6 to 12 months offer significant growth opportunities, with multiple key milestones anticipated



# Crebankitug

# Crebankitug, a fully human IL-7Rα antibody

- Originally developed by Pfizer
- IL-7Rα inhibition has potential to inhibit two critical immune pathways (IL-7 and TSLP)
- Potential applicability in broad range of T-cell mediated diseases and atopic diseases.

# Well tolerated in Phase 1 and Phase 1b studies

- >90 participants dosed with crebankitug
- Adverse events generally mild and not treatment-related.

### Phase 1b data demonstrate clear evidence of impact on key T-cell compartments

- Only anti-IL7R program that has reported safety, PK, and PD data in participants with an auto immune disease (not just healthy volunteers)
- Potentially clinically relevant changes observed in memory T-cell counts and T<sub>reg</sub>: T<sub>memory</sub> ratios.

## Activ

- Ongoil planni in area needs.
- Will be Phase TSLP c readou

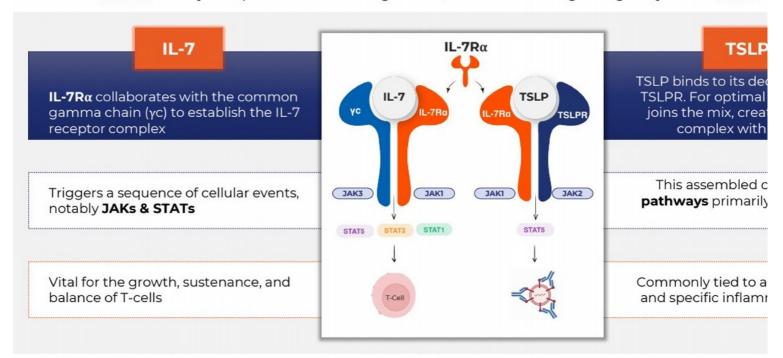
**creban-** creating balance

**ki-** cytokine or cytokine receptor

tug- unmodified imr

# Crebankitug: A Multi-Functional Antibody That Blocks Signaling via IL-7 and TSLP Pathways

IL-7Rα is a key receptor in immune regulation, central to the signaling of cytokines IL-7 ar

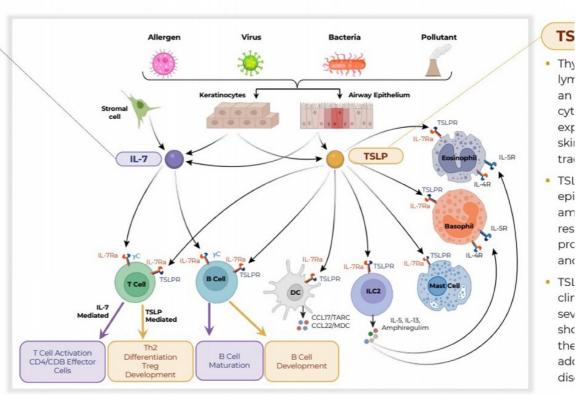


Positioning crebankitug for potential applications in diverse immune-related and autoimmun

# Both TSLP and IL-7 Have a Role in Activating Th1, Th2, and Th17-Driven Inflammation

### **IL-7 PATHWAY**

- IL-7 is a growth factor that binds to the heterodimeric receptor of IL-7R:γC and is critical for the survival, development and homeostasis of central and effector memory T cells <sup>4</sup>
- Due to the high expression of IL-7R on T<sub>eff</sub> compared to T<sub>reg</sub>, inhibition results in a 20-fold greater activity in reducing T<sub>eff</sub>, leading to an increase in T<sub>reg</sub>:T<sub>eff</sub> ratio 5,6



1 Ebina-Shibuya, R. and Warren L.eonard. Nature Reviews Immunology, doi:10.1038/s41577-022-00735-y; Marone, G., et al. Expert Opinion on Investigational Drugs, doi:10.1080/13543784.2019.1672657; Menzies-Gow, A., et al. Respiratory Research, doi:10.1186/s12931-020-01505-x; Chen, 2021. Frontiers Immunol, S. Herold, K., et al. JCI Insight, doi:10.1172/jci.insight.126054; Graphic created in BioRender; Martin, M. and Badovinac P. Frontiers in Immunology, doi:10.3389/fimmu.2018.02692; Waickman, A., et al. iScience, doi:10.1016/j.isci.2020.101421; Marković, I. and Savvides S. Frontiers in Immunology, doi:10.3389/fimmu.2020.01557.

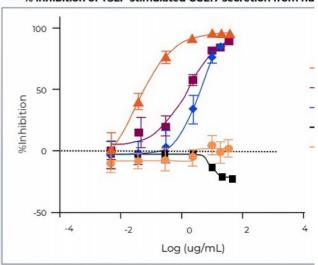
## Crebankitug Is the Only mAb to Potently Inhibit Both IL-7R and TSLP



#### Inhibition of TSLP stimulated CCL17 secretion from human monocytes

## World Allergy Congress Poster, Dec % inhibition of TSLP stimulated CCL17 secretion from hu

	AstraZeneca AMGEN	<b>⊚32</b> BIO	v zurabio	
	tezepelumab (TSLP)	bempikibart (IL-7Rα)	crebankitug (IL-7Rα)	
	TSLP mAb	IL-7Rα mAb	IL-7Rα mAb	
TSLP- Induced Signals	67 ng / ml / 0.44nM (CCL17) <sup>(5)</sup>	24 nM (CCL2) <sup>(4)</sup>	7.5 ng / ml / 0.05nM (CCL17) <sup>(i)</sup> 11 ng / ml / 0.07nM (CCL22) <sup>(i)</sup> <b>0.08 nM (CCL2)</b> <sup>(4)</sup>	
IL-7-Induced Signals	Neg	0.6 nM (IL-7 at 0.25ng/ml) <sup>(4)</sup> 2.1 nM (IL-7 at 2.5ng/ml) <sup>(4)</sup>	0.46nM (pSTAT5) <sup>(2)</sup>	

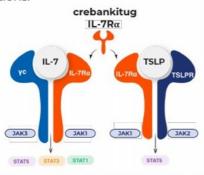


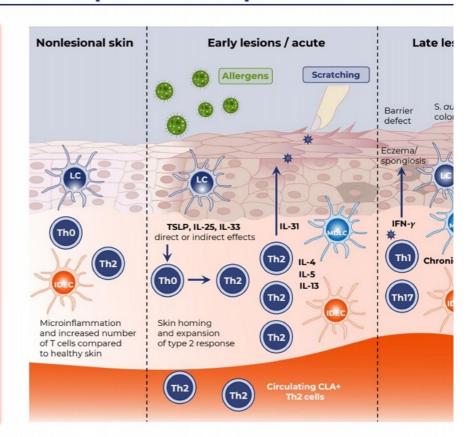
Source: <sup>1</sup> Zura Internal Data; <sup>2</sup>Herold, Kevan C., et al. JCI Insight, doi:10.1172/jci.insight.126054; <sup>3</sup> Numazaki, Mako, et al. Journal of Pharmacology and Experimental Therapeutics, doi:10.1124/jpet.121.000686; <sup>4</sup> Yamniuk, Aaron P., et al. Antibodies against II-7r Alpha Subunit and Uses Thereof. 18 May 2021.

Acronyms: CCL17, C-C motif chemokine ligand 17; IL, interleukin; mAb, monoclonal antibody; TSLP, thymic stromal lymphopoietin

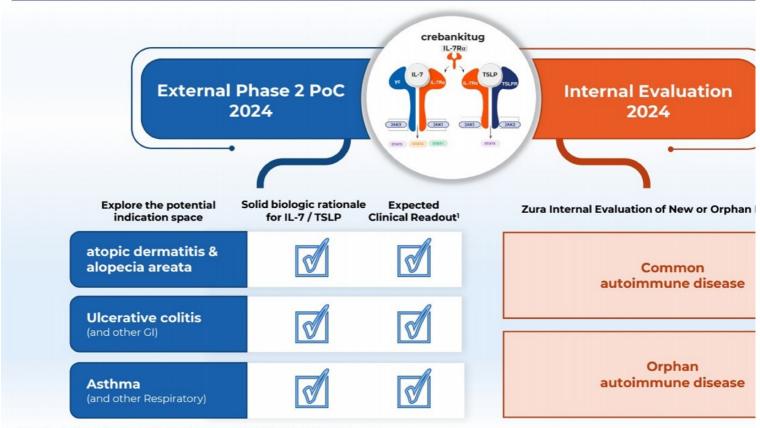
## Dual Inhibition of Th1 and Th2 May Offer Broader or Deeper Levels of Response in Atopic Dermatitis

- TSLP and IL-25 activate Th2 cells, which are crucial in the early stages of atopic dermatitis.
- As the condition progresses, the influence of Th2 decreases, while Th1 and Th17 responses become more prominent.
- Targeting both Th2 and Th1 pathways may offer broader and more effective treatment options.





# Crebankitug Provides Optionality for Clinically Validated Development or Novel Indications



 $Sources: \ ^1Clinical Trials.gov\ database, Company\ Presentations; ^2Zura\ Internal\ Planning\ Acronyms: \ Gl,\ gastrointestinal;\ IL,\ interleukin;\ PoC,\ proof-of-concept;\ TSLP,\ thymic\ stromal\ lymphopoietin$ 



# **Crebankitug Summary**

Crebankitug targets immune-related and autoimmune conditions linked to IL-7R or TSLP signaling

In three Phase 1 and 1b studies involving 93 participants, crebankitug was well-tolerated, with most adverse events being mild and unrelated to the treatment

Only anti-IL- $7R\alpha$  program with clinical data showing impact on key T-cell subpopulations, indicating potential for broad T-cell mediated and atopic diseases

Advancing indication planning and monitoring IL-7R and TSLP therapies to support Phase 2 strategy



## **Torudokimab Asset Overview**

### About torudokimab

- IL-33 implicated in driving Th2 biology through ST2 and Th1/Th17 through alternative signaling 1
- 03 The target engagement evaluation suggested binding to IL-33 and treatment emergent ADA had no apparent impact on PK or target engagement
- Well tolerated in Phase 1 and Phase 2 trials conducted by Eli Lilly 2

141 healthy volunteers in Phase 1 study

Analyses confirmed key biomarker reductions (IL-13, periostin and CCL17/TARC) and no ADA impact 3

103 participants with moderate to severe atopic dermatitis in Phase 2

Potential utility in diseases driven by epithelial inflammation 1

### **Mechanism of Action**

01 Inhibition of IL-33 blocks both ST2 and RAGE signaling 4

Initial Focus on Respiratory, Dermatologic, Gastrointestinal and Orphan Autoimmune Indications

01 Potential for 1st-in-class opportunities 02 Validated pathways in COPD 4 and asthma 5



Cohen, S., et al. Nature Communications, doi:10.1038/ncomms9327; 2 Clinicaltrials.Gov, clinicaltrials.gov/ct2/show/NCT03913260. Accessed 26 Aug. 2024; Clinicaltrials.Gov, clinicaltrials.gov/ct2/show/NCT03343587. Accessed 26 Aug. 2024; Clinicaltrials.gov, clinicaltrials.gov/ct2/show/NCT03831191. Accessed 26 Aug. 2024; Section 6.1, DSUR for period 23-Sep-2019 22-Sep-2020; 3 Laquer, V., et al. British Journal of Dermatology, doi:10.1111/bjd.21631. 4 Okragly, A., et al. Journal of Inflammation Research, doi:10.2147/jir.s320287. 5 Wechsler, M., et al. New England Journal of Medicine, doi:10.1056/nejmoa2024257.

## **Torudokimab IL-33 Pathway**

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IL-33 is a member of the IL-1 cytokine family that is constitutively expressed in structural and lining cells including fibroblasts, endothelial, and epithelial cells of skin, gastrointestinal tract, and lungs <sup>1</sup>

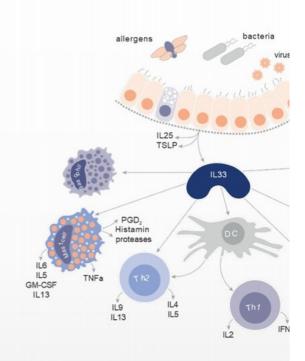
IL-33 is released from the epithelium by disease exacerbating environmental factors and is an important amplifier of innate inflammation during exacerbations <sup>2</sup>

Polymorphisms in IL-33 and ST2 are associated with increased eosinophil production as well as respiratory diseases such as COPD and severe asthma

IL-33 inhibition clinically validated in severe asthma, COPD <sup>3</sup>, and subsets of other epithelial disorders <sup>4</sup>

Pre-clinical data demonstrates superior activity of torudokimab compared with etokimab and itepekimab suggesting the potential for best-inclass activity <sup>5</sup>

Emerging biology suggests expanding opportunity for IL-33 in fibrotic and autoimmune conditions <sup>6</sup>

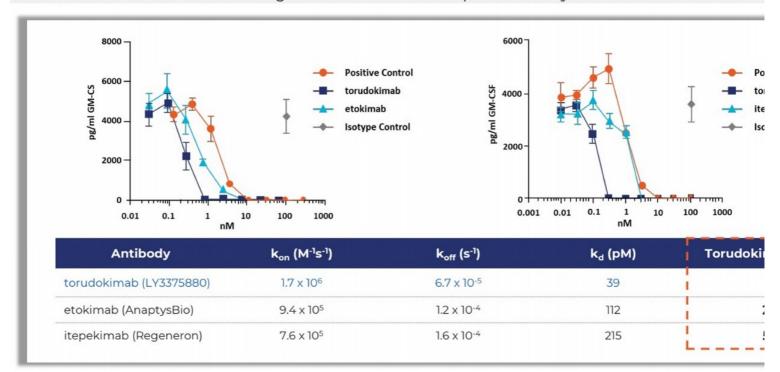


Sources:

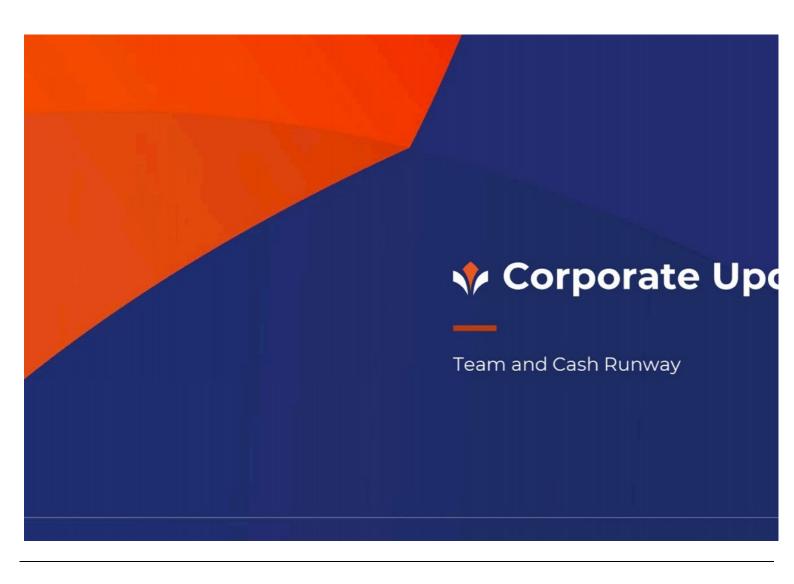
<sup>1</sup> Chan, B., et al. Frontiers in Immunology, doi:10.3389/fimmu.2019.00364; <sup>2</sup> Cayrol, C. and Girard, J.P. Cytokine, doi:10.1016/j.cyto.2022.155891. <sup>3</sup> Gudbjartsson, D., et al. Nature Genetics, doi:10.1038/ng.323; Ketelaar, M., et al. Journal of Allergy and Clinical Immunology, doi:10.1016/j.jaci.2020.04.051; <sup>4</sup> Singh, D. The Lancet Respiratory Medicine, doi:10.1016/s2213-2600(22)0005 Wechsler, M., et al. New England Journal of Medicine, doi:10.1056/nejmoa2024257; Chen, Y-Ling, et al. Science Translational Medicine, doi:10.1056/scitranslmed.aax2945; <sup>5</sup> Zura Internal dat <sup>6</sup> Pei, C., et al. Immunology, doi:10.1111/imm.12174; Kurimoto, M., et al. Frontiers in Physiology, doi:10.3389/fphys.2021.781012; Dong, Y., et al. Frontiers in Medicine, doi:10.3389/fmed.2021.73948

# **Torudokimab Has Potential for "Best-in-Class" Activity**

**Torudokimab was 2.9 and 5.5-fold more potent than etokimab and itepekimab**, respectively inhibiting IL-33-induced GM-CSF production by human mast cells



Sources: Zura Internal Data



## Zura's Leadership: Driving Innovation in I&I







Robert Lisicki
Chief Executive Officer
and Director



Verender Badial Chief Financial Officer



Kiran Nistala, MBBS, PhD Chief Medical Officer and Head of Development



Gary Whale PhD
Chief Technology
Officer



Kim Davis JD

Chief Legal Officer and
Corporate Secretary

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Steven Ziegler, PhD

Acronyms: 1&I, inflammation and immunology; SAB, scientific advisory board

#### Key milestones\* expected through 2026 Cash runway expected through 2027 MILESTONE LEGEND: 2H-2024 2025 □ Internal Zura Select CRO ▲ External Catalyst ☐ Phase 2 study recruitment □ SSc Topline SSc study Obtain IND from US FDA Pending dat Initiate a Phase 2 study in SSc tibulizumab Obtain IND from US FDA ■ Select CRO ☐ HS Topline HS study Pending dat ☐ Initiate a Phase 2 study in HS ☐ Select indication for future Complete internal indication planning development\* Indication selection to guide future crebankitug m ▲ 4Q-2024: Phase 2a Topline Data bempikibart in AA, Q32 Bio Indication crebankitug Planning ▲ 4Q-2024: Phase 2 Topline Data Ongoing bempikibart in AD, Q32 Bio ▲ 3Q-2024: Phase 3 Topline Data tezepelumab in Asthma (reducing corticosteroid), Amgen ▲ 2Q-2025: Phase 3 Study Complete itepekimab in COPD, Sanofi Indication ▲ 2Q-2025: Phase 3 Topline Data torudokimab

**Evaluation** 

On-going

The timing of regulatory and clinical trial milestones are subject to change and additional discussion with the FDA Internal Zura Planning

AA, alopecia areata; AD, atopic dermatitis; COPD, chronic obstructive pulmonary disease; CRO, contract research organization; HS, hidradenitis suppurativa; SSc, systemic sclerosis; US FDA, United States Food & Drug Administration

astegolimab in COPD, Roche

Indication planning to guide future torudokimab n

Complete internal indication

planning



Nasdaq ticker: ZURA April 2024 Photo courtesy of ®Nasdaq, Inc.

Our mission: Driving scientific breakthroughs by turning drug transformative, life-saving treatments.

**Tibulizumab shows best-in-class potential:** Introducing a teti therapy designed to target and potentially treat autoimmune

**Promising pipeline for value creation:** Integrating validated k pathways into multifunctional antibody assets to potentially in therapeutic outcomes.

**Upcoming external catalysts:** Anticipating near-term develop further expand the pipeline's potential.

**Proven leadership:** Experienced team with a track record of coover \$8 billion in mergers and acquisitions in the past three years.

**Strong financial position:** With approximately \$188 million<sup>1</sup> in equivalents, and investments, we are funded to support our plathrough 2027. The 3Q 2024 IPO warrant exchange has streaml structure, and additional financing through ATM options rema future needs. As of August 29, 2024, we have 63,774,183 Class A outstanding<sup>2</sup>.

Source: <sup>1</sup> Cash includes cash and cash equivalents as of 30-June-2024; <sup>2</sup> S-3 dated 03-Sept-2024 Acronyms: ATM, at-the-market offering; IPO, initial public offering