



## Safe Harbor Statements

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# Today's agenda and presenters

Topic	Presenter	Title
Opening Remarks and Topline Summary	Ronald Martell	Chief Executive Officer
SPOTLIGHT Preliminary Results Summary	Edwin Tucker, MD, MRCP	Chief Medical Officer
Upcoming Milestones and Closing Remarks	Ronald Martell	Chief Executive Officer



Edwin Tucker, MD, MRCP **SPOTLIGHT Preliminary Results Summary** 



# CIndU can be a severe & debilitating disease resulting in a major negative impact on quality of life

- Chronic inducible urticaria (CIndU) is a debilitating inflammatory condition of the skin with a specific trigger such as heat, cold, sunlight, rubbing or scratching the skin or tight clothing
- Mast cell degranulation, leading to the release of histamine and other inflammatory mediators, is the key driver of severe itching, hives and angioedema in ClndU patients
- CIndU patients suffer both physically and psychologically. Severe disease has a similar negative impact on QoL as other dermatologic diseases like plaque psoriasis
- Targeting the c-Kit receptor with briquilimab disrupts a critical survival on mast cells leading to mast cell apoptosis and disease resolution







<sup>1</sup> Munoz M, et al. Current Allergy and Asthma Reports June 2024

<sup>2</sup> Ozdemir SO, et al. JEADV Mar 2024

<sup>3</sup> Maurer M, et al. J Allergy Clin Immunol 2017

<sup>4</sup> Nikolaev I, et al. EAACI Hybrid Congress, July 1-3, 2022

## Phase 1b/2a SPOTLIGHT study of subcutaneous briquilimab in CIndU



Open-label, cold urticaria & symptomatic dermographism, single ascending dose study

### Screening/Eligibility

- Diagnosis of Cold Urticaria (ColdU) or Symptomatic Dermographism (SD) for ≥ 3 mos.
- H1-antihistamine-failed
- 18+ years

### **Study Operations**

- Lead PI: Martin Metz, MD
- 7 sites in the EU
- N = ~27
- 180mg enrollment upcoming

#### **Key Assessments**

- Provocation Test: TempTest (ColdU), FricTest (SD)
- Disease Scores: UCT
- Mast Cell Depletion & Recovery: Serum Tryptase,
   Skin Biopsies
- Safety: TEAEs, SAEs

40 mg n=3
120 mg n=12
180 mg n=12
Single
Subcutaneous
Dose

12 Week Efficacy Observation Period
(6 Week Preliminary Analysis)
+ 24 Week Additional Safety Observation

## **Provocation Tests Used for Clinical Evaluation**

FricTest<sup>™</sup> - Symptomatic Dermographism

CR - No response at Fric Level 4

 $PR - \ge 2$  pin improvement



TempTest™ - Cold Induced Urticaria

CR - Negative test at  $\leq 4^{\circ}$ C

PR - Improvement by > 4°C







# **SPOTLIGHT** Baseline Demographics

	Briquilimab 40mg (n=3)	Briquilimab 120mg (n=12)
Age (years), mean (SD)	35.3 (8.0)	46.4 (13.8)
Female, n (%)	1 (33%)	8 (67%)
Weight (kg), median (range)	86.0 (69-94)	99.0 (57-115)
Cold Urticaria, n	1	4
Symptomatic Dermographism, n	2	8
Baseline Provocation Threshold		
TempTest™ (°C), mean (range)	16.0 (16-16)	20.8 (15-27)
FricTest™ (Pin Count), mean (range)	3.5 (3-4)	3.9 (3-4)
Urticaria Control Test (UCT) score, mean (SD)	3.7 (2.5)	6.3 (3.3)
Tryptase (ng/ml), mean (range)	4.7 (4.1-5.3)	7.6 (3.6-25.7)



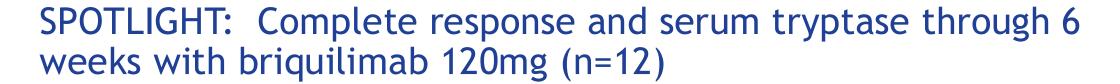


## SPOTLIGHT 6 Week Efficacy Evaluation

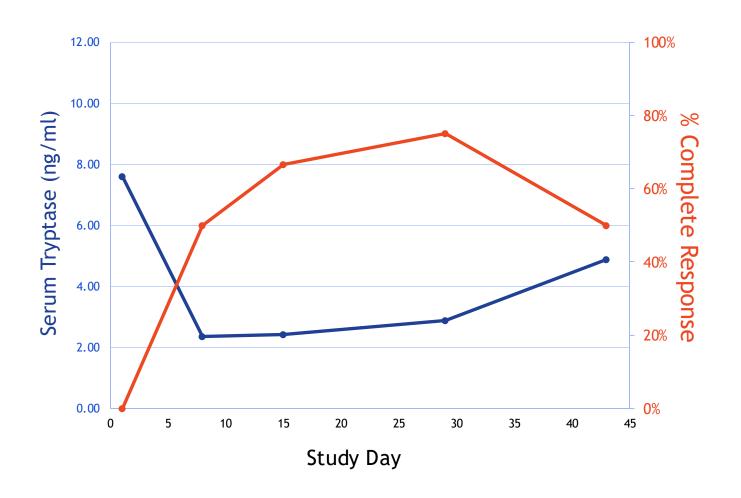
Briquilimab 120mg single dose achieved 83% (10 of 12) complete response

	Briquilimab 40mg (n=3)	Briquilimab 120mg (n=12)	Briquilimab All doses (n=15)
Complete Response, n (%)	1 (33%)	10 (83%)	11 (73%)
ColdU, n	0	3	3
Symptomatic Dermographism, n	1	7	8
Partial Response, n (%)	2 (66%)	1 (8%)	3 (20%)
ColdU, n	1	0	1
Symptomatic Dermographism, n	1	1	2
Complete or Partial Response at any time, n (%)	3 (100%)	11 (92%)	14 (93%)









- 11 of 12 patients achieved either Complete or Partial Response at Day 15
- 6 Complete Responses and 1 Partial Response at Day 43, durability assessment ongoing
- 10 of 12 patients achieved UCT score of 16 (complete control) or 12-15 (well controlled) at Day 29





## SPOTLIGHT safety and tolerability

	Briquilimab 40mg (n=3)	Briquilimab 120mg (n=12)
Any adverse event*	2**	10***
Any serious adverse event	0	0
Hypersensitivity reaction	0	0
Any adverse event leading to discontinuation	0	0
Adverse event leading to death	0	0
Adverse event ≥ grade 3	0	0

<sup>\*</sup>AEs occurring in ≥2 participants: fatigue, dizziness, headache, nasopharyngitis, blood CK increased, diarrhea, muscle tightness, nausea



<sup>\*\*</sup>AE report of Grade 1 neutropenia at Day 94, ANC 1825, resolved by Day 164

<sup>\*\*\*</sup>AE report of Grade 1 neutrophil decreased at Day 29, ANC 1570, resolved by next measurement, Day 39

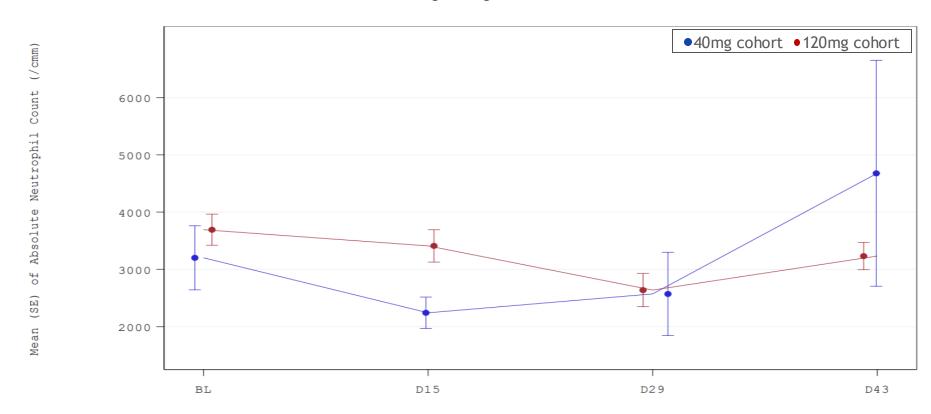




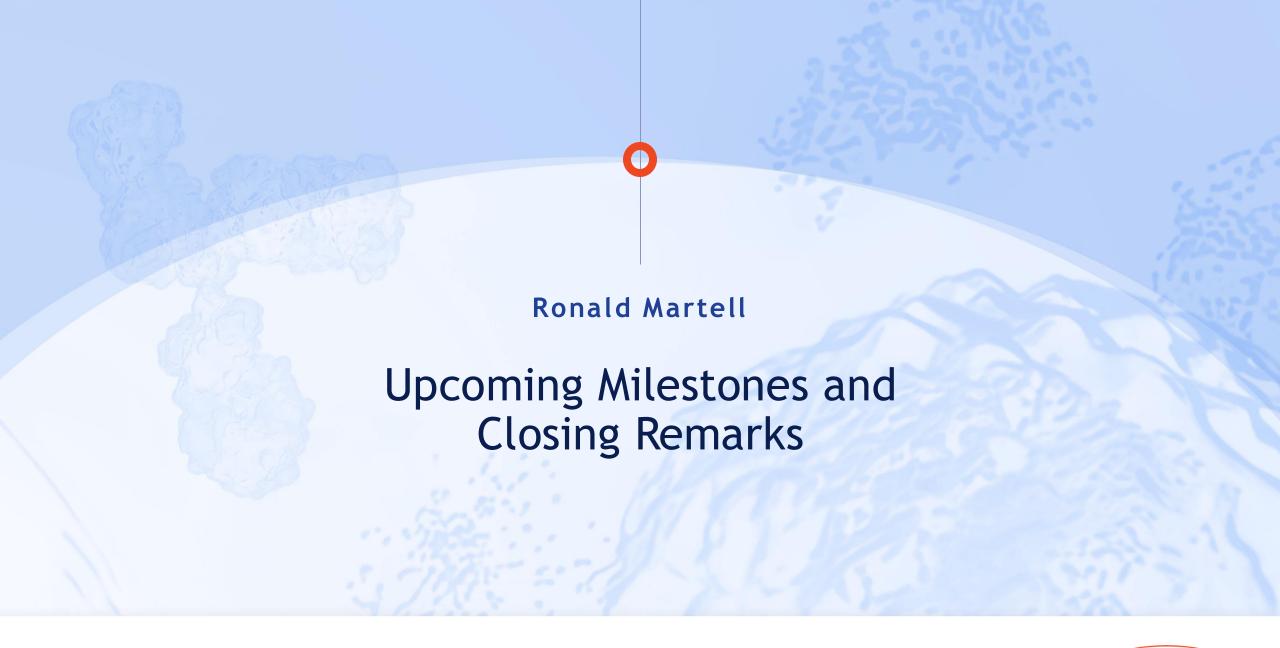
## No ANC values observed below 1500 and no association with infection

Figure AD\_F0007. Mean (SE) of Absolute Neutrophil Count (/cmm) over Visit by Cohort (up to Week 6 (Day 43))

Safety Analysis Set









# Positive preliminary SPOTLIGHT results demonstrate robust clinical activity and support optimal biologic dosing to minimize unwanted effects of c-Kit inhibition



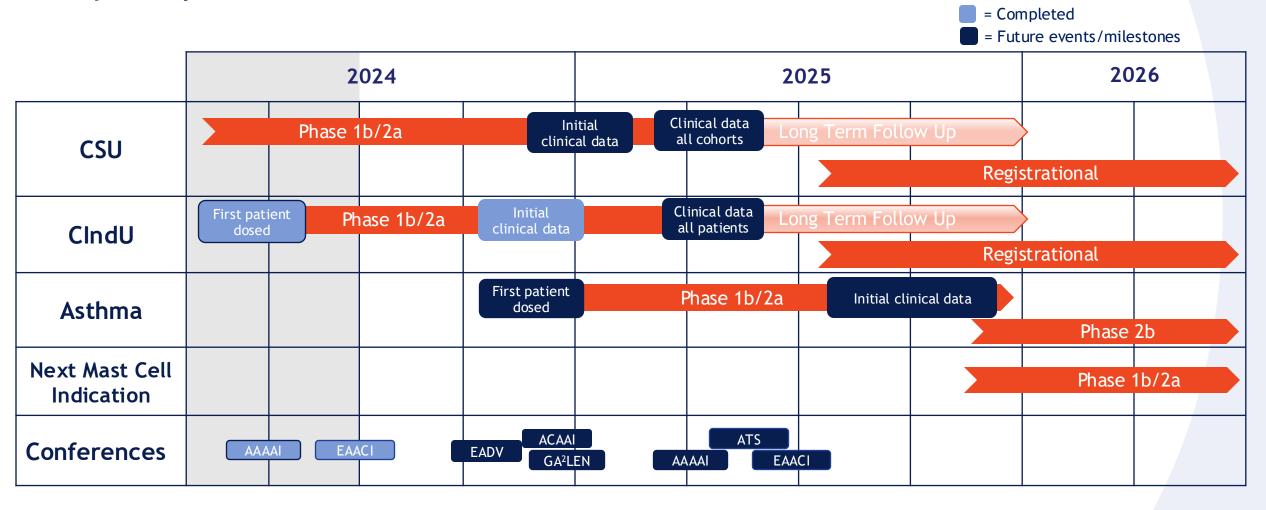


## SPOTLIGHT and BEACON Study Updates

- 180mg SPOTLIGHT cohort cleared by EU regulatory authorities
  - Enrollment to begin soon
  - Full data expected in the first half of 2025
- BEACON study data will be presented week of Jan 6<sup>th</sup>, 2025
  - Both 180mg Q8W and 240mg single dose cohorts fully enrolled
  - Data release to include 180mg Q8W and 240mg cohorts



## Key Briquilimab Mast Cell Franchise Milestones





## **Closing Remarks**

- Briquilimab demonstrated exceptional efficacy
  - 93% (14/15) of patients achieving clinical benefit
  - 83% (10/12) of 120mg patients reaching a complete response
- Briquilimab achieved rapid reduction of tryptase and disease control with 92% (11/12)
   120mg patients reaching a CR or PR at day 15
- Briquilimab was well tolerated with no SAEs, no AEs of Grade 3 or higher, no AEs of anemia and no skin or hair color changes
- Full SPOTLIGHT study results, including 180mg cohort, to be presented in 1st half of 2025
- These results demonstrate briquilimab's potential for optimal biologic dosing to balance efficacy and safety in mast cell driven diseases
- Thank you to the patients and trial investigators who support Jasper's clinical studies





