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### Today's agenda and presenters

Topic	Presenter	Title (Affiliation)	
Opening Remarks and Topline Summary	Ronald Martell	Chief Executive Officer	
BEACON Preliminary Results Summary	Edwin Tucker, MD, MRCP	Chief Medical Officer	
Briquilimab for Chronic Urticaria	Thomas B Casale, MD	Prof of Medicine and Pediatrics, University of South Florida	
Upcoming Milestones and Closing Remarks	Ronald Martell	Chief Executive Officer	



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



### Phase 1b/2a BEACON study in chronic spontaneous urticaria

Randomized, double-blind, placebo-controlled, multiple ascending dose study



- CSU diagnosis ≥ 6 mos.
- UAS7 ≥ 16
- 18+ years

 Intolerant or refractory to omalizumab

H1-antihistamine-failed

#### **Study Operations**

- US Lead: Thomas Casale, MD
- EU Lead: Martin Metz, MD
- ~30 sites in the US & EU
- n = ~77



#### **Key Assessments**

- ✓ Disease Scores: UAS7, UCT
- ✓ Mast Cell Depletion & Recovery: Serum Tryptase, Skin Biopsies
- ✓ **Safety:** TEAEs, SAEs
- ✓ PK

#### **Participants** Dose Treatment Period (24 weeks) (Randomization) Group N=310 mg Open Label Weeks 0, 4, 12, 20 N=340 mg Q8W N=8(3:1)80mg Q8W 120mg N=6 (2:1) N=6 (2:1) 120mg **Q12W Double-Blind** Placebo-N=10(3:1)180mg Q8W Controlled N=9(3:1)180mg **Q12W** N=4(3:1)240mg Single Dose N=4(3:1)360mg Single Dose (ongoing, data not available)



## Baseline demographics were generally balanced across the cohorts Representative of a population of moderate to severe patients with CSU



	10mg / 40mg <sup>1</sup> (N=6)	80mg Q8W (N=6)	120mg pooled (N=8)	180mg pooled (N=14)	240mg² (N=3)	Pooled Placebo (N=12)
Age (years), median (range)	55 (31-63)	63 (22-77)	43 (23-82)	38 (18-73)	44 (29-64)	39 (26-60)
Female Sex, n (%)	6 (100%)	3 (50%)	5 (63%)	7 (50%)	3 (100%)	10 (83%)
Weight (kg), median (range)	66 (55-93)	98 (77-129)	88 (63-122)	84 (64-131)	76 (67-84)	78 (66-110)
BMI, median (range)	25 (22-30)	34 (24-50)	29 (22-43)	31 (22-41)	27 (27-31)	27 (24-42)
UAS7 (0-42), mean (SD)	26.1 (9.5)	31.0 (7.9)	27.9 (8.6)	25.9 (7.8)	26.6 (10.9)	28.6 (9.4)
UCT (0-16), mean (SD)	3.6 (2.8)	3.3 (2.4)	3.7 (1.5)	4.5 (3.1)	3.7 (1.5)	3.7 (3.6)
Serum Tryptase (ug/L), mean (SD)	6.6 (1.4)	8.4 (2.6)	7.8 (5.1)	6.0 (3.2)	4.5 (1.0)	8.5 (4.7)

<sup>1</sup> Briquilimab 10mg and 40 mg doses were administered at Week 0, 4, 12 and 20;

All participants were refractory or intolerant to omalizumab, representing a CSU population of highest unmet medical need



<sup>2</sup> Briquilimab 240 mg was administered as a single dose

### Briquilimab demonstrated deep reductions in UAS7 scores

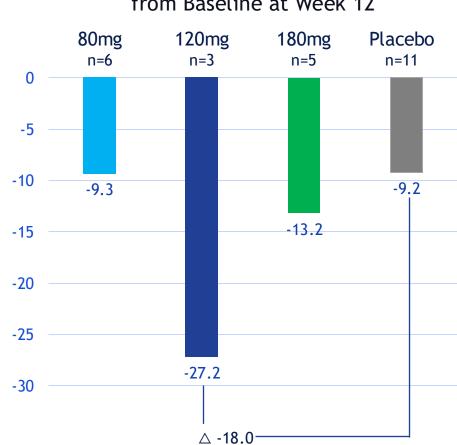




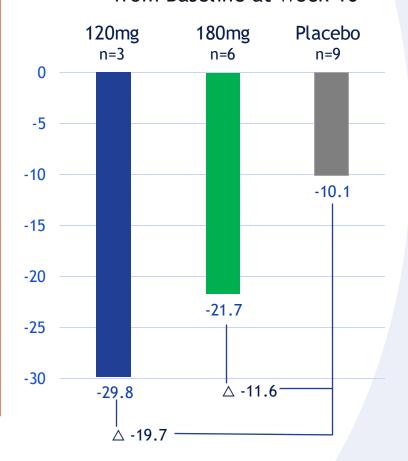
240mg SD UAS7 Mean Change from Baseline at Week 8



Q8W regimens UAS7 Mean Change from Baseline at Week 12



Q12W regimens UAS7 Mean Change from Baseline at Week 16



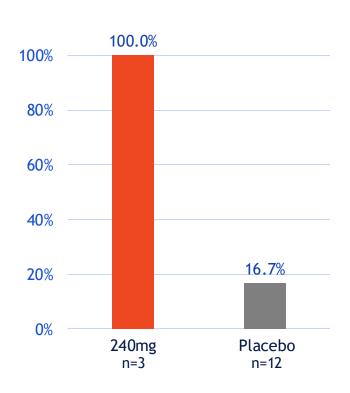


### Dose dependent increase in patients achieving Complete Response (UAS7=0)

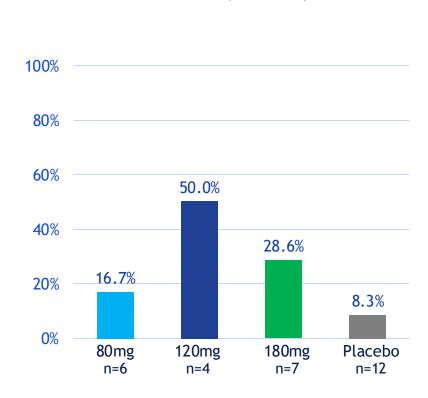




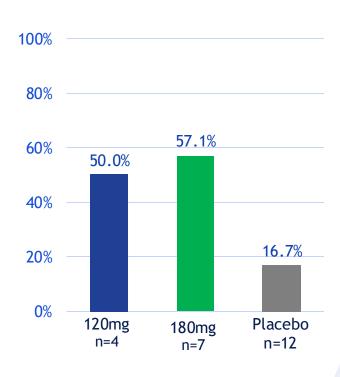
240 mg Complete Response at Week 8 (UAS7=0)



**Q8W Complete Response** at Week 12 (UAS7=0)



Q12W Complete Response at Week 16 (UAS7=0)



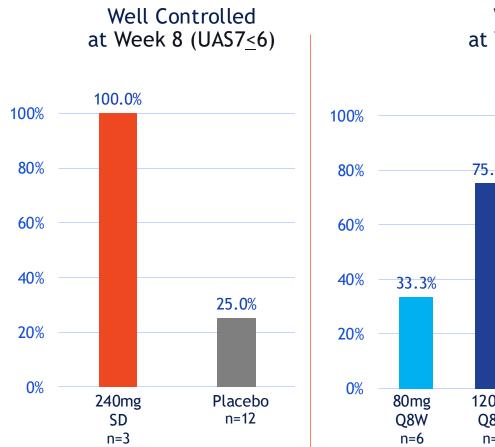
The last observation carried forward (LOCF) method was used for data imputation

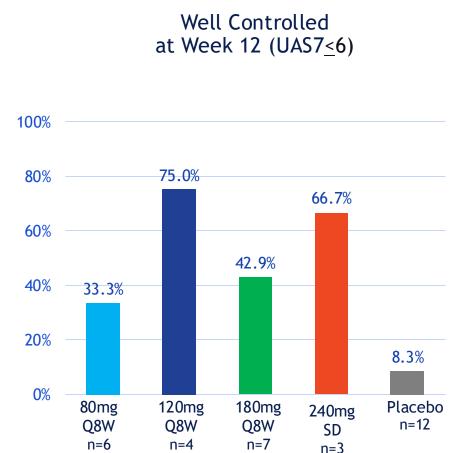


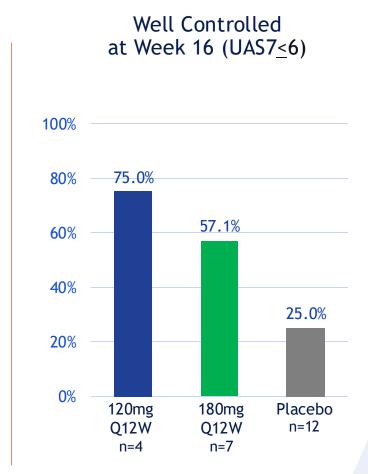
### Dose dependent increase in patients achieving Well Controlled Disease



50% or more of patients achieved well-controlled disease 4 weeks post-dosing in multiple dose regimens







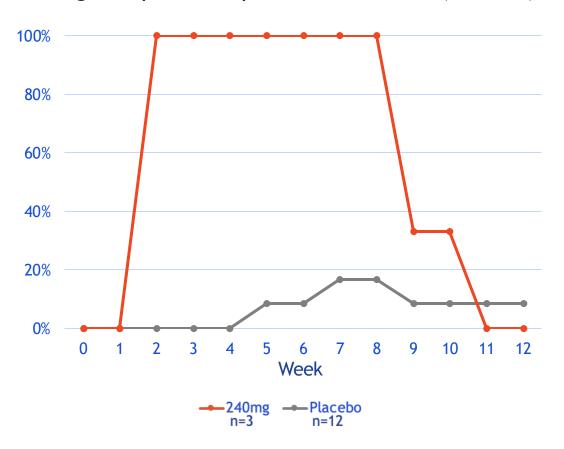
The last observation carried forward (LOCF) method was used for data imputation



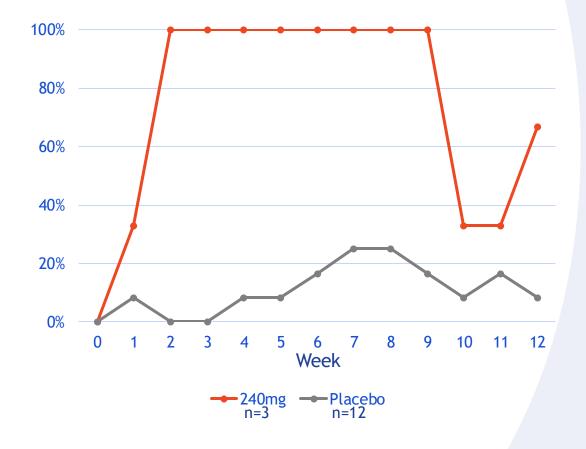
### All patients in the 240mg single-dose cohort maintained CR to 8 weeks

All patients achieving CR by week 2, with 66% Well Controlled at Week 12

240mg Complete Response Weeks 1-12 (UAS7=0)



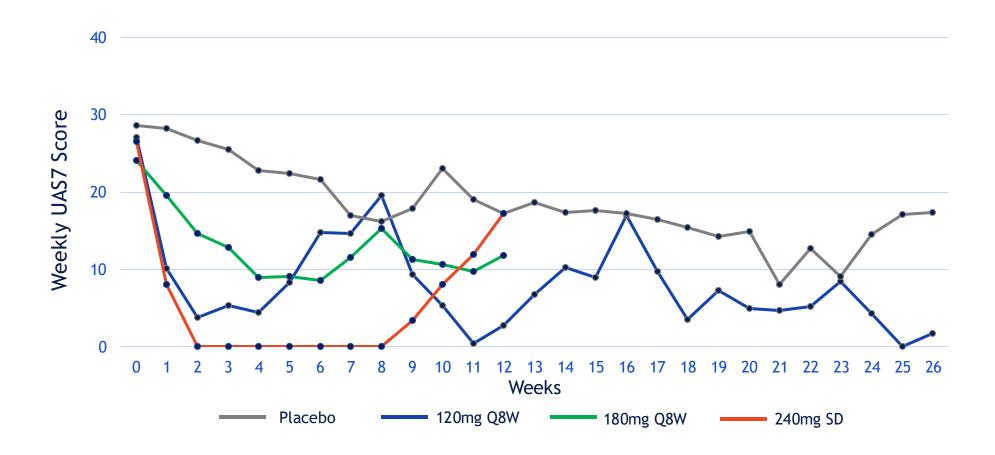
240mg Well Controlled Weeks 1-12 (UAS7 ≤ 6)





### Dose dependent UAS7 reductions observed over 26 weeks

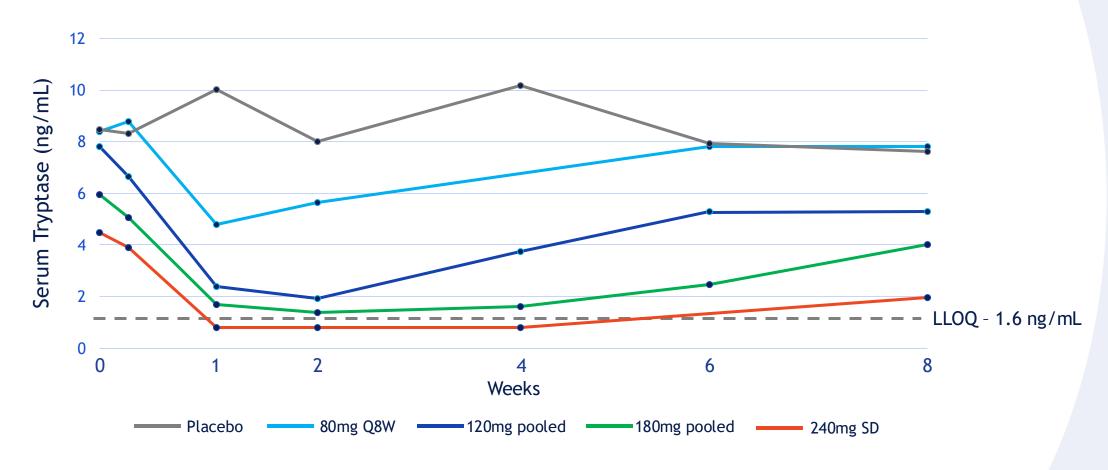
Deeper UAS7 reductions observed in subsequent doses





### Dose dependent reductions in serum tryptase

Reduction to LLOQ seen in multiple patients at 180mg Q8W and all patients at 240mg dose levels



<sup>\*</sup> All values below LLOQ (1.6 ng/ml) are represented as 50% of LLOQ (0.8 ng/ml)

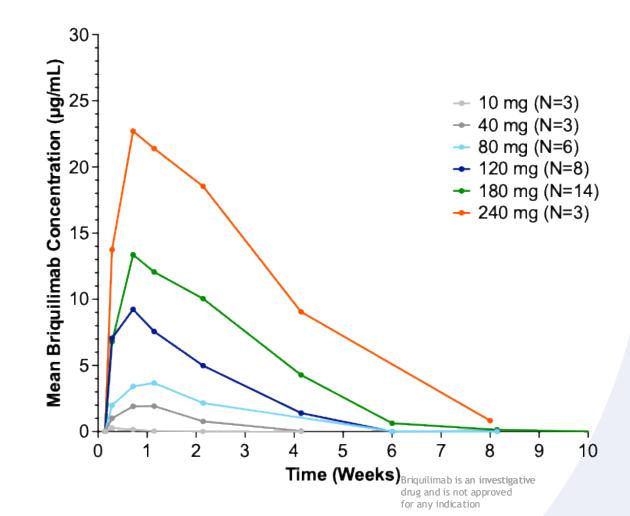


## Briquilimab PK demonstrates early Cmax consistent with rapid onset of response in patients with CSU



- Preliminary PK data in patients with CSU indicates briquilimab PK is comparable to historical data in healthy volunteers
- 240mg briquilimab SC Tmax is 4-7 days with a half-life of approximately 9 days
- No accumulation predicted for repeat dosing of 240mg SC briquilimab on a Q8W dosing schedule
- Preliminary data indicate 34% incidence of anti-drug antibodies (ADA) and no clinically meaningful effect of ADAs on briquilimab PK in CSU patients

### Briquilimab Serum Concentration over Time in CSU Patients Following SC Administration







### Briquilimab was well tolerated and demonstrated a favorable safety profile

>24-week exposure for 10mg-180mg doses, 12-weeks for 240mg dose as of 31Dec24 data cut

Number of Participants With	Pooled Briquilimab (N=37) n (%)	Pooled Placebo (N=12) n (%)
Any DLT	0 (0)	0 (0)
Any TEAE	26 (70.3)	8 (66.7)
Any Treatment-Related Serious TEAE	1 (2.7)1	0 (0)
Any Hypersensitivity	1 (2.7)1	0 (0)
Any Anaphylaxis	0 (0)	0 (0)
Any TEAE Leading to Discontinuation of IP	1 (2.7)1	0 (0)
Adverse Event > Grade 3	1 (2.7) <sup>2</sup>	1 (8.3) <sup>3</sup>

Most commonly reported AEs (≥5 participants): nasopharyngitis, fatigue, hair color change, taste changes

<sup>&</sup>lt;sup>2</sup>Single participant, 180mg Q12W, CTCAE grade 3 AE: neutropenia, unrelated - prior history of idiopathic neutropenia, thrombocytopenia <sup>3</sup>Single participant, placebo, CTCAE grade 3 bronchitis



<sup>&</sup>lt;sup>1</sup>Single participant, 180mg Q8W, CoFAR grade 2 hypersensitivity reaction

## Safety observations possibly related to c-Kit blockade were infrequent and generally limited to low grade events



Majority resolved during repeat dosing and none resulted in discontinuations or dose delays

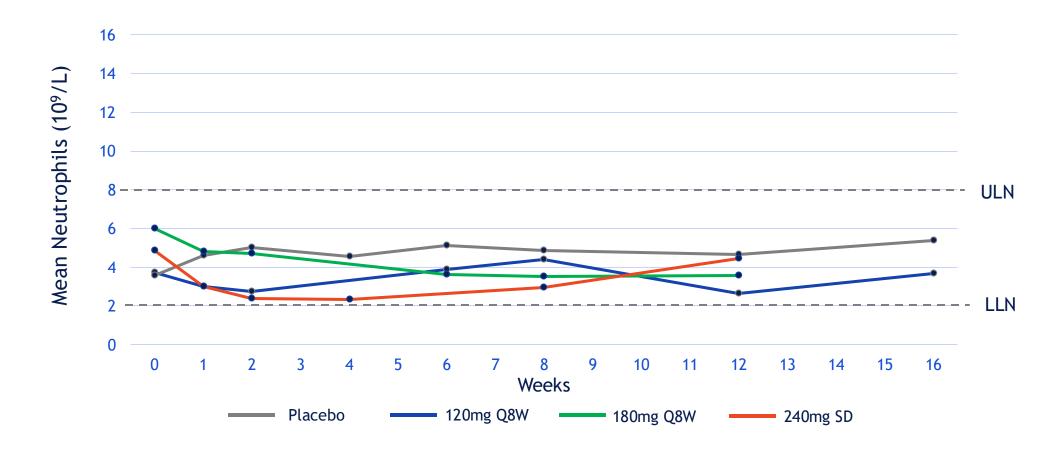
Adverse Event as reported term	Pooled Briquilimab N=37 (%)	Pooled Placebo N=12 (%)	CTCAE Grade / Comments
Hair color changes	4 (10.8)	1 (8.3)	<ul> <li>4 reported as Grade 1, 1 Grade unreported</li> <li>2 cases reported to be resolved/resolving</li> </ul>
Skin discoloration	0 (0)	1 (8.3)	<ul> <li>No skin discoloration observed with patient exposure up to 24 weeks</li> </ul>
Taste change/ Hypogeusia	6 (16.2)	0 (0.0)	<ul> <li>All mild, Grade 1 occurring on first dose, 1 recurrence (resolved)</li> <li>Taste reductions: bitter, salt, umami</li> <li>Resolved in 4 patients: Median time to resolution of 31 days</li> </ul>
Neutropenia	3 (8.1)	1 (8.3)	<ul> <li>Grade 3 neutropenia in a single participant with prior history of idiopathic neutropenia and thrombocytopenia</li> <li>Grade 1 neutropenia in 3 participants, all resolved prior to subsequent dose</li> <li>No fevers or infections associated</li> </ul>
Neutrophil count decreased	2 (5.4)	0 (0.0)	<ul> <li>2 Grade 1 decreases in neutrophil counts resolved prior to subsequent dose</li> <li>No fevers or infections associated</li> </ul>



## Neutrophil counts generally remained stable, with predictable reduction which subsequently recovered



No discontinuations or dose delays due to reductions in neutrophil counts



Source: Figure 14.3.4.1



## Preliminary BEACON study results demonstrate briquilimab achieved rapid, deep and durable responses in patients with moderate to severe CSU



- Participants had moderate to severe CSU and were omalizumab experienced
  - Clinical responses in this hard-to-treat population are encouraging for a broader CSU population
- Briquilimab demonstrated rapid and deep disease control
  - Rapid onset of effect
    - Clinical responses as early as 1 week post first dose
  - Deep dose-dependent response:
    - Multiple dosing regimens ≥120mg demonstrated UAS7 changes of more than -25 points
    - Deepest responses shown of -29 on the UAS7 scale
  - Complete and durable control demonstrated
    - Complete responses seen at all dose cohorts ≥ 80mg
    - 100% complete control with 240mg by week 2, durable to 8 weeks
    - Repeat dosing shows deepening clinical responses across multiple dose cohorts
- Rapid, dose-dependent tryptase reductions correlated with early onset of clinical response
  - Reduction to LLOQ observed in multiple dose cohorts

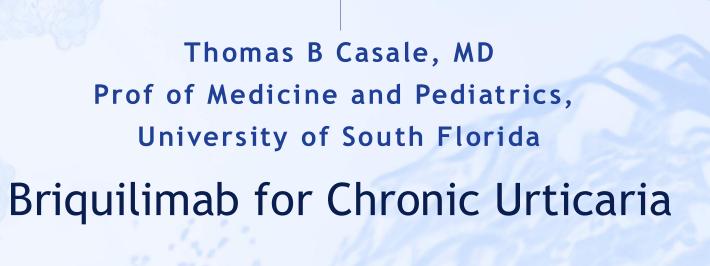


## Efficacy, safety and PK informs an optimal biologic dose selection for briquilimab CSU registrational program expected to be initiated in 2H 2025



- Briquilimab was well tolerated and had a favorable safety profile in the study
  - Low and comparable frequency of Grade 1 hair color changes in both active and placebo
  - Mild taste changes observed on first dose with majority resolving by a median of 31 days
  - No dose delays or discontinuations due to neutrophil reductions and no association with infection
    - Neutrophil recovery between doses
  - Single discontinuation due to AE
- Registrational program in CSU expected to commence second half of 2025
  - Deep and durable efficacy to 240mg dose, combined with the favorable safety profile observed support advancing into Phase 2b portion of a registrational program
- Ongoing trials continue to generate clinical data to support registrational program
  - Expansion of 240mg and 360mg single dose cohorts ongoing
  - Additional cohorts of 240mg Q8W and 240mg induction dose followed by 180mg Q8W
  - Additional 180mg Q8W data from BEACON and SPOTLIGHT Open Label Extension study
  - These data will further inform final dose selection for the Phase 2b portion of our registrational program

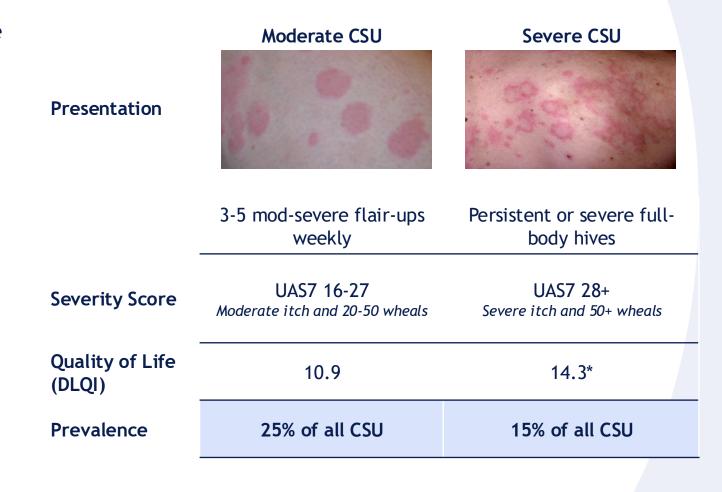






### Moderate-to-severe CSU may lead to significant impact to patient's lives and is associated with poorer outcomes

- CSU is a recurring inflammatory condition of the skin lasting 6 weeks or more, characterized by the development of itchy wheals (hives), angioedema, or both<sup>1</sup>
- CSU has a significant negative impact on daily life including sleep, relationships and ability to work<sup>2</sup>
- CSU is associated with higher risk of suicide, depression, anxiety and all-cause mortality<sup>3</sup>
- Approximately 1.4m patients in the US, Germany, France, Italy, Spain and the UK have moderate to severe CSU<sup>4</sup>
- Current approved therapies limited to antihistamines and a single anti-IgE biologic (omalizumab)





1 Lambert et al. 2021; 2 Weller K, et al. EADV 2023; 3 Kolkhir et al. 2025; 4 Balp MM, et al., EADV 2023, Jasper Market Research and Expert Interviews

<sup>\*</sup> Comparable to DLQI in moderate-severe psoriasis (Average DLQI of 14.8); other QoL measures (MCS, PCS) are similar across CSU, AD, and PsO (Nikolaev I, et al. EAACI Hybrid Congress, July 1-3, 2022)

## Preliminary BEACON data in CSU show that briquilimab leads to deep and durable efficacy with a favorable safety profile

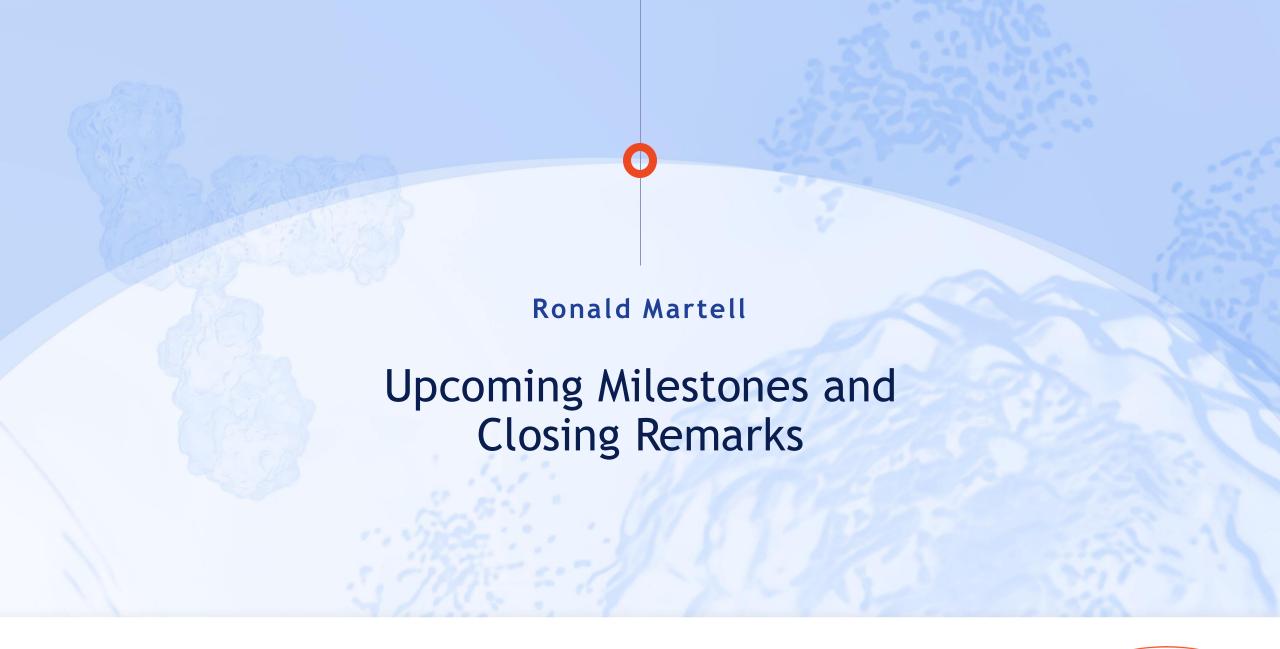
- Mast cell degranulation is the central pathogenic driver of chronic urticarias
- Briquilimab blocks c-Kit signaling and may lead to depletion of mast cells
- Preliminary BEACON efficacy results show multiple regimens associated with clinically meaningful declines in UAS7
- Preliminary efficacy results show rapid onset of action, with the 240mg dose showing high 100% CR, durable to 8 weeks
- Preliminary BEACON safety results show low incidence of manageable AEs
- Based on these data, briquilimab appears to a promising new therapy for moderate to severe CSU patients
- Advancement to registrational trials is warranted





<sup>1</sup> Moller C et al. Blood (2005)

<sup>2</sup> Hundley TR et al. Blood (2004)



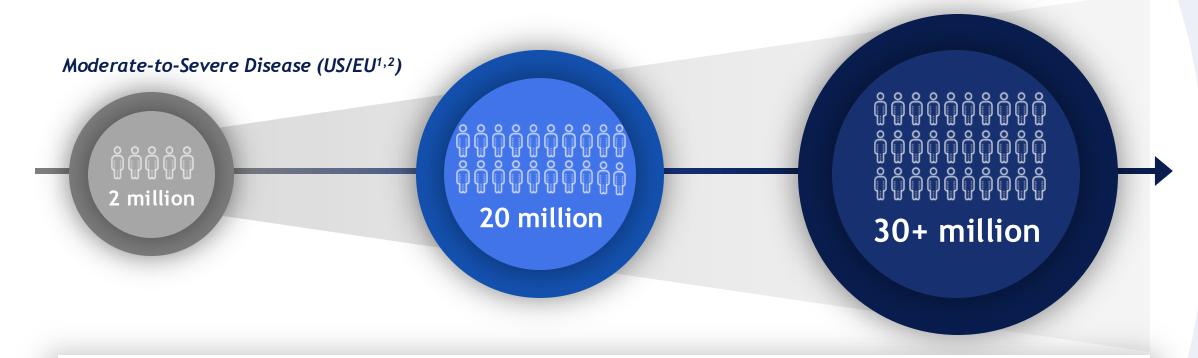


# Positive preliminary BEACON study results support commencing briquilimab registrational program in CSU in 2H 2025

- Briquilimab demonstrated rapid onset of action with disease control observed as early as one week after initial dose
- Complete responses were observed at doses as low as 80mg Q8W and 240mg dose demonstrated 100% Complete Responses with durability out to 8 weeks
- Serum tryptase reductions below the lower limit of quantification were observed in multiple dose cohorts
- Favorable safety profile observed in preliminary data support the potential of optimal biologic dosing
  - On target adverse events seen were low-grade and at low incidence rates
  - Many of the possible on-target AEs resolved between doses
- Additional BEACON cohorts and the open label extension study will further inform final dose selection for Phase 2b study planned to commence 2H 2025



## Briquilimab has the potential to be a major immunology franchise by delivering control to millions of patients with mast-cell driven diseases



#### **Chronic Atopic and Mast Cell Driven Diseases**

- Chronic Spontaneous Urticaria
- Chronic Inducible Urticaria
- Asthma
- COPD
- Chronic Rhinosinusitis with Nasal Polyps
- Prurigo Nodularis
- Atopic Dermatitis

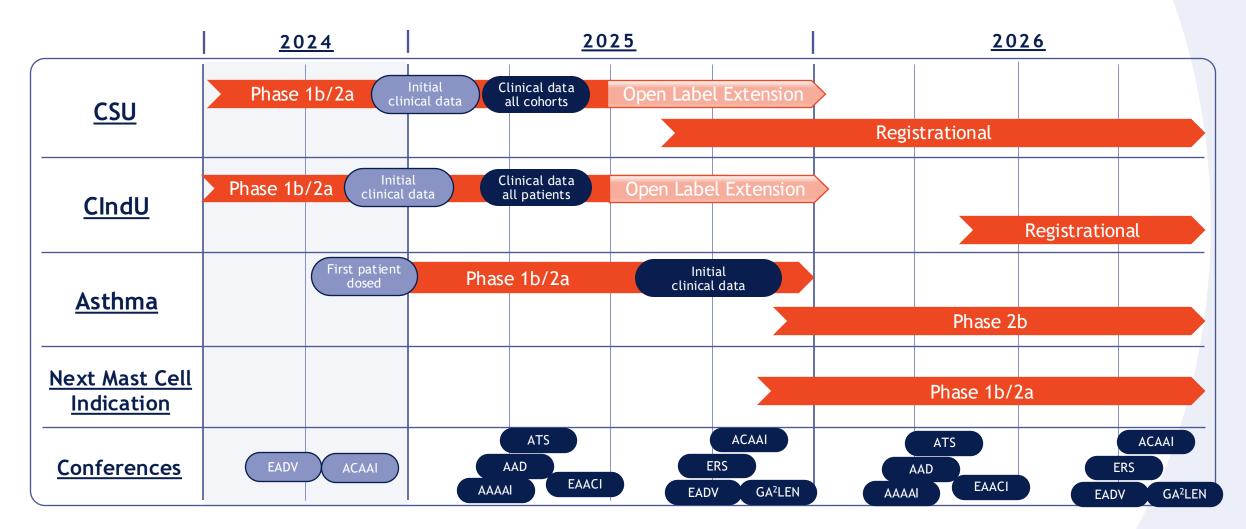
- Eosinophilic Esophagitis
- IBD
- Food Allergies



Briquilimab is an investigative drug and is not approved for any indication

### Key milestones







### A#Q





