CDX-0159 Phase 1b CIndU Interim Results

March 29, 2021

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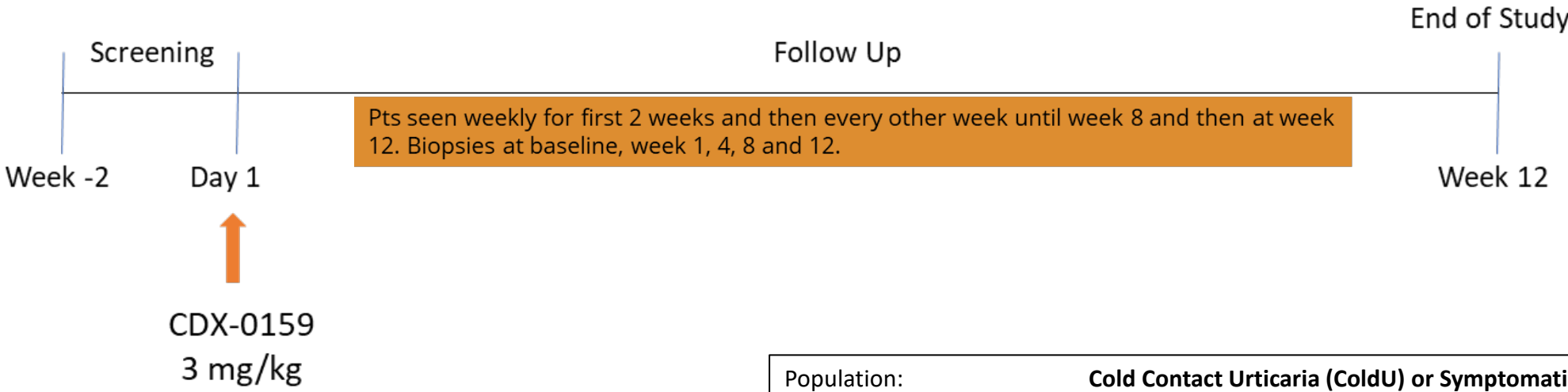
Phase 1b Single Dose of CDX-0159 in Chronic Inducible Urticaria (CIndU) Trial Design

- **Goals: Establish early proof of concept in patients with inducible manifestations**
  - **Explore impact on mast cells in skin (biopsy)**



Cohort	CIndU	CDX-0159 (mg/kg)	Patients
1	CCU	3	10
2	SD	3	10
Total			20

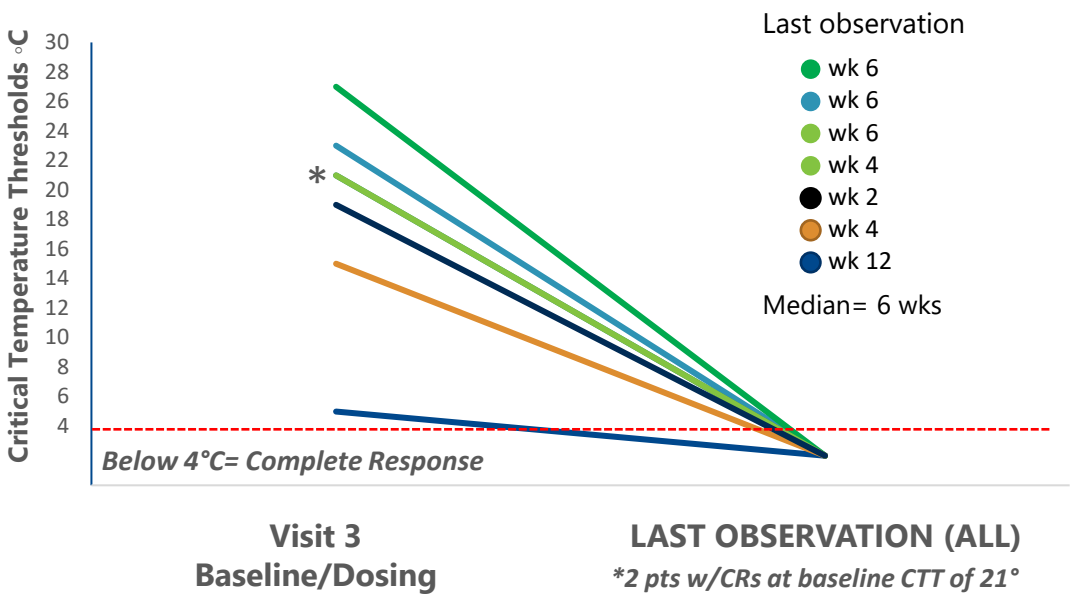
Population:	**Cold Contact Urticaria (ColdU) or Symptomatic Dermographism (SD) patients refractory to antihistamines**
Design:	Single dose with 12 weeks follow up
Primary Endpoint:	Safety and Tolerability
Secondary Endpoints:	Activity, PK, PD
Size:	10 per cohort; total 20

Study being conducted by Dr. Marcus Maurer, Professor of Dermatology and Allergy at Charité - Universitätsmedizin in Berlin

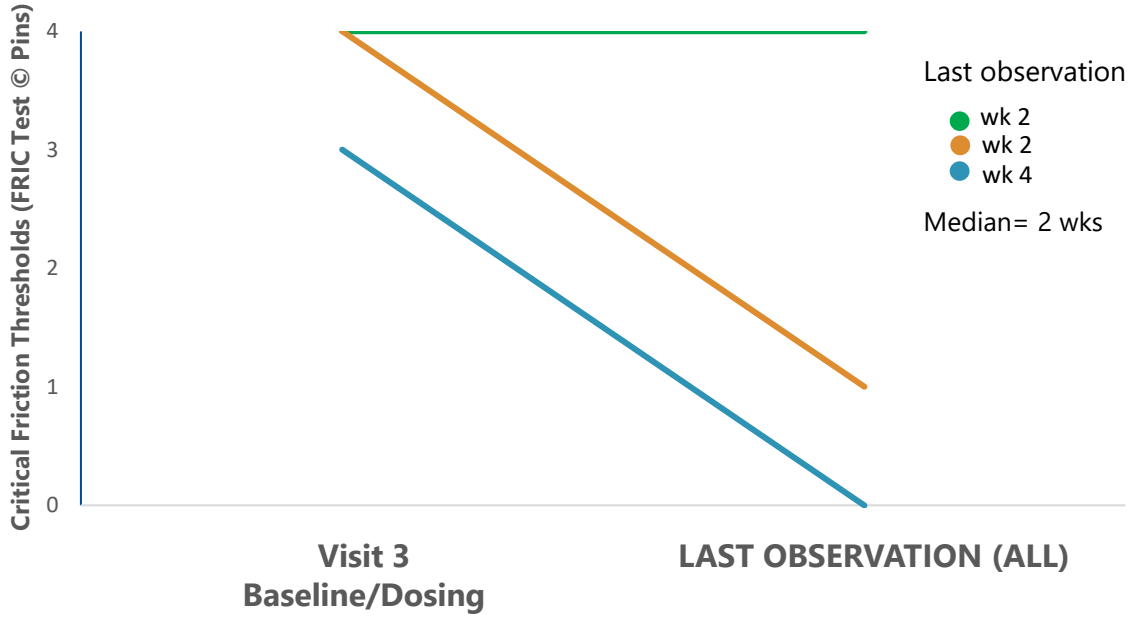
CDX-0159: Phase 1b Interim Results: 80% Complete Response Rate (n=8 of 10)

- 15 of 20 planned patients with antihistamine refractory CIndU received a single IV infusion of CDX-0159 at 3 mg/kg (9 ColdU and 6 SD); safety data on all 15 patients
- Activity results for all patients (n=10) assessed for at least 15 days/2 weeks after treatment (7 ColdU and 3 SD)
- Patients had high disease activity as assessed by provocation testing—baseline ColdU critical temperature thresholds were 18.7 +/- 2.7 °C (range: 5-27°C) and SD FricTest® thresholds were 3.7 +/- 0.3 (range: 3-4) of 4

ColdU - Individual Provocation Thresholds; n= 7 CRs



SD - Individual Provocation Thresholds; n=1 CR



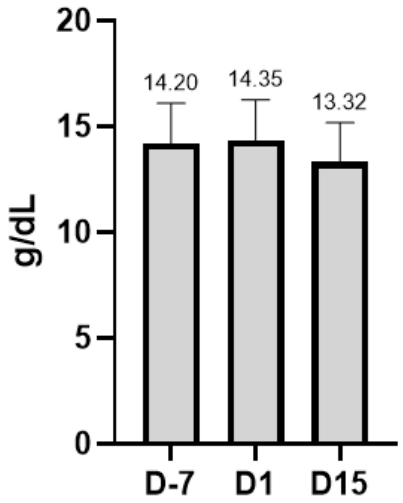
Serum tryptase levels (available for the first six patients – **all ColdU and all CRs** – were 3.3 +/- 0.2 ng/ml at baseline and at or below the limit of detection on day 15 after treatment

- Five of 8 complete responses (CRs) were present at day 15.
- Patient and physician global assessment (Pat-GA/Phy-GA) consistent with provocation testing results.

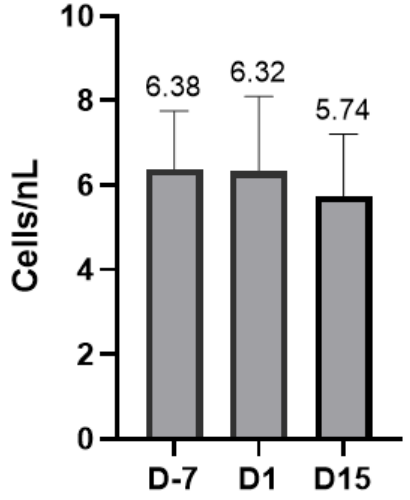
CDX-0159: Phase 1b Interim Results: Generally Well Tolerated

- Six of 15 patients with mild infusion reactions
  - Areas of localized redness/itching; resolved rapidly
- Single severe infusion reaction observed
  - Single hive followed by brief loss of consciousness, awoke with diffuse shaking, followed by profuse sweating; patient rapidly recovered
    - > Treated with antihistamines and steroids. No epinephrine administered
    - > No evidence of mast cell activation (tryptase levels decreased)
  - Patient hospitalized for overnight observation with no further manifestations of this event
- No significant laboratory findings through Day 15
  - Three patients with mild, transient changes in hemoglobin and no patients with meaningful decreases in white blood cells

Mean HgB Values Through Day 15 (n=10)



Mean WBC Values Through Day 15 (n=10)



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