

# Phase 2 Topline Eosinophilic Esophagitis (EoE) Results

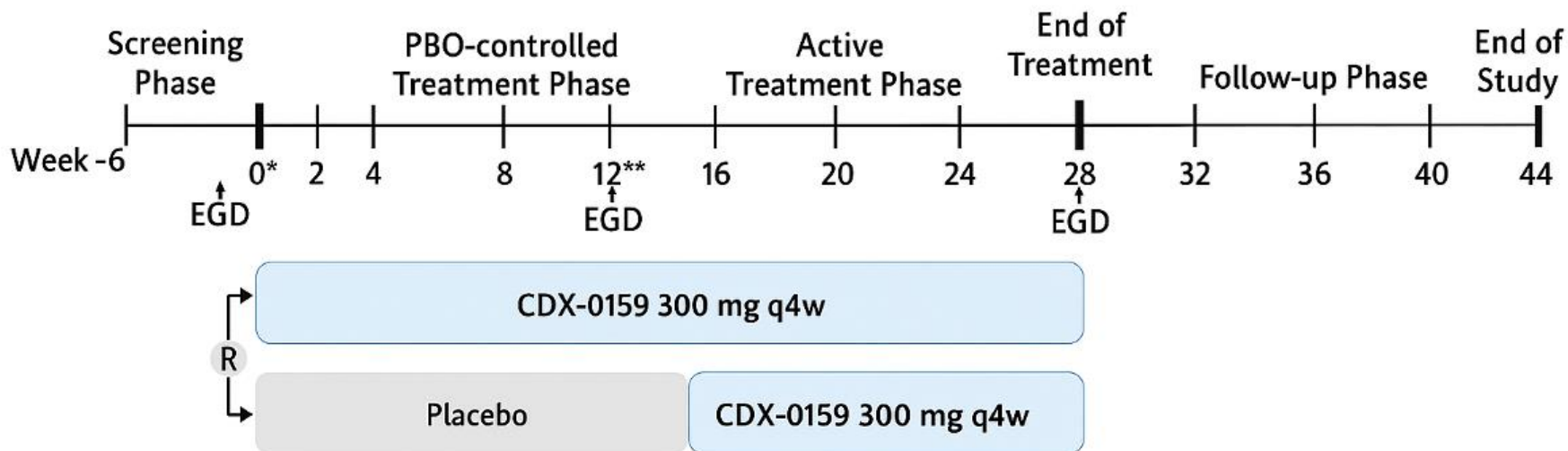
AUGUST 19, 2025

DATA CUTOFF: JULY 24, 2025

# Safe Harbor Statement

This communication contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "will," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future. These forward-looking statements are subject to risks and uncertainties that may cause actual future experience and results to differ materially from those discussed in these forward-looking statements. Important factors that might cause such a difference include, but are not limited to, the timing, cost and uncertainty of obtaining regulatory approvals for product candidates; our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors; the validity of our patents and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Celldex does not undertake any obligation to release publicly any revisions to such forward-looking statement to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

# Phase 2 Study Design (n=65 patients; 300 mg q4w or placebo)



R = randomization; \* = Baseline; \*\* = primary endpoint

Randomized, double-blind, placebo-controlled study in adults with active eosinophilic esophagitis conducted at 54 sites across 8 countries

Key Inclusion Criteria: documented endoscopic EoE diagnosis, peak intraepithelial eosinophil count of 15/hpf in 2/3 esophageal segments

**Primary Endpoint:** Absolute change from baseline to Week 12 in the peak esophageal intraepithelial mast cell (PMC) count

**Secondary Endpoints:** dysphagia symptom reduction, reduction in esophageal intraepithelial infiltration of eosinophils, safety

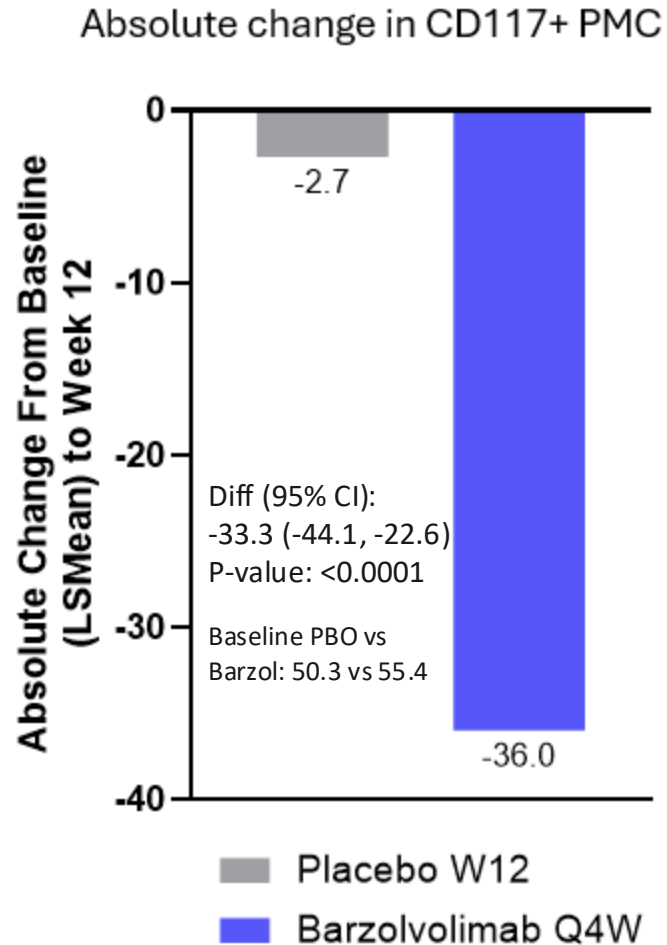
**Exploratory Endpoint:** endoscopic scoring of EoE-related inflammation & fibrosis (EREFS)

## Highly Symptomatic Patient Population with Moderate/Severe Disease

	Placebo Q4W (n=31)	Barzolvlimab 300mg Q4W (n=34)
Age (years)	38.6 (11.75)	42.1 (11.97)
Male, n (%)	17 (54.8)	18 (52.9)
BMI (kg/m <sup>2</sup> )	28.61 (5.50)	29.87 (6.78)
Duration of EOE (years)	5.63 (4.05)	5.63 (4.63)
Prior use swallowed TCS, n (%)	15 (48.4)	14 (41.2)
History of esophageal dilation, n (%)	16 (51.6)	20 (58.8)
History of atopic disease, n (%)	25 (80.6)	23 (67.6)
DSQ score	35.36 (13.51)	35.03 (10.91)
PMC/hpf	50.3 (26.14)	55.4 (26.13)
PEC/hpf	145.5 (63.07)	150.1 (88.23)
EREF Total Score (0-18)	6.9 (3.97)	7.3 (2.36)

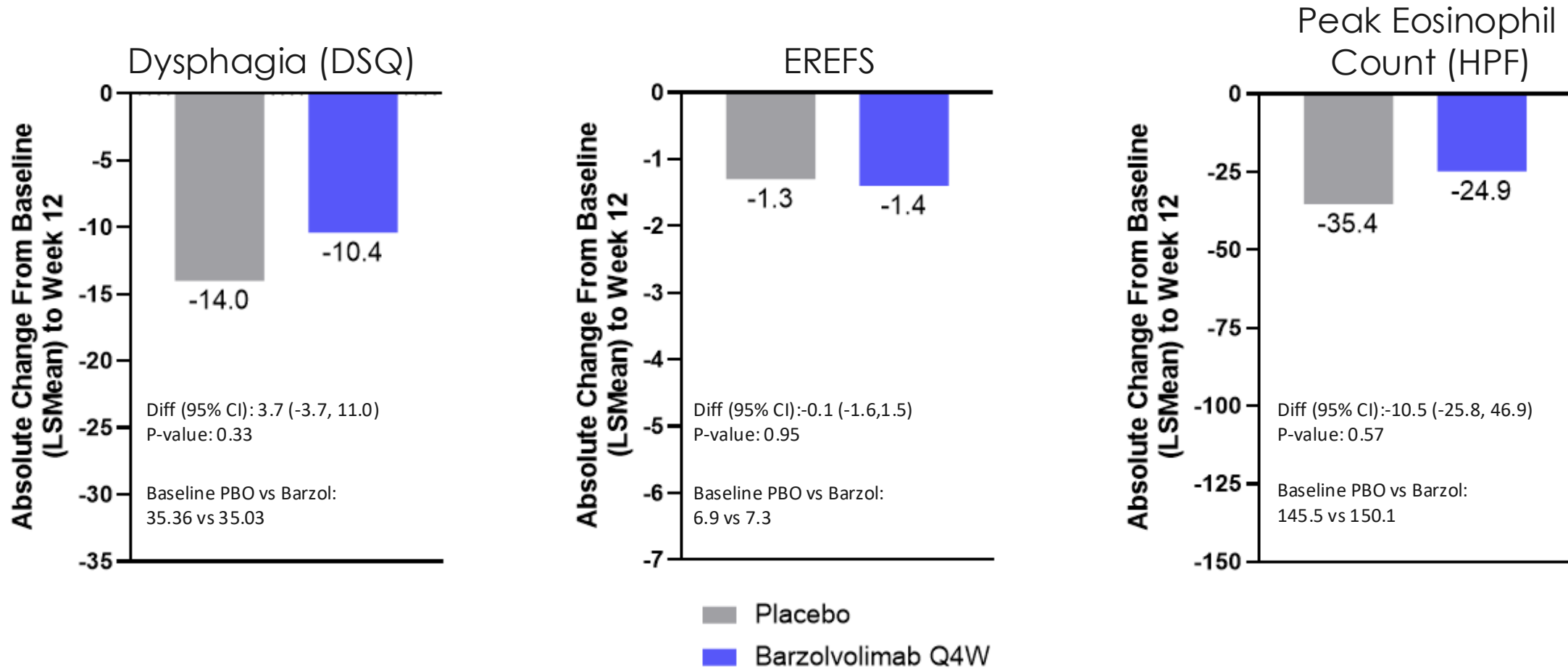
Data are mean (SD) unless otherwise noted.

# Primary Endpoint Achieved: Significant Decrease in Peak Mast Cell Count (PMC): Absolute Change from Baseline to Week 12



- 72% mean decrease in CD117+ cells from baseline at Week 12
- 75% mean decrease in tryptase positive mast cells from baseline at Week 12; depletion continued to deepen to 90% at Week 28 (based on available data)

# Secondary and Exploratory Endpoints: Absolute Change from Baseline to Week 12



Outcomes consistent at Week 28 based on available data.

# Favorable, Consistent Safety Profile through Week 16

- Barzolvolimab safety profile at 300 mg Q4W consistent with prior studies where barzolvolimab 300 mg was dosed less frequently

Patients, n (%)	Placebo Q4W (N= 31)	Barzolvolimab 300 mg Q4W (N= 34)
<b>Any AE</b>	22 (71.0)	28 (82.4)
<b>Any SAE</b>	1 (3.2) Syncope: “related”	1 (2.9) Vertigo: “unrelated”
<b>Discontinued study treatment due to AE</b>	4 (12.9)	1 (2.9)
<b>Most frequent AEs (≥10% in any treatment group)</b>		
Hair color change	1 (3.2)	14 (41.2)
Nasopharyngitis	2 (6.5)	4 (11.8)
Fatigue	0 (0.0)	4 (11.8)

#### Discontinuations due to AE:

- Placebo: syncope, pneumonia, hypersensitivity, erectile dysfunction
- Barzolvolimab: hair color/hypogeusia (taste) changes

#### Hair color changes:

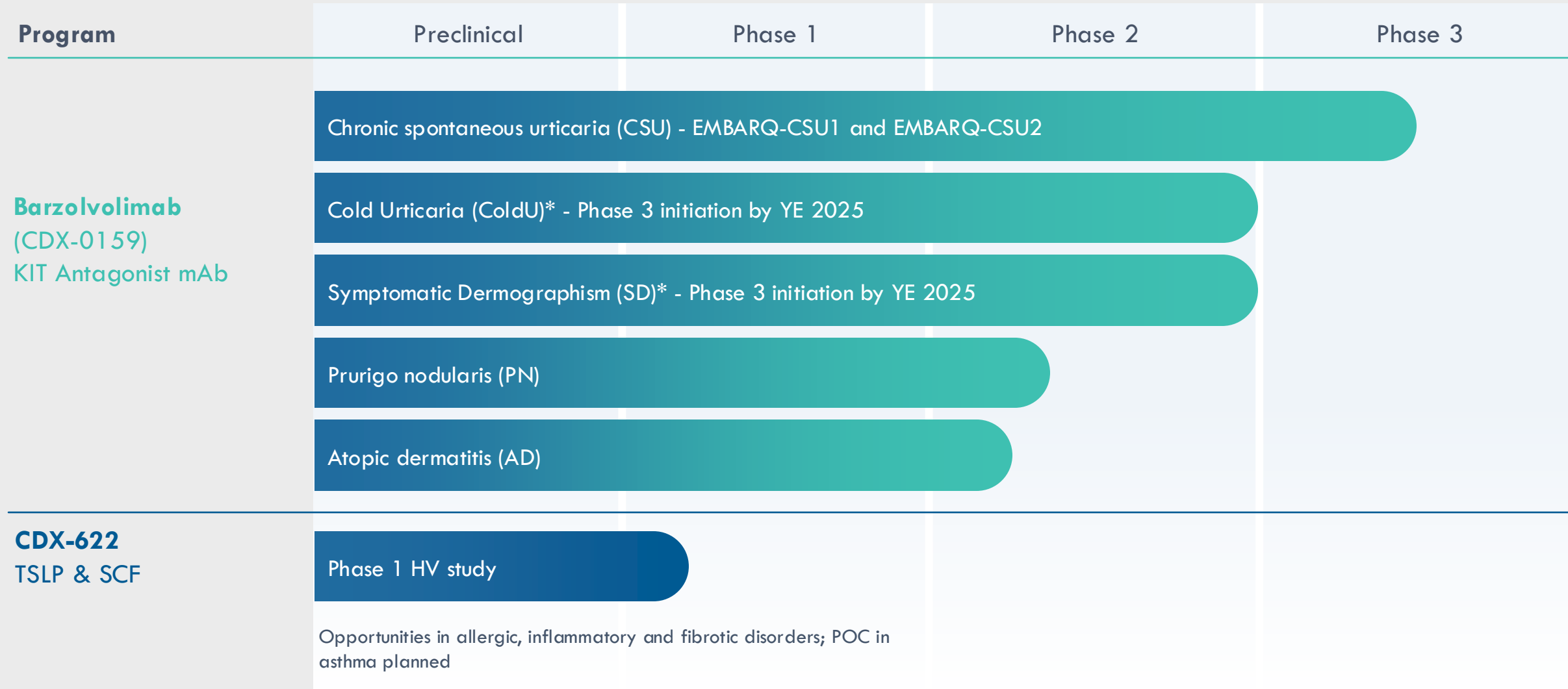
- Average age: 40 (range: 20-58)
- 13 Grade 1; 1 Grade 2
- Most reports were of changes in facial/neck hair (beard)

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# Summary

- Primary endpoint met. Have now demonstrated that barzolvolimab profoundly depletes intraepithelial (mucosal) mast cells, as well as cutaneous mast cells (demonstrated in prior studies), supporting broad development across multiple indications
- Mast cell depletion did not result in improved clinical outcomes in EoE providing direct evidence that mast cells are not a primary driver in EoE—furthering the science in EoE
- Completing Phase 2 study but will not pursue further development in EoE
- Confirmed barzolvolimab 300 mg favorable safety profile in more frequent dosing regimen
- Committed to leading the science in the exploration of mast cell biology to deliver life-changing therapies to patients in need

# Strong Clinical Pipeline with Multiple Inflection Points



\*ColdU and SD are subtypes under the global Phase 3 CIndU program

A night sky filled with stars and the Milky Way galaxy. A bright green laser beam originates from a silhouette of a person sitting on a rock on the right side of the frame and extends diagonally across the sky. The background is a deep blue and purple, with the Milky Way appearing as a dense band of white and yellow stars. In the bottom right corner, there are several overlapping geometric shapes in shades of green and teal.

# Questions

Celldex