
**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

Date of Report (Date of earliest event reported): October 12, 2026

FIRST TRACKS BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-43177
(Commission File Number)

39-5003207
(IRS Employer
Identification No.)

10770 Wateridge Circle, Suite 210
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's Telephone Number, Including Area Code: 858 362-6295

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check 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 communications 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)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ 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
Common stock, par value \$0.001 per share	TRAX	The Nasdaq Stock Market LLC

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. ☐

Item 7.01 Regulation FD Disclosure.

On October 12, 2026, First Tracks Biotherapeutics, Inc. (the “Company”) updated its corporate investor presentation, a full copy of which is attached hereto as Exhibit 99.1.

The information in 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, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On October 12 2026, the Company issued a press release announcing positive topline data from the first Phase 1b cohort of ANB033 in Celiac Disease. A copy of the press release is filed herewith as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Title or Description
99.1	First Tracks Corporate Presentation October 2026.
99.2	First Tracks Biotherapeutics, Inc. Press Release, dated October 12, 2026.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

SIGNATURES

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

FIRST TRACKS BIOTHERAPEUTICS, INC.

Date: October 13, 2026

By: /s/ Ajim Tamboli

Name: Ajim Tamboli

Title: Chief Financial Officer



Safe harbor statement

This presentation and any accompanying oral presentation contain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential benefits, efficacy and safety profile of ANB033 and the Company's other product candidates; the Company's regulatory plans and the anticipated timing of initiation of, enrollment in, and data from, its clinical trials; strategic options for rosnilimab; and the potential market opportunity for ANB033. Statements including words such as "plan," "expect," "anticipate," "potential" or "ongoing" and statements in the future tense are forward-looking statements. Top-line results are based on a preliminary analysis and may change following a more comprehensive review of the data, and results from a Phase Ib trial may not be predictive of results in later-stage trials.

This presentation concerns drug candidates that are under clinical investigation, and which have not been approved by the U.S. Food and Drug Administration. These are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

The assumptions used in the presentation, although considered reasonable to us at the time of preparation, may prove to be incorrect. You are cautioned that the information is based on assumptions as to many factors and that actual results may vary from the results projected and such variations may be material. Accordingly, you should not place undue reliance on any forward-looking statements contained herein or rely on them as predictions of future events. All forward-looking statements in this presentation apply only as of the date made and are expressly qualified by the cautionary statements in this presentation. We do not undertake to update any forward-looking statements, except in accordance with applicable securities laws.

Certain information contained in this presentation may be derived from information provided by industry sources. The Company believes such information is accurate and that the sources from which it has been obtained are reliable. However, the Company cannot guarantee the accuracy of, and has not independently verified, such information.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

This presentation contains data based on cross-study comparisons and not based on any head-to-head clinical trials. Cross-study comparisons are inherently limited and may suggest misleading similarities and differences. The values shown in the cross-study comparisons are directional and may not be directly comparable.

Developing differentiated antibody therapeutics in autoimmune and inflammatory diseases

Focused strategy to efficiently advance high-value immunology portfolio

- Data-driven development approach prioritizing differentiation, speed and capital efficiency
- Global clinical development strategy
- Deep immunology and translational R&D expertise

Lead program, ANB033, has pipeline-in-a-product potential across gastroenterology, dermatology and other broad autoimmune disease areas

ANB033

(CD122 antagonist)

- Phase 1b in CeD
- Phase 1b in EoE
- Anticipate Phase 2 expansion in H1 2027 into vitiligo and one additional indication

Rosnilimab

(Pathogenic T Cell depleter)

- Phase 2b completed in RA

ANB101

(BDCA2 modulator)

- Phase 1a completed in healthy volunteers

Leading pipeline designed to deliver meaningful advances for patients with autoimmune diseases

		Development Stage and Anticipated Milestones					
	Antibody Program	Therapeutic Indication	IND Enabling	Phase 1a	Phase 1b	Phase 2	Phase 3
Immune Cell Modulators	ANB033 (CD122 antagonist)	Celiac Disease FDA Fast Track Designation				Top-line P1b Cohort 2 data in Q1 2027 Initiate late-stage trial in 2027	
		Eosinophilic Esophagitis				Top-line P1b data in Q3 2027	
		Vitiligo				Initiate in H1 2027	
		Inflammatory Disease				Initiate in H1 2027	
	Rosnilimab (Pathogenic T cell depleter)	Rheumatoid Arthritis				Assessing ROE-maximizing strategic options	
	ANB101 (BDCA2 modulator)	Inflammatory Disease			Completed P1a in healthy volunteers		



ANB033

CD122 antagonist

ANB033 blocks CD122 to inhibit pathogenic immune cells

CD122 is the beta subunit (IL-2R β) of the receptor for IL-15 and IL-2

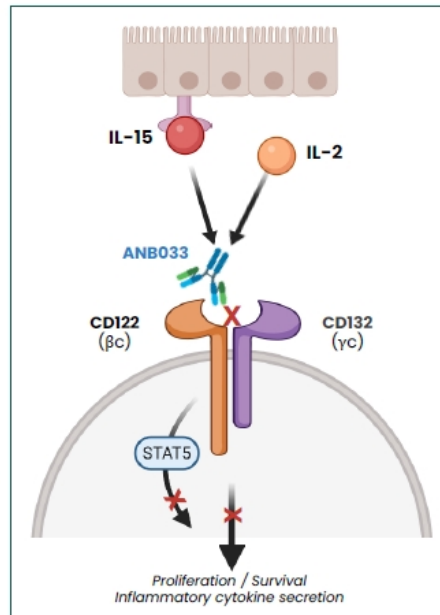
- Expressed on subsets of CD8+ and CD4+ T cells and NK cells

CD122 antagonism reduces these immune cell subsets

- Dependent on IL-15 and/or IL-2 for proliferation and survival

Overexpressed in select diseases, including CeD gut or EoE

- CeD: IELs, including cytotoxic CD8+ and NK cells
- EoE: ILC2s



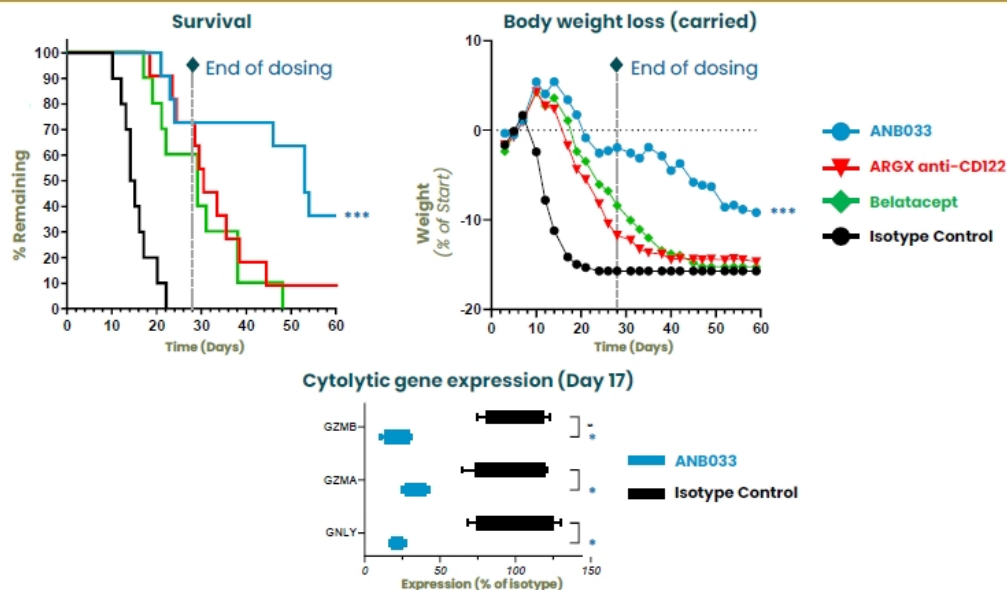
Broad therapeutic potential across autoimmune and inflammatory diseases

Gastroenterology	Dermatology	Other Areas
Celiac Disease (CeD)	Atopic Dermatitis	Asthma/COPD
Eosinophilic Esophagitis (EoE)	Alopecia Areata	Multiple Sclerosis
Crohn's Disease	Hidradenitis Suppurativa	Psoriatic Arthritis
Ulcerative Colitis	Lichen Planus	Type 1 Diabetes
	Vitiligo	Solid Organ Transplant

Other clinical-stage drugs targeting IL-15 or CD122

NOVARTIS	IL-15	- PoC in CeD and EoE - Atopic dermatitis, vitiligo, and cutaneous lichen planus
teva	IL-15	- CeD and vitiligo - Assessing atopic dermatitis, alopecia areata and EoE
argenx	CD122	CeD, vitiligo, alopecia areata

ANB033 shows strong survival benefit and reduced cytolytic gene expression in aggressive GvHD mouse model



GvHD (severe phenotype) model using human IL-15 transgenic mice that support human T cell and NK cell engraftment. 60-day study. Mice dosed 3 mg/kg BIW (belatacept 75 µg TIW) through Day 28. N=10 per group (Isotype control and Belatacept) or 11 per group (test articles). ***Survival: ANB033 statistically significant vs Isotype control ($P<0.0001$), Belatacept ($P=0.003$), Argenx anti-CD122 (first achieved on Day 38, $p=0.031$, with significance deepening through Day 60, $P=0.0032$) log-rank Mantel-Cox test; Body weight loss: ANB033 statistically significant vs isotype control ($p<0.001$), Belatacept ($p=0.0016$), Argenx anti-CD122 (first achieved on Day 28, $p=0.037$, with significance deepening through Day 60, $P=0.0003$). Unpaired Student's t-tests. Gene expression data generated from purified human immune cells isolated from spleen on day 17. * $p<0.05$ Unpaired Student's t-tests.

Phase 1a demonstrated favorable safety, tolerability and PK profile with clear impact on immune cells driving CeD

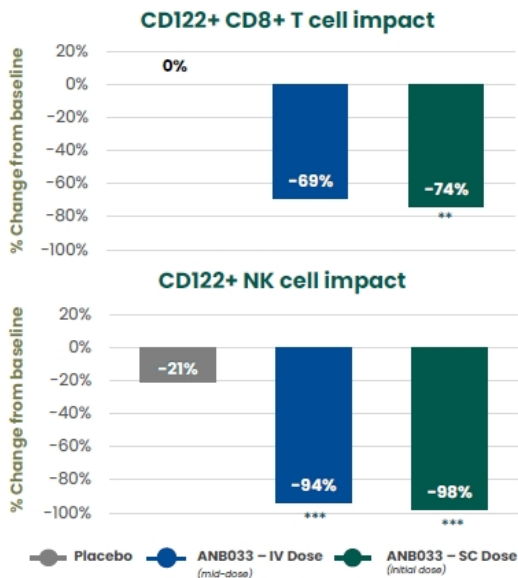
ANB033 Phase 1a results¹

Rapid and sustained PK profile

- Up to 3-week half-life with IV and SQ dosing
- Full receptor occupancy (RO) within hours and maintained for >30 days
- Dose response observed
- Modeled to achieve >IC90 on CD8+ T cell subsets in GI tissue

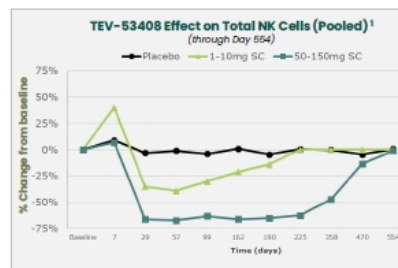
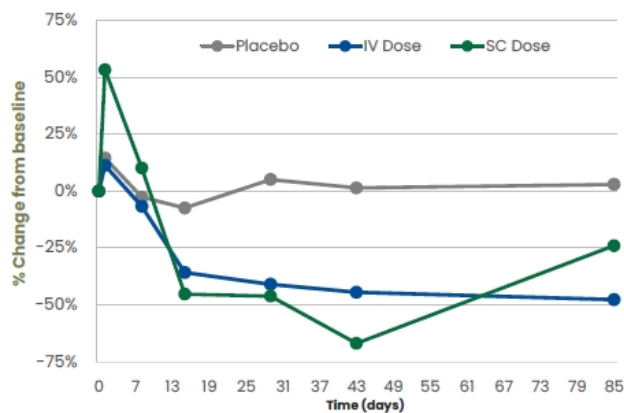
Favorable safety and tolerability at all doses

- No viral infections or unexpected lab abnormalities
- Overall, no impact on peripheral total Treg counts



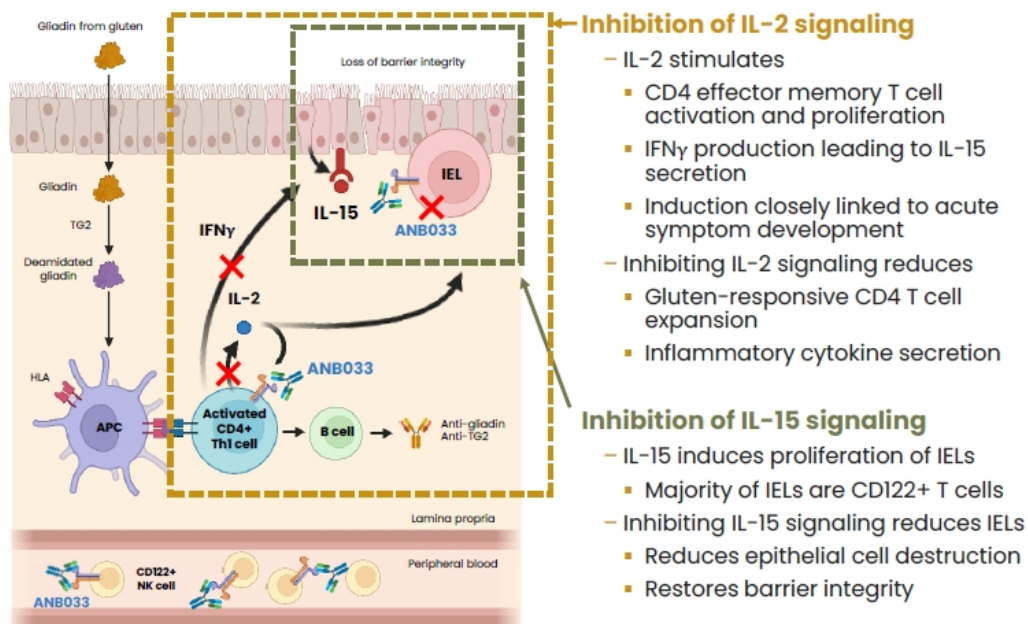
Anti-IL-15 and CD122 therapies have demonstrated sustained reduction in CD122+ NK cells with no observed safety issues

ANB033 effect on total NK cells



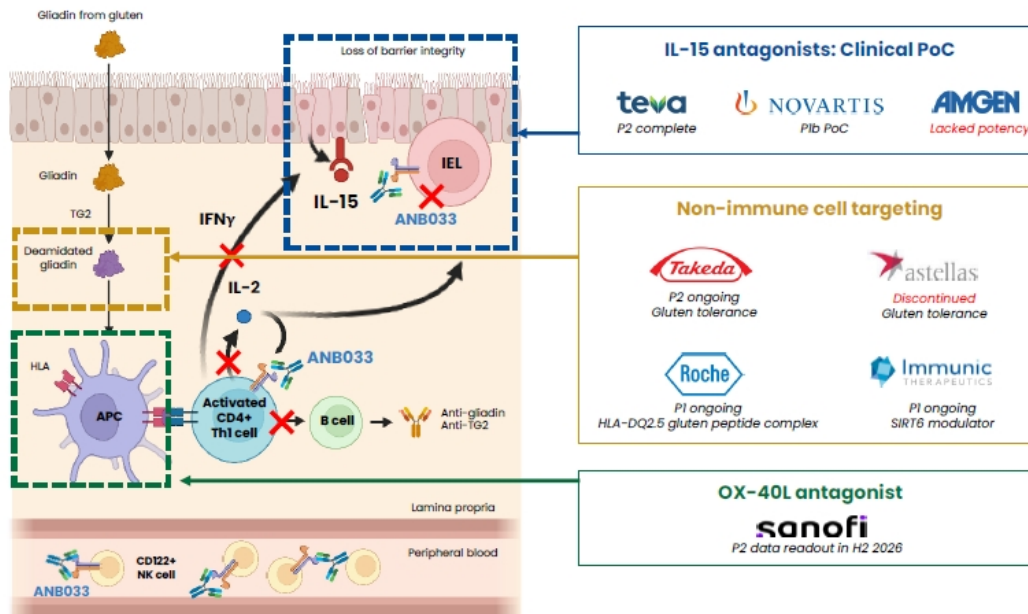
ANB033's MOA is an ideal fit for targeting CeD inflammation

CeD marked by excessive IL-2 and IL-15 production which perpetuates disease

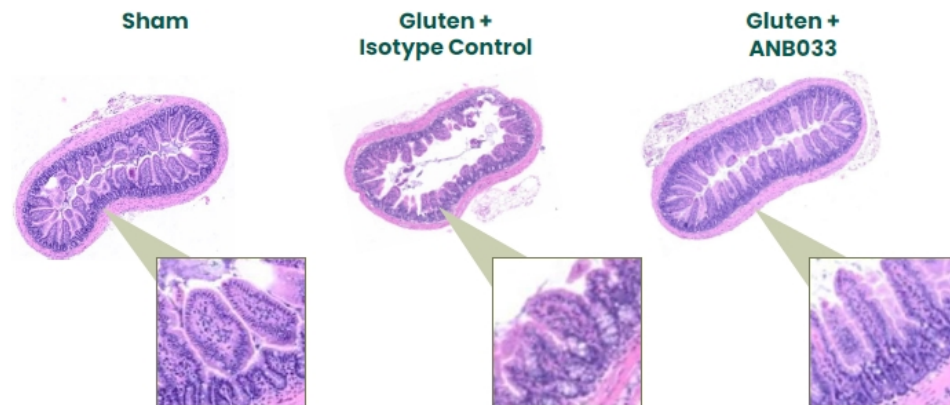


Previous approaches have not addressed the multiple pathogenic drivers of CeD

However, a CD122 antagonist targets both key pathogenic drivers of CeD

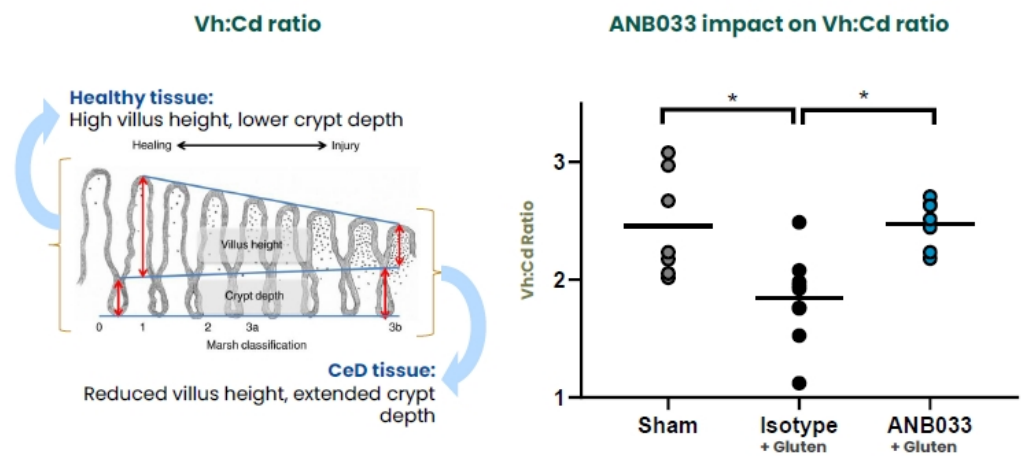


ANB033 prevents key CeD histologic manifestation of gluten-induced villous atrophy



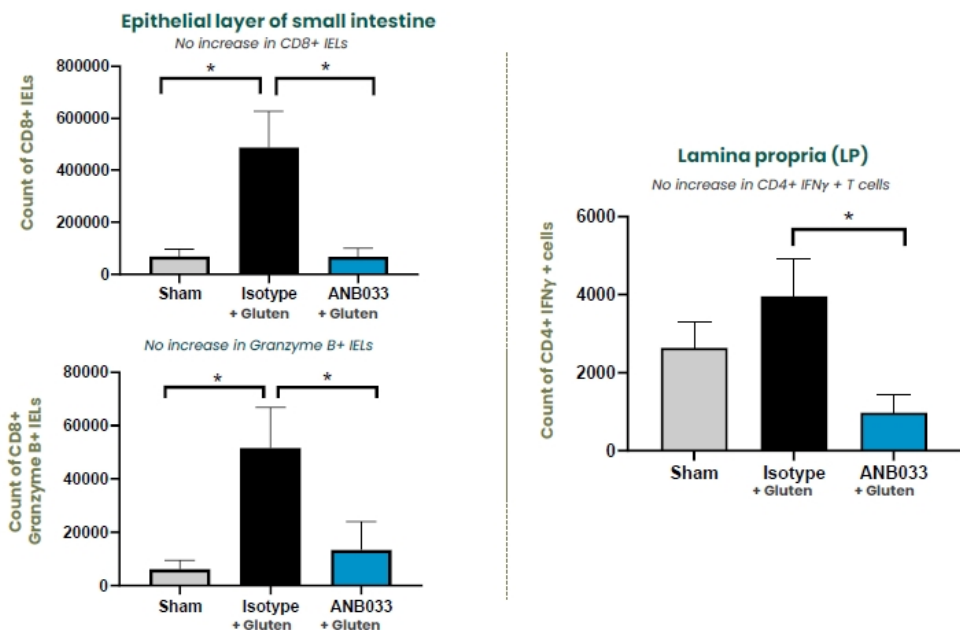
**ANB033 treatment shows improved histology:
preserves villus height and crypt depth (Vh:Cd) in CeD mouse model**

ANB033 significantly prevents the reduction of Vh:Cd ratio compared to control

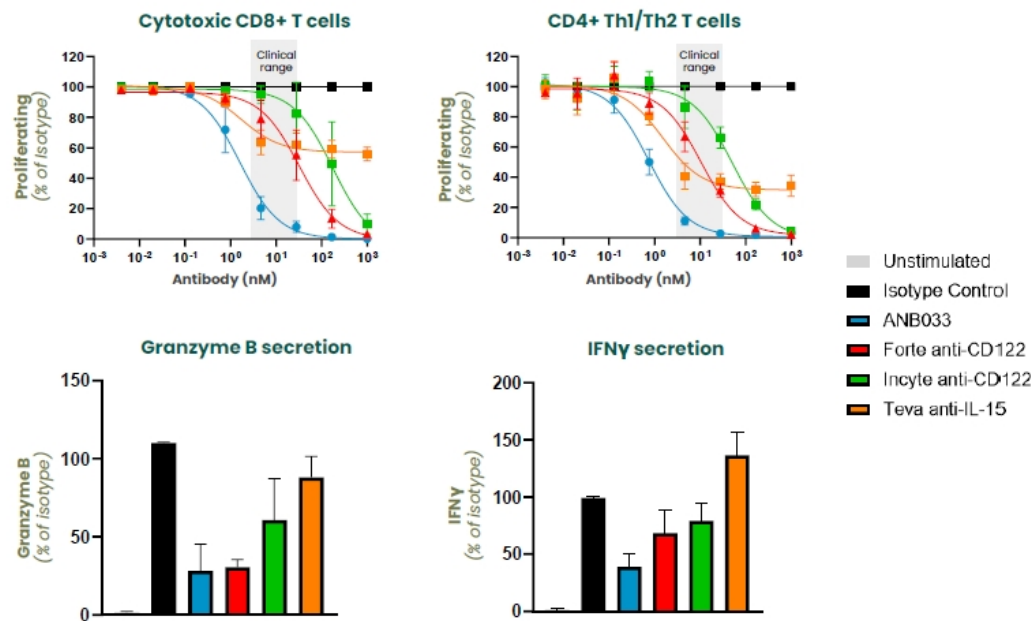


**ANB033 treatment shows improved histology:
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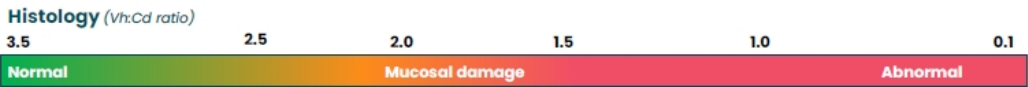
ANB033 prevents gluten-induced intestinal inflammation



ANB033 shows differentiated impact in CeD patient-derived PBMCs compared to competing anti-IL-15s and CD122s



CeD patients present with range of histologic activity and symptoms that are often not directly correlated



Symptoms are intermittent and can vary from none to mild to moderate to severe across histological damage

First Tracks (Phase 1b)

Cohort 1 (Vh:Cd ≥ 2.0)
Gluten challenge to assess the prevention of intestinal damage

Cohort 2 (Vh:Cd ≤ 2.5)
Added additional cohort to Plb to inform on potential to heal mucosa in patients with existing histologic intestinal damage and further derisk future development

Competitive Landscape



(Phase 2a)



(Phase 1b)



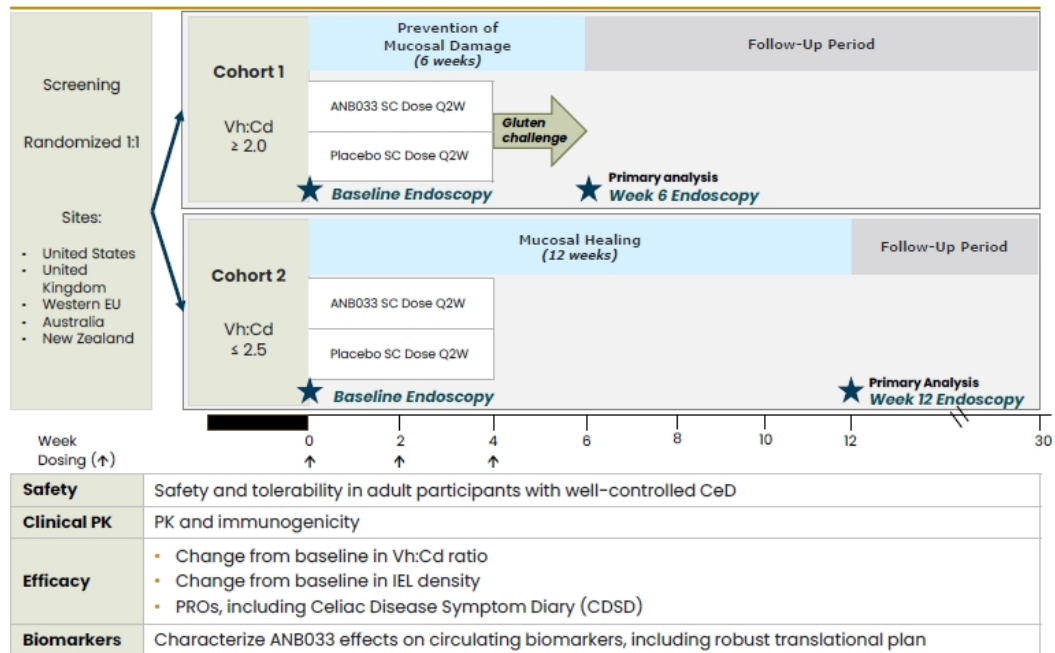
(Phase 1b/2a)

Gluten challenge: patients with higher Vh:Cd ratios (>2.5 or >2.0)

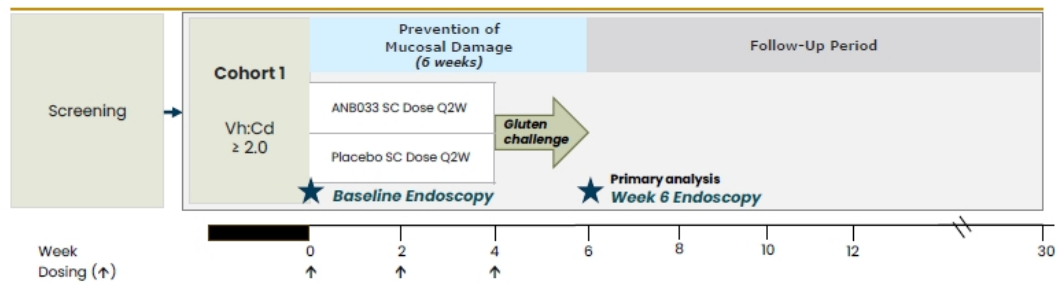
sanofi
(P2 data readout in H2 2026)
Phase 2b study to assess if drug can heal damaged mucosa and restore normal symptomatology (Vh:Cd ≤ 2.5)

ANB033 Phase 1b trial in CeD

Anticipate top-line Cohort 2 data in Q1 2027



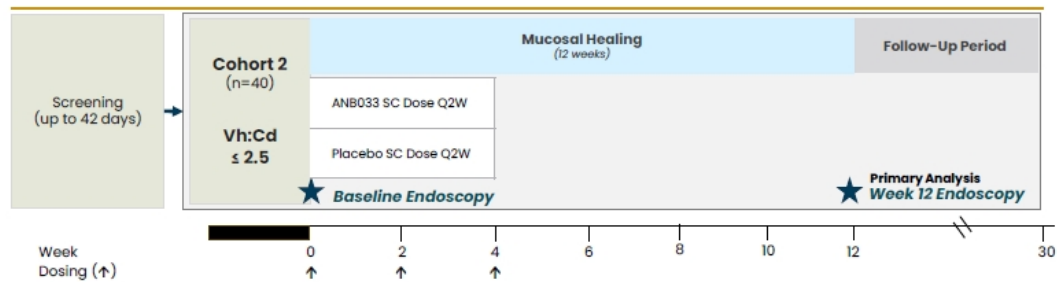
Cohort 1 (gluten challenge) to assess prevention of mucosal damage and symptoms



Minimal evidence of mucosal damage (Vh:Cd ≥ 2.0)

- Symptom-controlled CeD patients
 - Receive gluten challenge after pre-treatment with ANB033 vs. PBO
- ANB033 subcutaneous loading dose at Week 0, 2, 4 (pre-gluten challenge)
 - Gluten challenge allowed for controlled induction of mucosal damage
 - Beginning Week 4, 6g gluten dose daily (two 3g study supplied cookies) for 14 days through Week 6
 - Endoscopy at Week 6
 - Assessed prevention of gluten-induced mucosal damage and daily symptoms

Cohort 2 (Vh:Cd ≤ 2.5) assesses ability to heal mucosal damage in patients with a broad range of histologic and symptom severity



Persistent evidence of histologic CeD activity (Vh:Cd ≤ 2.5)

- Broad range of histologic (Vh:Cd ratio ≤ 2.5) and symptom severity
 - Substantial mucosal damage already present (no gluten-challenge)
 - Proxy: nonresponsive patients
- ANB033 dose at Week 0, 2, 4
 - Endoscopy at Week 12
 - Assess healing 8 weeks after last ANB033 dose
 - Maximize healing time given ANB033 prolonged tissue exposure and PD properties

ANB033 top-line Phase 1b cohort 1 gluten challenge

Results summary

Achieved a statistically significant and clinically meaningful protective effect on both gluten-induced intestinal damage and symptoms

LS mean change from baseline in Vh:Cd ratio of **-0.17 on ANB033 vs. -0.66 on placebo, a +0.49 placebo-adjusted delta (p=0.009)**

LS mean change from baseline in IEL density of **-1.20 on ANB033 vs. +18.83 on placebo, a -20.03 placebo-adjusted delta (p<0.001)**

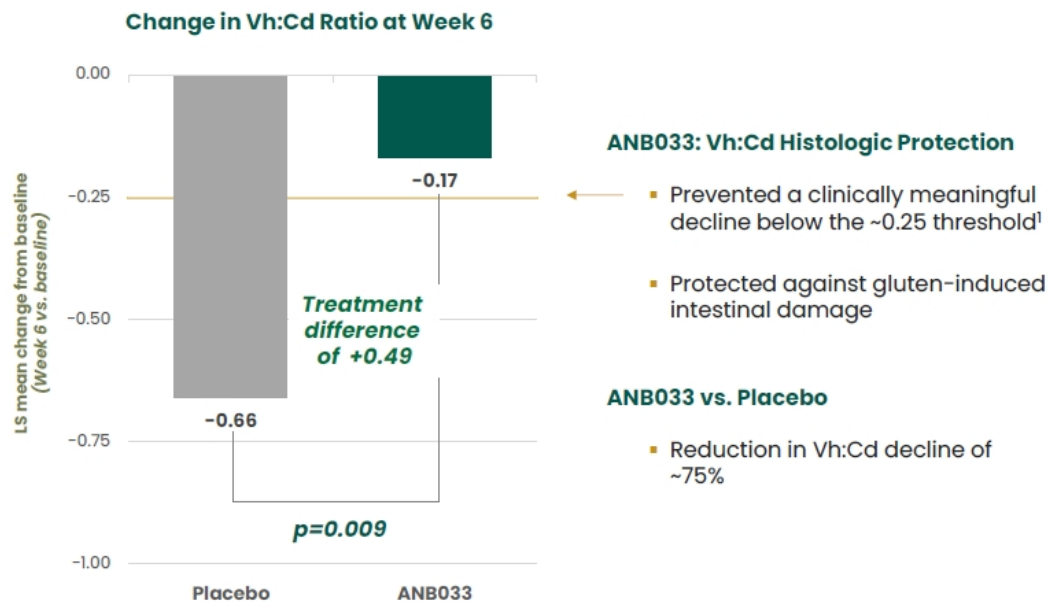
Prevented an increase in symptoms throughout the entire gluten challenge, with lower CDSD score on ANB033 vs. placebo that was statistically significant from the first day

Well tolerated with no safety signals observed to date

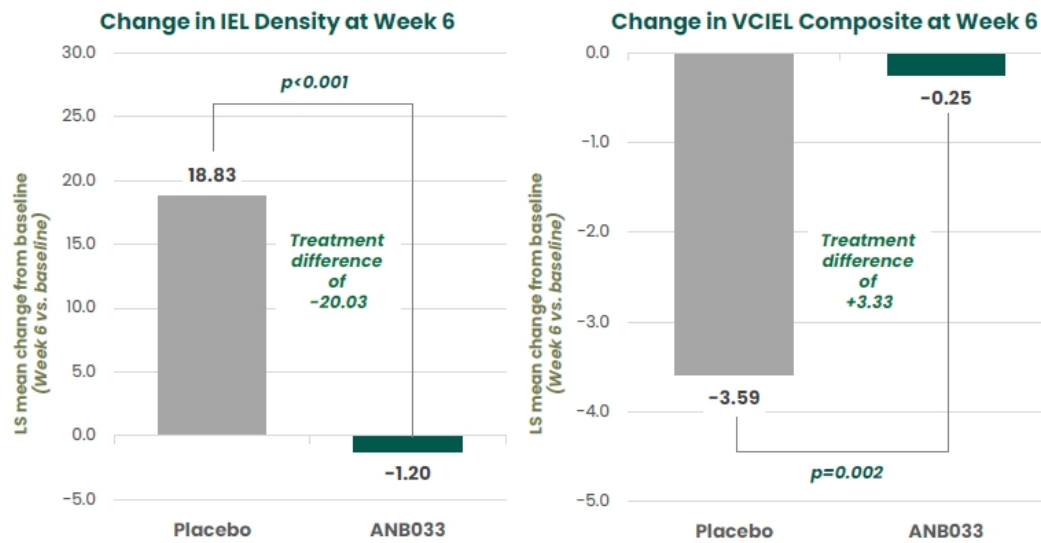
Cohort 1 baseline characteristics

Baseline Characteristic	Placebo (n=15)	ANB033 (n=17)	Overall (n=32)
Age (years)	41.1	44.3	42.8
Sex (n, %) Male Female	2 (13.3%) 13 (86.7%)	5 (29.4%) 12 (70.6%)	7 (21.9%) 25 (78.1%)
Baseline mean Vh:Cd ratio	2.77	2.74	2.75
Baseline mean IEL density/100 enterocytes	22.50	23.20	22.90
Baseline mean VCIEL	-0.004	-0.146	-0.080

ANB033 demonstrated a statistically significant Vh:Cd histologic benefit vs. placebo



ANB033 demonstrated statistically significant IEL density and composite VCIEL benefit vs. placebo



ANB033 not only prevented an increase, but reduced IEL density, despite an intense gluten challenge

ANB033 is the first therapy to report statistical significance on both histology and symptoms

Placebo patients experienced a marked increase in symptoms consistent with an intense gluten challenge

ANB033 prevented an increase in symptoms throughout the entire gluten challenge

47% of placebo patients and only 6% of ANB033 patients took permitted medications to mitigate their GI symptoms

Lower CDSD score on ANB033 vs. placebo, **a statistically significant difference from the first day through the seventh day**

Lower moderate-to-severe symptoms on ANB033 vs. placebo, **a statistically significant difference from the first day through the twelfth day**

ANB033 well tolerated with no safety signals observed to date

Treatment	Placebo (n=16)	ANB033 (n=18)	Overall (n=34)
Participants with any AE	16 (100%)	16 (88.9%)	32 (94.1%)
Any SAE	0 (0%)	0 (0%)	0 (0%)
Any severe AE	1 (6.3%)	0 (0%)	1 (2.9%)
Any moderate AE	12 (75.0%)	3 (16.7%)	15 (44.1%)
AE leading to treatment discontinuation	1 (6.3%)	0 (0%)	1 (2.9%)
AEs occurring in ≥ 3 participants			
Nausea	7 (43.8%)	1 (5.6%)	8 (23.5%)
Abdominal pain	6 (37.5%)	2 (11.1%)	8 (23.5%)
Injection site erythema	2 (12.5%)	5 (27.8%)	7 (20.6%)
Fatigue	5 (31.3%)	1 (5.6%)	6 (17.6%)
Diarrhea	4 (25.0%)	2 (11.1%)	6 (17.6%)
Vomiting	4 (25.0%)	2 (11.1%)	6 (17.6%)
Upper respiratory tract infection	3 (18.8%)	2 (11.1%)	5 (14.7%)
Injection site bruising	3 (18.8%)	1 (5.6%)	4 (11.8%)
Headache	3 (18.8%)	1 (5.6%)	4 (11.8%)
Abdominal distension	3 (18.8%)	0 (0%)	3 (8.8%)
Constipation	3 (18.8%)	0 (0%)	3 (8.8%)
Flatulence	3 (18.8%)	0 (0%)	3 (8.8%)

ANB033 achieved statistically significant and clinically meaningful protective effect on both gluten-induced damage and symptoms

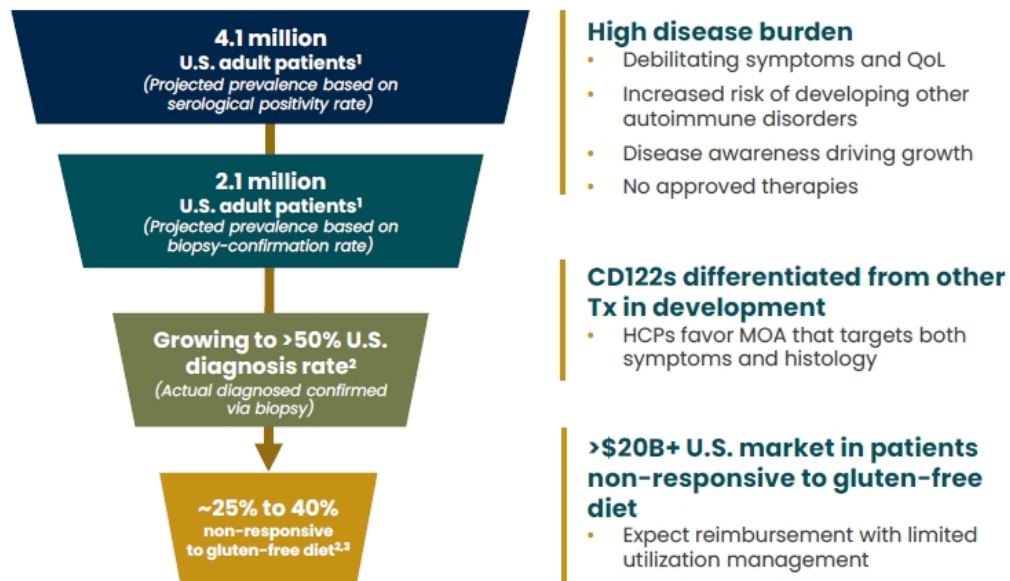
Endpoint		Target	Result
Histology	Vh:Cd	Stat. sig. benefit	0.49 Δ vs. placebo (p=0.009)
		Protective effect (Vh:Cd < 0.25)	0.17 change Below clinically meaningful threshold
	IEL density	Stat. sig. benefit	20.03 Δ vs. placebo (p<0.001)
		Protective effect (No increase)	1.20 decrease (improvement)
Symptoms	Total	Trend	Prevented an increase in symptoms throughout entire gluten-challenge Lower CDSD score vs. placebo; Stat sig difference from first day
	Moderate-to-severe	Trend	Stat sig difference from first day
Safety	Safety and tolerability	Well tolerated	Well tolerated with no safety signals

ANB033 achieved statistically significant and clinically meaningful protective effect on both gluten-induced damage and symptoms

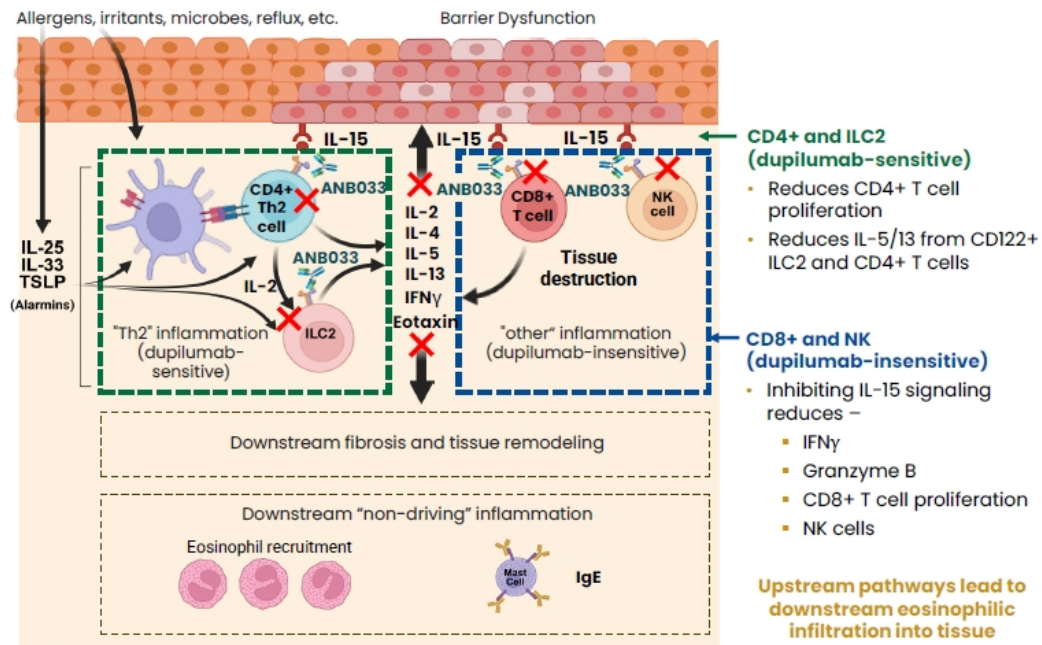
Program / Company	Gluten Challenge	Admin / MOA	Change in Vh: Cd	Change in IEL Density	Symptom Benefit
ANB033 <i>First Tracks</i>	Phase 1b (n=32, 1:1) 14-day, 6g per day	SC (CD122)	Drug: -0.17 Placebo: -0.66 0.49 PBO Δ $p=0.009$	Drug: -1.20 Placebo: +18.83 20.03 PBO Δ $p<0.001$	Prevented an increase in symptoms throughout gluten challenge Lower CDSD scores vs. placebo; stat sig difference from first day
TEV-53408 ¹ <i>Teva</i>	Phase 2a (n=50, 1:1) 6-week, 3g gluten/day	SC (IL-15)	Drug: -0.43 Placebo: -0.88 0.45 PBO Δ $p<0.05$	Drug: +0.37 Placebo: +27.60 27.2 PBO Δ No stats reported	"Stable CDSD scores on drug; worse on placebo" No stats reported
FB-102 ^{2,3} <i>Forte / Argenx</i>	Phase 1b (n=32, 3:1) 16-day, 2g, 4g, to 8g/day	IV (CD122)	Drug: -0.046 Placebo: -0.173 0.13 PBO Δ p value not significant	Drug: -1.5 Placebo: +13.3 14.8 PBO Δ $P=0.0035$	4.0 drug vs. 6.9 placebo cumulative symptoms +AEs /subject No stats reported
	Phase 2a (n=126, 2:2:1) 54-day, 8g to 3g gluten/day	IV (CD122)	Data not reported $p=0.0176$	Data not reported	"prevent emergence of patient symptoms" No stats reported

Note: Data reflect cross-trial comparisons and not head-to-head studies. Caution should be used when comparing data due to differences in trial designs, participant characteristics and endpoint definitions.

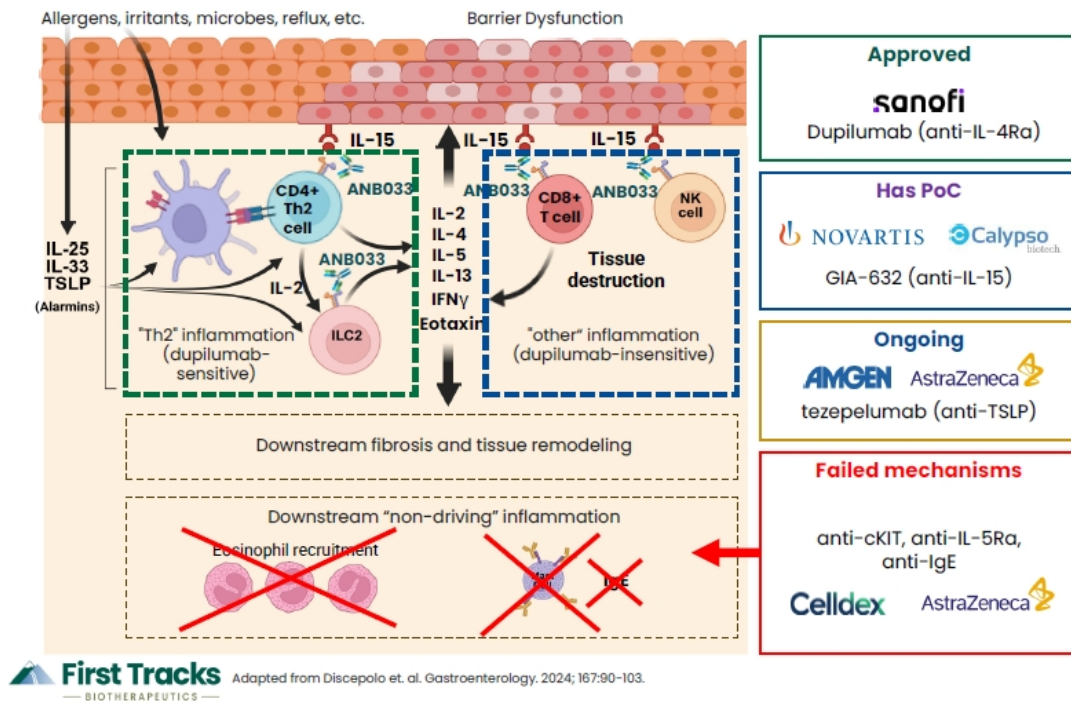
Potential blockbuster opportunity for ANB033 in non-responsive CeD



Similar to CeD, ANB033 targets multiple drivers of EoE biology addressing both dupilumab sensitive and insensitive pathways

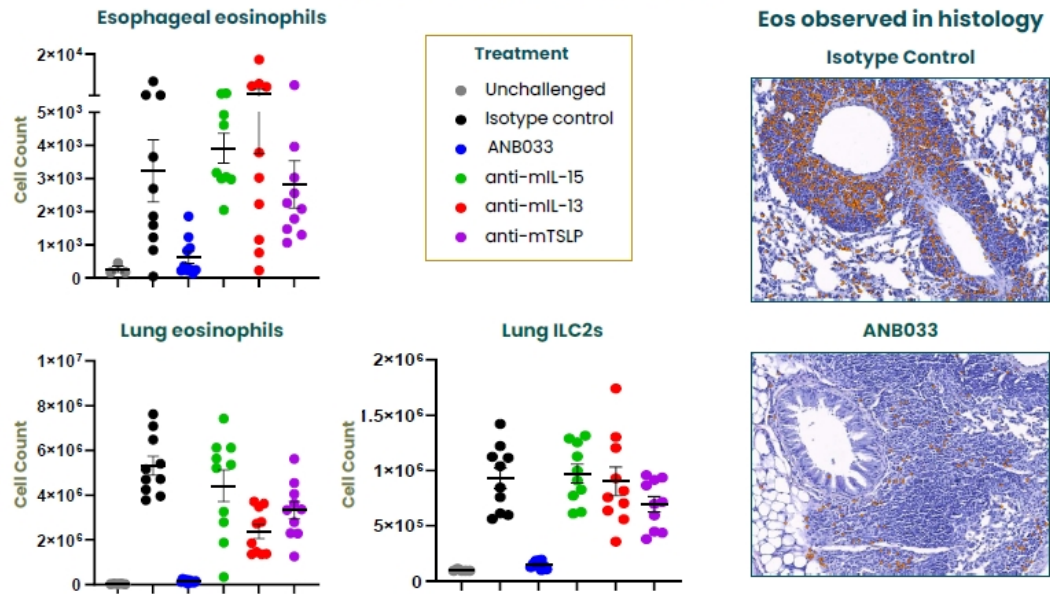


Mechanisms that target only downstream signals of inflammation have not been successful in EoE



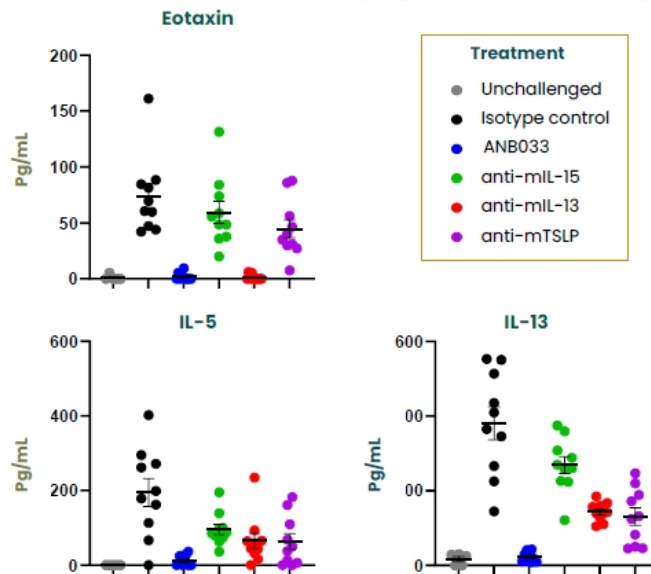
ANB033 prevents eosinophilia by targeting upstream inflammation

Aspergillus-induced eosinophilia



ANB033 also prevents cytokine secretion and chemokine secretion responsible for eosinophil expansion and recruitment

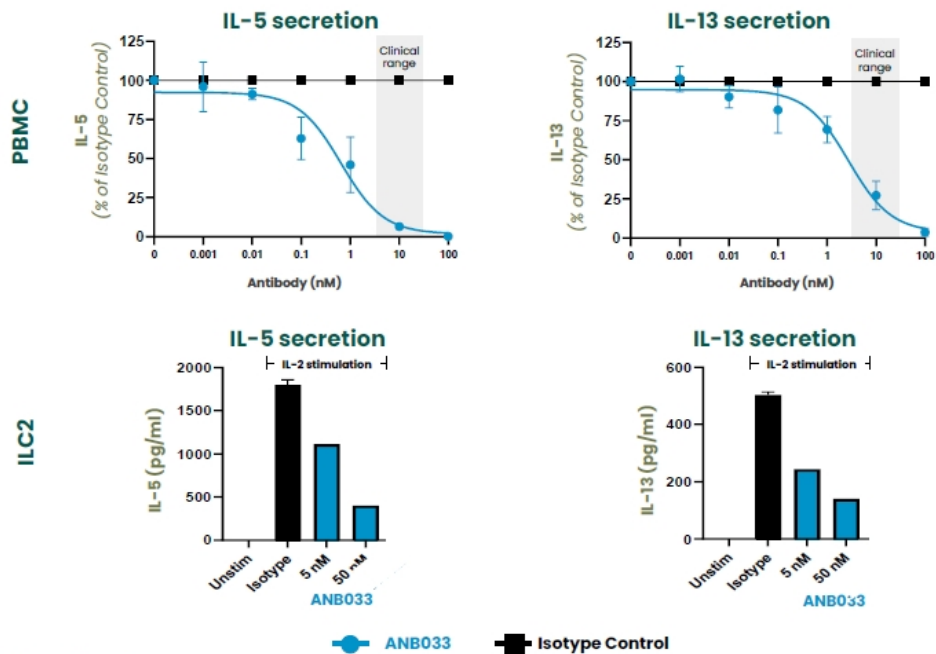
Aspergillus-induced eosinophilia



ANB033 prevents –

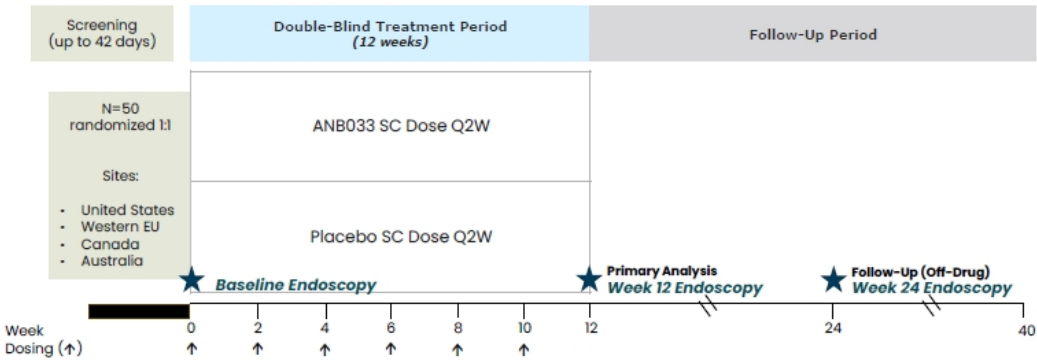
- Cytokine secretion (IL-5/IL-13) responsible for eos expansion
- Chemokine secretion (eotaxin) responsible for eos recruitment

ANB033 reduces CD4+ T cell and ILC2 derived Th2 cytokines, proven drivers of EoE pathology



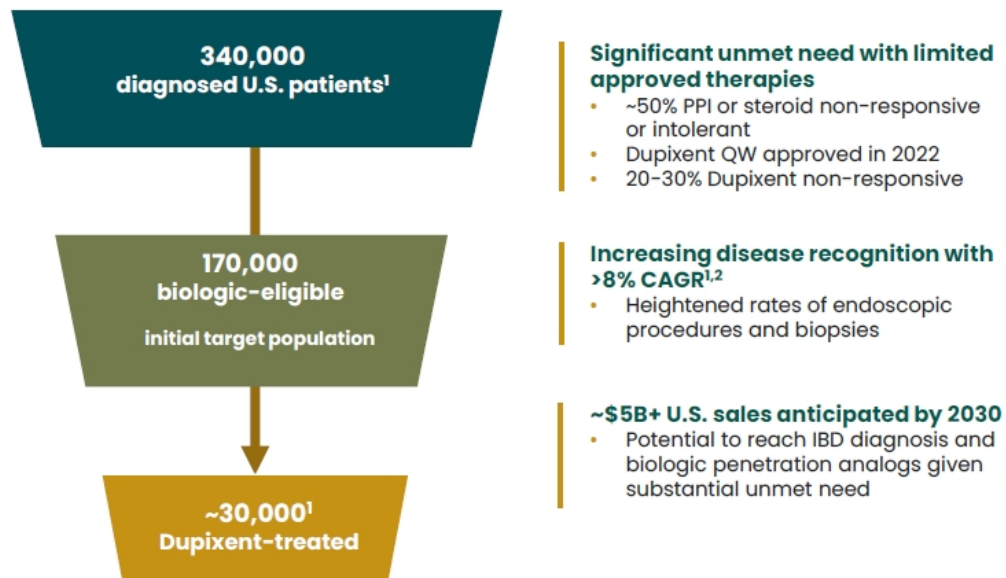
ANB033 Phase 1b trial in EoE ongoing

Anticipate top-line data in Q3 2027



Population	Adult participants with EoE, including dupilumab-experience (<25% of trial) Peak eosinophil count ≥ 15 /hpf at the screening endoscopy and with symptomatic dysphagia
Safety	Safety and tolerability
Clinical PK	PK and immunogenicity
Efficacy	• Peak esophageal intraepithelial eosinophilic count (eos/hpf) • Change from baseline in dysphagia symptom questionnaire (DSQ)
Biomarkers	Characterize ANB033 effects on circulating biomarkers, including robust translational plan

EoE is a significant market with increasing prevalence and unmet need

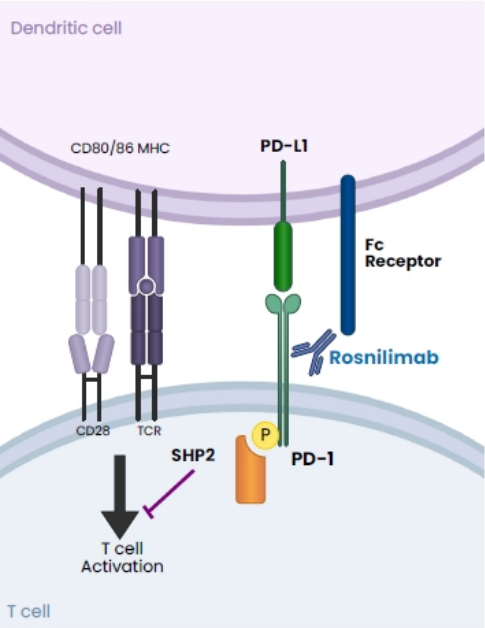




Rosnilimab

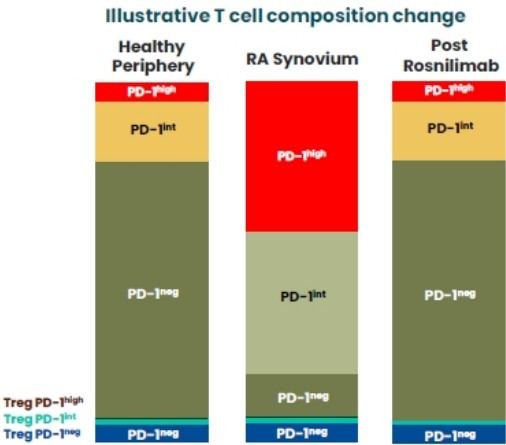
Pathogenic T cell depleter

Rosnilimab selectively targets pathogenic T cells in periphery and inflamed tissue to restore immune homeostasis



Rosnilimab aims to:

- 1 Leverage natural immune regulatory pathway to safely restore immune homeostasis
- 2 Achieve durable remission and modify disease



Pathogenic Teff and Tfh/Tph cells mediate autoimmune pathology



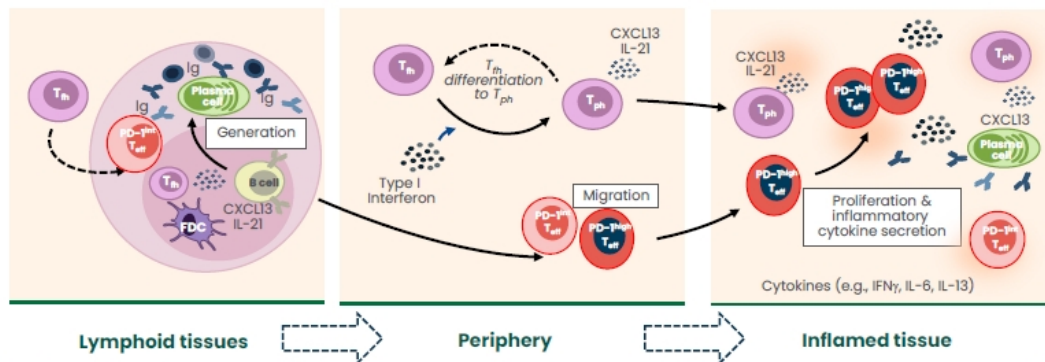
T_{fh} (follicular helper)
T_{ph} (peripheral helper)

- Secrete CXCL13 and IL-21 which recruit and mature B cells into "autoantibody secreting" plasma cells
- Depletion results in downstream effect on B cells, plasma cell generation and autoantibody levels

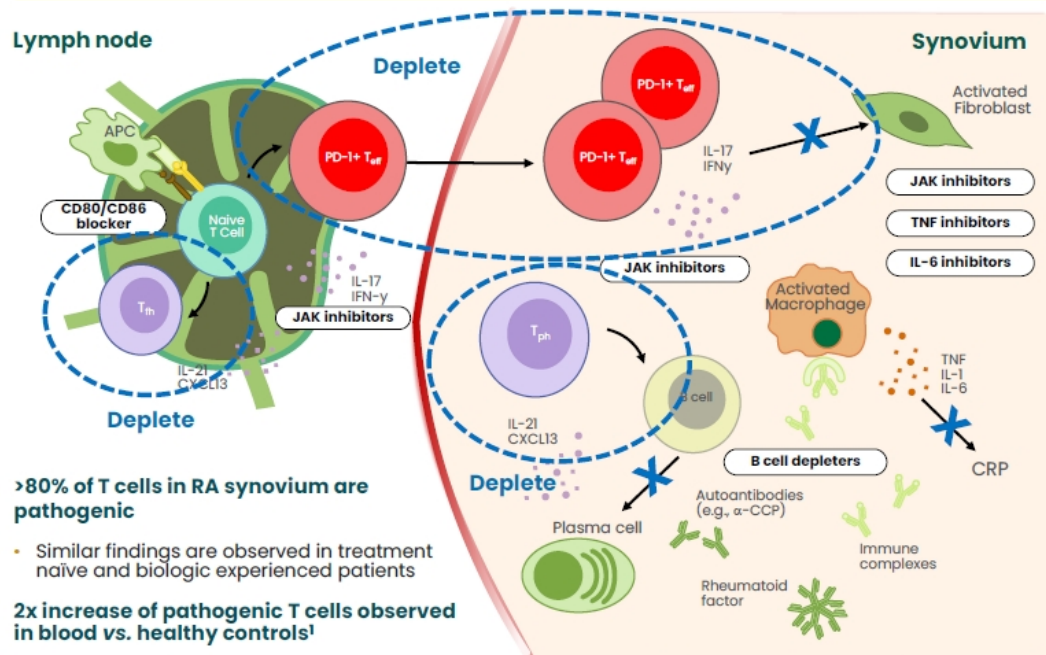


T_{off} (effector)

- In response to stimulation, become highly activated
- Secrete inflammatory cytokines, cause tissue damage and perpetuate inflammatory cycle
- Depletion results in reduced T cell proliferation, T cell migration and cytokine secretion

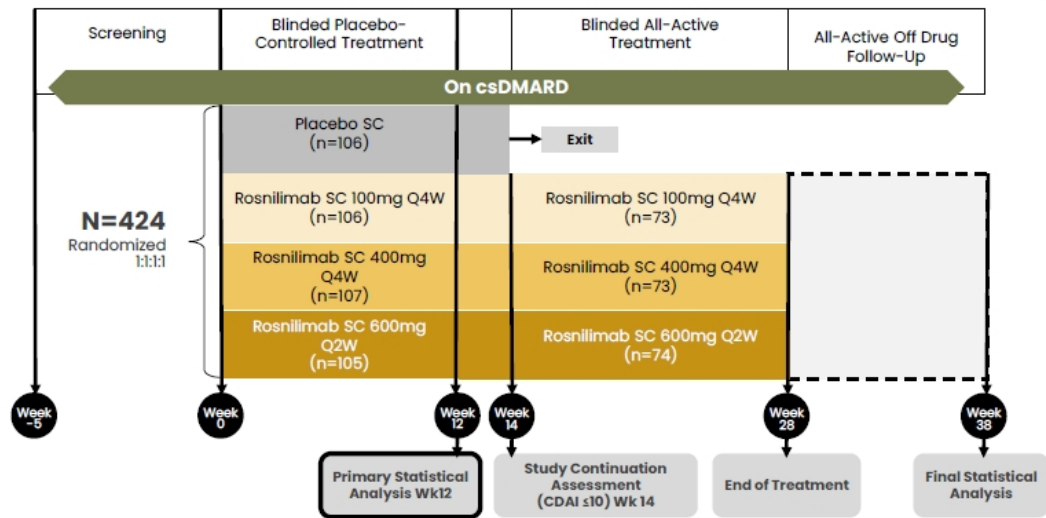


Depleting pathogenic T cells broadly impacts multiple downstream, clinically validated drivers of RA pathogenesis



Rosnilimab Phase 2b trial in RA

95% completed 6-month all-active treatment period supporting rosnilimab's favorable efficacy and tolerability profile



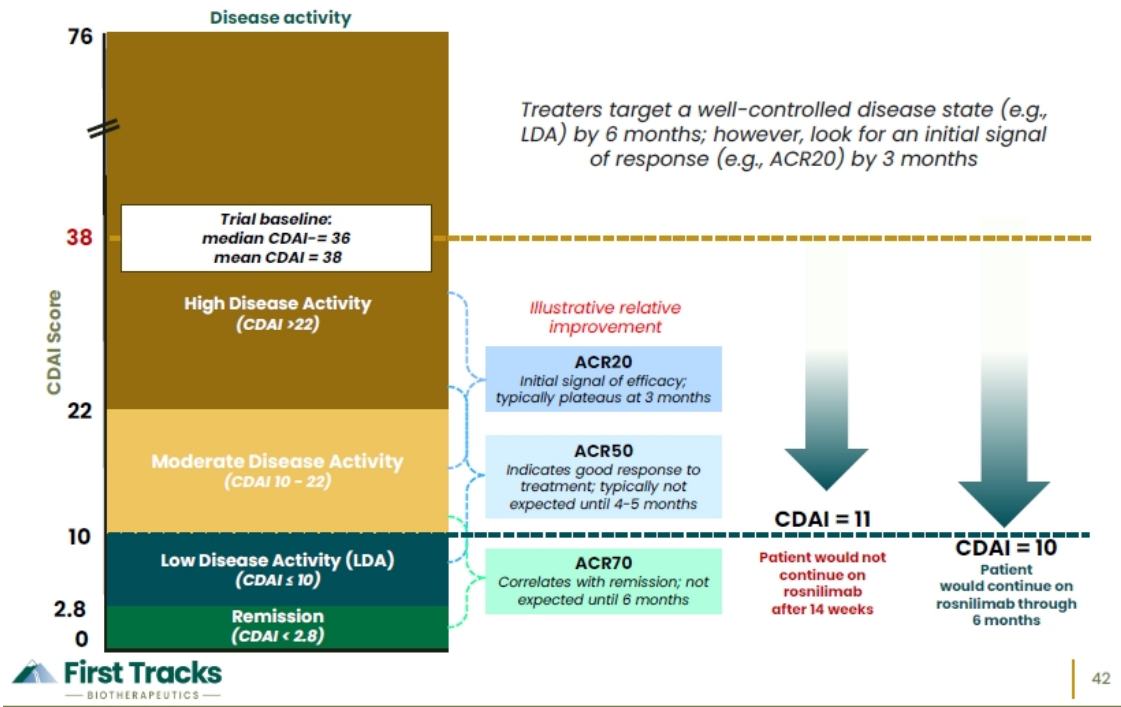
Key Inclusion Criteria – Seropositive RA, ≥6 swollen and ≥6 tender joints, hs-CRP ≥ 3mg/L during Screening, Concurrent use of 1 or 2 csDMARDs that were initiated at least 3 months before screening

Key Exclusion Criteria – Inadequate response, loss of response, or intolerance to any combination of ≥ 3 b/tsDMARD classes

Primary Endpoint – Mean change from baseline at Week 12 for DAS28-CRP

LDA requirement at 14 weeks to continue on rosnilimab was a high bar for patients with baseline high disease activity

95% of trial participants had high disease activity (CDAI > 22) at baseline



Rosnilimab demonstrates best-in-disease profile in RA

Late-breaking oral presentation by Professor Paul Emery at ACR Convergence 2025

1

Best-in-disease profile through 6 months

- JAK-like efficacy in both 3-month placebo-controlled portion and through 6 months
- Similar responses observed across more stringent endpoints regardless of prior therapy type, including JAKs
- Favorable safety and tolerability, particularly when compared to standard of care
- Monthly (Q4W) dosing

2

Max response rates have not yet been observed

- Strict continuation criteria prevented patients with improvement at 3 months from continuing in this P2b trial
- Many patients beyond 3 months achieved, or were trending toward, CDAI LDA and ACR50

3

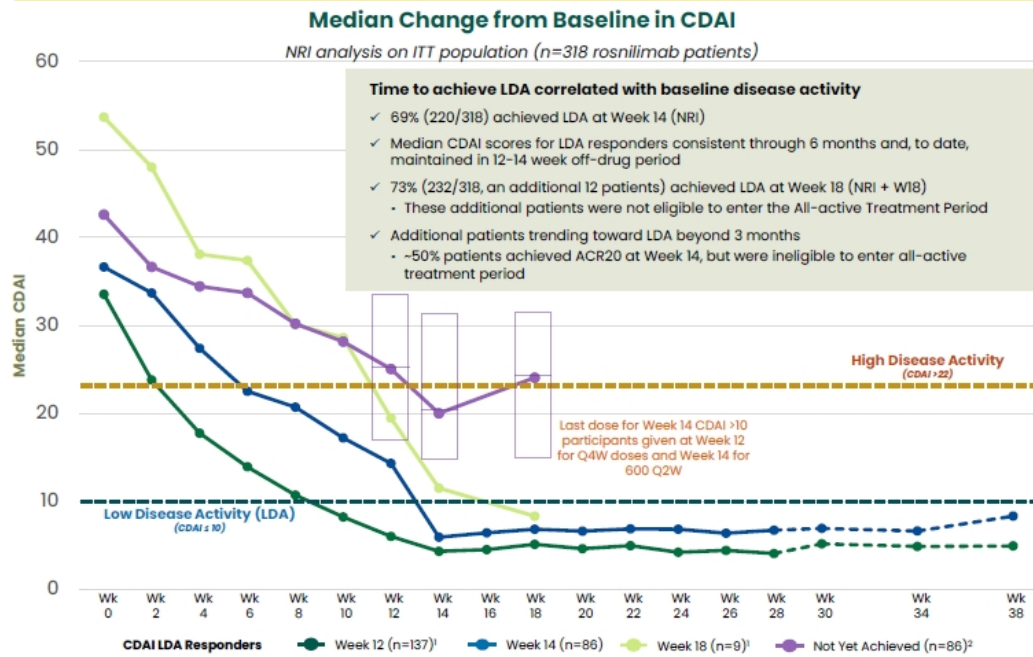
Responses durable for at least 3-months off-drug

- Potential for maintenance dosing with extended dosing intervals (e.g. Q8W or Q12W)

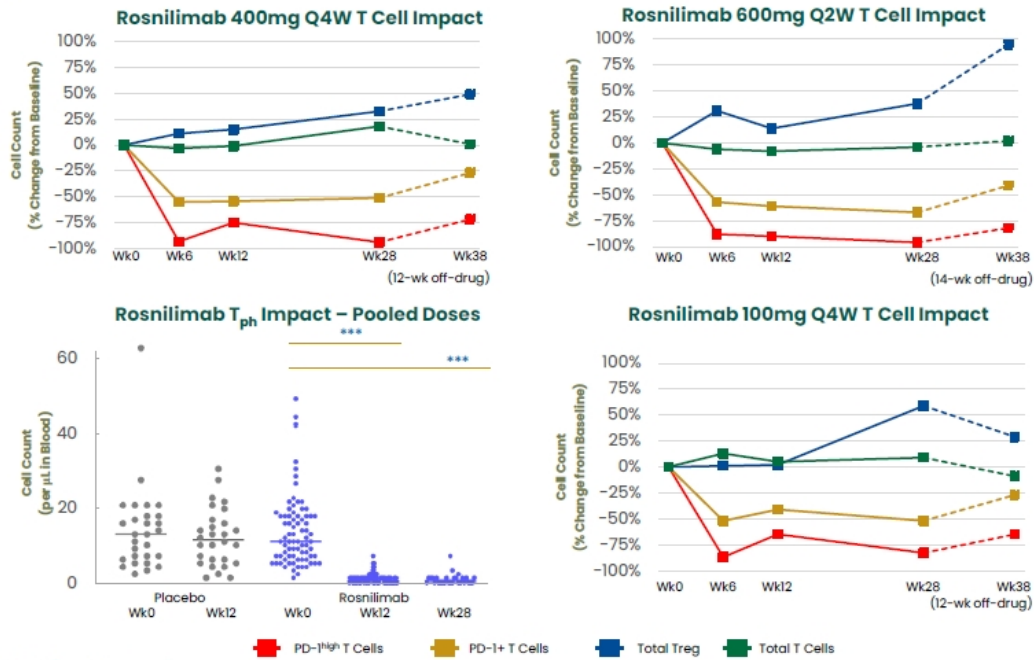
Rosnilimab, a pathogenic T cell depleter, is well-positioned for the ~\$20 billion U.S. RA market which hasn't had a new mechanism approved since 2012

Max response was not achieved in this Phase 2b trial

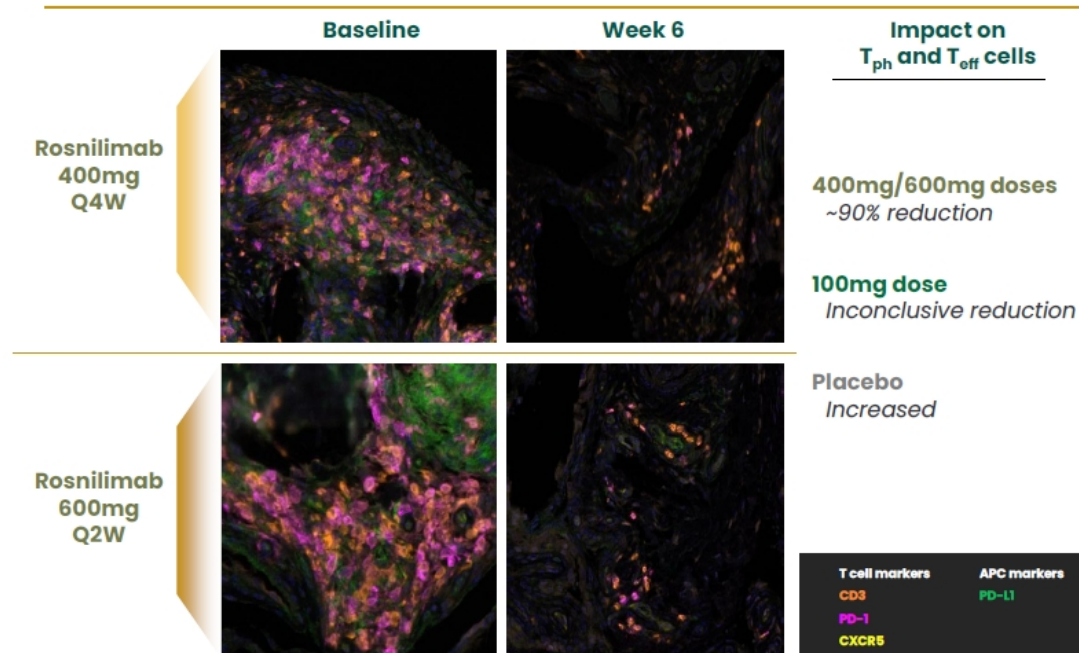
On average, patients with higher disease activity take longer to achieve CDAI LDA



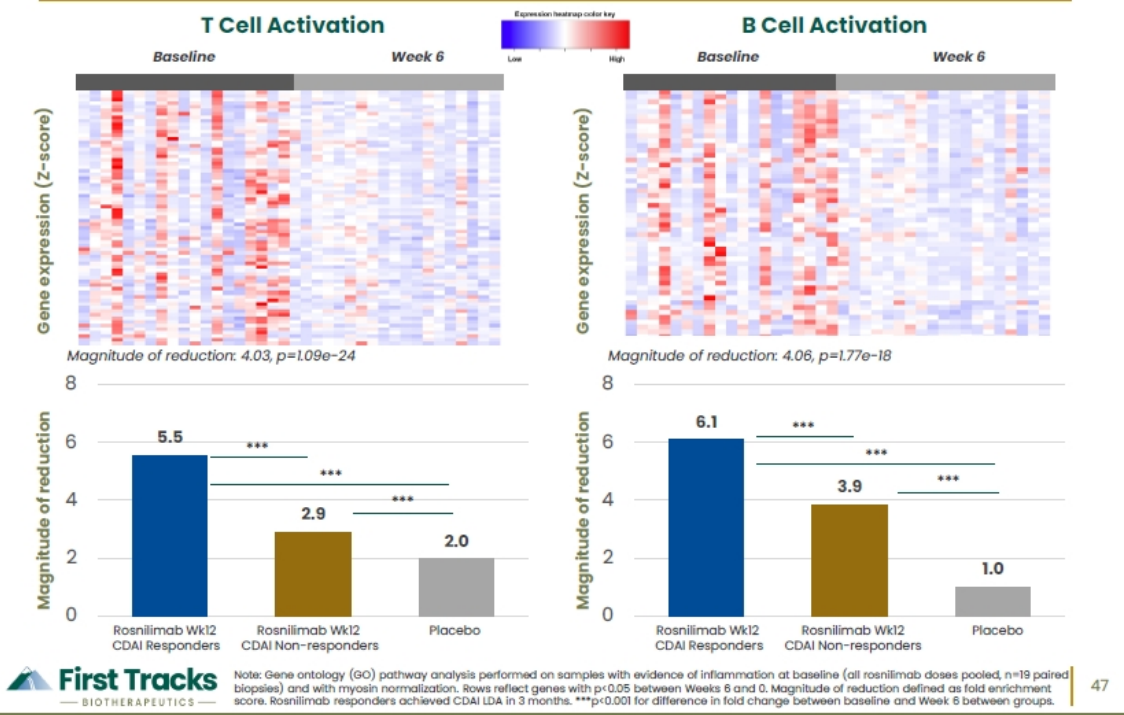
Deep, sustained reduction of pathogenic T cells led to favorable T cell composition reflective of immune homeostasis and durable response



Synovial biopsies show ~90% reduction of pathogenic T cells in the target issue



Significant reduction of T and B cell activation demonstrate on target pharmacology within the synovium



Rosnilimab well tolerated with no safety signals

<2% dropout rate overall due to AEs through 6 months, with only 1 dropout due to AE (headache-moderate) after 3 months

Study Period	Week 0 through Week 12 (N=424)				Week 0 through Week 38 (N=424)			
	Participants with Adverse Events, n (%)				Participants with Adverse Events, n (per 100 PY) *			
	Placebo (n=106)	100mg Q4W (n=106)	400mg Q4W (n=107)	600mg Q2W (n=105)	Placebo (n=106)	100mg Q4W (n=106)	400mg Q4W (n=107)	600mg Q2W (n=105)
Any AE	36 (34%)	51 (48%)	48 (45%)	38 (36%)	47 (152.7)	75 (238.3)	69 (190.4)	57 (140.1)
Any SAE	1 (1%)	1 (1%)	1 (1%)	3 (3%)	1 (2.4)	3 (4.5)	5 (7.3)	4 (6.1)
Any Drug-Related SAE	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (2.4)	0 (0)	0 (0)	0 (0)
Severe AE	2 (2%)	1 (1%)	0 (0%)	4 (4%)	3 (7.1)	4 (6.0)	3 (4.4)	4 (6.1)
Drug-Related AE	18 (17%)	13 (12%)	18 (17%)	17 (16%)	19 (51.2)	17 (29.1)	28 (49.5)	20 (35.4)
AE Leading to Treatment Discontinuation	1 (1%)	1 (1%)	2 (2%)	2 (2%)	1 (2.4)	1 (1.5)	3 (4.4)	2 (3.0)
Infections	14 (13%)	24 (23%)	21 (20%)	12 (11%)	23 (60.2)	43 (87.3)	43 (83.8)	35 (64.7)
Serious	1 (1%)	1 (1%)	0	0	1 (2.4)	1 (1.5)	1 (1.5)	1 (1.5)
Opportunistic	2 (1.9%)	0 (0%)	0 (0%)	0 (0%)	2 (4.8)	1 (1.5)	1 (1.5)	1 (1.5)
MACE	0 (0%)	1 (1.5%)	0 (0%)	0 (0%)	0 (0)	1 (1.47)	0 (0)	0 (0)
Malignancies	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0)	0 (0)	0 (0)	0 (0)
Death	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0)	0 (0)	0 (0)	0 (0)
Participants with any AEs > 5%								
Headache	4 (4%)	7 (7%)	6 (6%)	4 (4%)	4 (9.6)	10 (16.0)	10 (15.4)	5 (7.8)
Upper respiratory tract infection	1 (1%)	7 (7%)	2 (2%)	3 (3%)	2 (4.7)	14 (22.5)	7 (10.6)	12 (19.1)
Nasopharyngitis	4 (4%)	5 (5%)	5 (5%)	0	6 (14.4)	9 (14.0)	9 (13.8)	5 (7.6)
Elevated ALT (alanine aminotransferase)	1 (1%)	4 (4%)	3 (3%)	3 (3%)	1 (2.4)	8 (12.4)	4 (6.0)	4 (6.2)

* Exposure adjusted incidence rate per 100 person-year = 100 x (Number of subjects with AE in the given period / Total years of exposure in the given period across all subjects at risk for the treatment). All adverse events (AEs) that are summarized above are treatment emergent adverse events. SAE=serious adverse event. N = total number of subjects in analysis set, n = number of subjects in specific category.

Next steps for rosnilimab

Rheumatoid Arthritis

Positive Phase 2b data reported

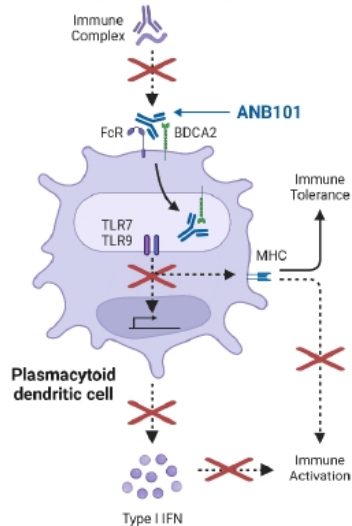
- Best-in-disease profile
 - Favorable safety and tolerability
 - JAK-like efficacy through 6 months
 - Max response rates not yet observed due to trial design
 - Sustained 12–14 week off-drug responses through 9 months
 - Late-breaking data presented at ACR 2025
-
- Completed End-of-Phase 2 (EOP2) meeting with FDA in Q1 2026
 - Agency provided constructive feedback on a registrational Phase 3 path in RA, a disease with significant remaining patient unmet need
 - Currently assessing ROE-maximizing strategic options that may include a global partnership, out-license or asset financing to progress the potential development of rosnilimab in RA and other indications



ANB101: BDCA2 modulator of plasmacytoid dendritic cell (pDC) function

Phase I trial completed in healthy volunteers

BDCA2 is a molecule specifically expressed on pDCs



ANB101 potently inhibits interferon secretion and immune activation

Activated pDCs bridge innate and adaptive immunity

- Secrete Type I IFN (1000x increase over other cell types)
- Present antigens to adaptive immune system

pDCs enriched in tissue in rheumatology and other inflammatory diseases

- BDCA2 modulator mechanistic proof-of-concept (Biogen's litifilimab) in SLE / CLE

ANB101: BDCA2 modulator

- Potent and sustained internalization of BDCA2 on pDC cell surface
- Profound inhibition of interferon secretion reduces inflammation

Currently evaluating potential development approach informed by clinical and translational evidence, as well as competitive registrational data in SLE expected in Q4 2026 and CLE expected in early 2027

First Tracks Biotherapeutics Announces Positive Top-Line Results for ANB033 in Gluten-Challenge Study in Celiac Disease

- ANB033 achieved a statistically significant and clinically meaningful protective effect on both gluten-induced intestinal damage and symptoms
- LS mean change from baseline in Vh:Cd ratio of -0.17 on ANB033 vs. -0.66 on placebo, a +0.49 placebo-adjusted delta ($p=0.009$)
- LS mean change from baseline in IEL density of -1.20 on ANB033 vs. +18.83 on placebo, a -20.03 placebo-adjusted delta ($p<0.001$)
- Prevented an increase in symptoms throughout the entire gluten challenge, with lower CDSI score on ANB033 vs. placebo that was statistically significant from the first day
- Well tolerated with no safety signals observed to date
- Conference call and webcast today, Monday, Oct. 12, 2026, at 8:30 a.m. ET to discuss these results

SAN DIEGO, CA — Oct. 12, 2026 — First Tracks Biotherapeutics, Inc. (Nasdaq: TRAX), a clinical-stage biotechnology company advancing antibody therapeutics that modulate immune pathways implicated in autoimmune and inflammatory diseases, today announced positive top-line results from Cohort 1 (gluten challenge) of ANB033's Phase 1b trial in celiac disease (CeD). ANB033, an investigational, subcutaneously administered CD122 antagonist, is designed to inhibit the signaling of both IL-15 and IL-2 on immune cells.

ANB033 demonstrated a statistically significant difference compared to placebo across key histologic endpoints, including least squares (LS) mean change in villus height-to-crypt depth (Vh:Cd) ratio, intraepithelial lymphocyte (IEL) density, and VCIEL composite scale, as well as symptom endpoints using the Celiac Disease Symptom Diary (CDSI).

In the context of an intense gluten challenge, treatment with ANB033 not only prevented an increase in IEL density, but also protected against gluten-induced intestinal damage with changes in Vh:Cd ratio remaining below the threshold considered clinically meaningful.

“For people living with celiac disease, trace exposure to gluten can cause intestinal damage and debilitating symptoms despite general adherence to a gluten-free diet. After treatment with ANB033, patients underwent a 14-day gluten challenge consuming the equivalent of two slices of bread a day. ANB033 achieved a statistically significant and clinically meaningful protective effect against gluten-induced intestinal damage and symptoms, while maintaining a favorable safety profile,” said Daniel Faga, president and chief executive officer. “We look forward to continuing to work with regulators, clinicians and the patient community as we advance ANB033 into late-stage development in 2027.”

The randomized, placebo-controlled Phase 1b trial in CeD is evaluating subcutaneous ANB033 administered across two cohorts: Cohort 1, a 6-week study assessing prevention of gluten-induced intestinal damage and symptoms after a 14-day gluten challenge, and Cohort 2, assessing mucosal healing in patients with a broad range of histologic and symptom severity through 12 weeks.

Cohort 1 evaluated 32 patients (17 on ANB033 and 15 on placebo) who completed dosing and the gluten challenge at Week 6. Patients received three subcutaneously administered loading doses of ANB033 or placebo at Week 0, Week 2, and Week 4, followed by a 14-day gluten challenge (6g daily, the equivalent of approximately two slices of bread,

administered by two gluten cookies). The trial assessed safety and tolerability as well as key histologic and symptom endpoints used to measure clinical benefit with a primary analysis at Week 6.

Key Efficacy Endpoints Were Achieved in Cohort 1

ANB033 achieved the key histologic efficacy endpoints of LS mean change from baseline in Vh:Cd ratio, IEL density, and VCIEL vs. placebo at Week 6.

Histologic Endpoints (Week 6)	Placebo (n=15)	ANB033 (n=17)	Placebo-Adjusted Delta
LS Mean Change in Vh:Cd Ratio	-0.66	-0.17	+0.49 (p=0.009)
LS Mean Change in IEL Density	+18.83	-1.20	-20.03 (p<0.001)
LS Mean Change in VCIEL	-3.59	-0.25	+3.33 (p=0.002)

Using the Celiac Disease Symptom Diary (CDSD), symptoms were assessed daily through the entire 14-day gluten challenge. The CDSD is a validated, patient-reported outcome measure that assesses the frequency and severity of five key celiac disease symptoms which are abdominal pain, bloating, nausea, diarrhea and tiredness.

Symptom findings during the gluten challenge were as follows –

- Placebo patients experienced a marked increase in symptoms consistent with an intense gluten challenge
- ANB033 prevented an increase in symptoms throughout the entire gluten challenge
- 47% of placebo patients and only 6% of ANB033 patients took permitted medications to mitigate their GI symptoms
- Lower CDSD score on ANB033 vs. placebo, a statistically significant difference from the first day through the seventh day
- Lower moderate-to-severe symptoms on ANB033 vs. placebo, a statistically significant difference from the first day through the twelfth day

“It is remarkable to see, for the first time, both statistically significant prevention of symptoms and Vh:Cd benefit in the same study. Equally impressive, ANB033 showed changes from baseline that remained below the threshold considered clinically meaningful in an intense gluten challenge,” said Benjamin Lebwohl, M.D., MS, professor of Medicine and Epidemiology at NY-Presbyterian/Columbia University Irving Medical Center and director of Clinical Research at the Celiac Disease Center at Columbia University. “ANB033 takes a novel approach to treating celiac disease by targeting CD122 and blocking both IL-15 and IL-2 signaling, two key drivers of inflammation that damage the intestine, with IL-2 closely linked to symptom development. For the largest autoimmune disease without an approved therapeutic option, these findings are an important advance for the celiac disease community.”

ANB033 Well Tolerated with No Safety Signals Observed to Date

ANB033 demonstrated a consistent, favorable safety and tolerability profile with no serious adverse events (SAEs), no severe adverse events (AEs) and no AEs leading to discontinuation.

Participants with Adverse Events	Placebo (n=16)	ANB033 (n=18)	Overall (n=34)
Any AE (n, %)	16 (100%)	16 (88.9%)	32 (94.1%)
Any SAE	0 (0%)	0 (0%)	0 (0%)
Any severe AE	1 (6.3%)	0 (0%)	1 (2.9%)
Any moderate AE	12 (75.0%)	3 (16.7%)	15 (44.1%)
AE leading to treatment discontinuation	1 (6.3%)	0 (0%)	1 (2.9%)
AEs occurring in ≥ 3 participants			
Nausea	7 (43.8%)	1 (5.6%)	8 (23.5%)
Abdominal pain	6 (37.5%)	2 (11.1%)	8 (23.5%)
Injection site erythema	2 (12.5%)	5 (27.8%)	7 (20.6%)
Fatigue	5 (31.3%)	1 (5.6%)	6 (17.6%)
Diarrhea	4 (25.0%)	2 (11.1%)	6 (17.6%)
Vomiting	4 (25.0%)	2 (11.1%)	6 (17.6%)
Upper respiratory tract infection	3 (18.8%)	2 (11.1%)	5 (14.7%)
Injection site bruising	3 (18.8%)	1 (5.6%)	4 (11.8%)
Headache	3 (18.8%)	1 (5.6%)	4 (11.8%)
Abdominal distension	3 (18.8%)	0 (0%)	3 (8.8%)
Constipation	3 (18.8%)	0 (0%)	3 (8.8%)
Flatulence	3 (18.8%)	0 (0%)	3 (8.8%)

Safety analysis set includes two additional participants who were randomized in Cohort 1 but discontinued the study prior to initiating the gluten challenge, were therefore unevaluable for gluten challenge efficacy analysis and did not undergo the second biopsy at Week 6. The one participant on ANB033 discontinued due to a decision not to undergo the gluten challenge.

Next Steps for ANB033

First Tracks Biotherapeutics will continue to engage with regulatory agencies, including the U.S. FDA, which has already granted ANB033 Fast Track designation, to discuss and align on the next phase of development for ANB033 in CeD. We anticipate starting a late-stage clinical trial in CeD in 2027.

Cohort 2 of ANB033’s Phase 1b trial in CeD, which is assessing mucosal healing in patients with a broad range of histologic (Vh:Cd ratio ≤ 2.5) and symptom severity through 12 weeks, is on track to complete enrollment imminently, with top-line data anticipated in Q1 2027.

A Phase 1b cohort in eosinophilic esophagitis (EoE) is enrolling 50 patients with top-line data anticipated in Q3 2027. Additionally, we are also on track to initiate Phase 2 development in vitiligo and one additional indication in H1 2027.

“The consistency of the histologic and symptom findings strengthens our confidence in the underlying biology and supports continued development of ANB033 in celiac disease and other conditions driven by this pathway, including eosinophilic esophagitis and vitiligo,” added Paul Lizzul, M.D., Ph.D., chief medical officer. “We are deeply grateful to the patients, investigators and study teams who made this important milestone possible and look forward to presenting these results at ICDS in Melbourne in November.”

First Tracks Biotherapeutics Investor Call

Management will host an investor call and live webcast, with an accompanying slide presentation, to review the Cohort 1 results today, Monday, Oct. 12, 2026, at 8:30 a.m. ET / 5:30 a.m. PT. A live webcast of the call will be available on the First Tracks Biotherapeutics website at: <https://ir.firsttracksbio.com/news-events/events>. A replay of the webcast will be available for at least 30 days following the event.

About ANB033

ANB033, a potentially best-in-class CD122 antagonist, targets CD122, the common beta subunit of the IL-15 and IL-2 receptors, to reduce subsets of CD8+ and CD4+ T cells, NK cells, as well as ILC2s. Antagonizing CD122 has the potential to achieve and maintain remission of inflammation through the reduction of disease-causing cytolytic CD8 T cell subsets, including IELs and NK cells and reducing inflammatory cytokine secretion by activated CD4+ Th1 and Th2 cells, as well as ILC2 cells.

About First Tracks Biotherapeutics

First Tracks Biotherapeutics is a clinical stage biotechnology company advancing antibody therapies that modulate immune pathways implicated in autoimmune and inflammatory diseases. Its pipeline includes ANB033, a CD122 antagonist in development for celiac disease and eosinophilic esophagitis; rosnilimab, a pathogenic T cell depleter in development for rheumatoid arthritis; and ANB101, a BDCA2 modulator. To learn more, visit www.FirstTracksBio.com or follow us on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the potential benefits, efficacy and safety profile of ANB033 and the Company’s other product candidates; the Company’s regulatory plans for ANB033 in celiac disease; and the anticipated timing of the initiation of, enrollment in, and data from, the Company’s clinical trials, including top-line data from Cohort 2 of ANB033's Phase 1b clinical trial in celiac disease and Phase 1b clinical trial in eosinophilic esophagitis, a late-stage trial in celiac disease and Phase 2 development in vitiligo and one additional indication. Statements including words such as “plan,” “continue,” “expect,” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company’s ability to advance its product candidates, obtain regulatory approval of and ultimately commercialize its product candidates, the timing and results of preclinical and

clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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