

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): September 28, 2026

Adicet Bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38359
(Commission File Number)

81-3305277
(IRS Employer
Identification No.)

131 Dartmouth Street, Floor 3
Boston, Massachusetts
(Address of Principal Executive Offices)

02116
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 503-9095

Not applicable
(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 \$0.0001 per share	ACET	The Nasdaq Capital Market

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 September 28, 2026, Adicet Bio, Inc. (the Company or Adicet) issued a press release titled “Adicet Bio Announces Positive Safety and Efficacy Data from Prula-cel (formerly ADI-001) Study in Patients with Systemic Lupus Erythematosus with or without Lupus Nephritis.” A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Also, on September 28, 2026, the Company will host a webcast to discuss preliminary data from its Prula-cel Phase 1 study in patients with systemic lupus erythematosus with or without lupus nephritis. A copy of the presentation from the webcast will be available on the “Investors” page of the Company’s website at www.adicetbio.com and is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information under this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 hereto, is being furnished herewith and shall not be deemed “filed” for the 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 such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended (the Securities Act), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On September 28, 2026, the Company announced preliminary data from its Prula-cel Phase 1 study in patients with SLE with or without LN. The preliminary data, as well as additional corporate updates, are summarized below.

Prula-cel Phase 1 Study Data

Data highlights as of the August 28, 2026 cut-off date were as follows:

- 22 patients (16 LN and 6 extra renal SLE) were evaluated with follow-up ranging from 6-21 months.
- **Efficacy endpoints.** Prula-cel treatment yielded high rates of immunosuppressant-free responses in a heavily pretreated population. Patients had a mean baseline of Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) of 13 and those with LN had mean urine protein-to-creatinine ratio (UPCR) of 2.8, and all had received at least three prior therapies (71% received four or more). At the 12-month mark, 50% of evaluable lupus nephritis patients achieved a complete renal response (CRR) and 54% of evaluable patients achieved DORIS remission. All 12-month responses were ongoing at 12 to 21 months of follow-up, except 1 patient with UPCR 0.65 g/g who remains off immunosuppressants. Reductions in mean SLEDAI-2K and Physician’s Global Assessment (PGA) were rapid and sustained, consistent with autologous alpha beta CD19 CAR-T therapies, and 85% of patients with 12-month follow-up achieved a PGA score below 0.5.
- **Safety Profile.** As of August 28, 2026, prula-cel was generally well tolerated and showed a favorable safety profile appropriate for outpatient dosing. Across the 24 safety-evaluable patients dosed with prula-cel, there was no cytokine release syndrome (CRS) greater than Grade 2. Grade 1 or 2 CRS occurred in 25% of patients. There were no dose-limiting toxicities (DLTs), no immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS), and no Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Infections were reported in 54% of patients, with Grade 3 or higher in 8.3%. There were no cases of graft vs host disease (GvHD) observed. Per alignment with the U.S. Food and Drug Administration (FDA), this profile supports outpatient administration.
- **Immunosuppression and steroids.** All patients discontinued immunosuppressants, and all but one tapered background steroids to 5 mg or less of prednisone equivalent.
- **Immune reset.** Multiple independent biomarkers provided evidence of an immune reset. All efficacy evaluable patients (22 of 22) achieved undetectable CD19+ B cells, followed by naïve-dominant B-cell reconstitution. Reductions in anti-dsDNA antibodies were observed in 91% (10 of 11) of baseline-positive patients, and 90% (9 of 10) of patients with low baseline complement demonstrated complement recovery.

The Company approached the FDA regarding a pivotal study in lupus nephritis and aligned on a single-arm study in lupus nephritis patients with inadequate response to at least two immunosuppressants. The study is expected to enroll a double digit number of patients and the primary efficacy endpoint will be complete renal response at 12 months. The Company plans to initiate start-up activities for a pivotal study in LN in the fourth quarter of 2026.

The high DORIS remission rate observed to date may support the potential inclusion of lupus patients without nephritis in the single arm pivotal study, subject to regulatory alignment. The company plans to discuss with the FDA such potential expansion of the pivotal study to include lupus without nephritis in the fourth quarter of 2026.

There are approximately 35,000 LN patients and 35,000 patients with non-renal SLE who have organ/life threatening disease in the U.S. alone. Based on prula-cel enrollment track record to date and the level of interest expressed by patients and investigators in prula-cel, Adicet expects rapid enrollment to the pivotal study.

Anticipated milestones for prula-cel include:

- **Fourth quarter of 2026:** Initiate pivotal start up activities and align with FDA on the pivotal study population, including potential inclusion of SLE
- **First Half 2027:** Anticipated clinical data update in systemic sclerosis (SSc)
- **Mid 2027:** Anticipated clinical data update in LN/SLE

Forward-Looking Statements

The disclosure in this Current Report on Form 8-K contains “forward-looking statements” of Adicet within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the business and operations of Adicet. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: clinical development of Adicet’s product candidates, including future plans or expectations for prula-cel in autoimmune diseases and the potential safety, tolerability and efficacy for the treatment of autoimmune diseases and cancer as well as expectations to achieve a complete immune reset; expectations regarding future alignment with the FDA on regulatory path to approval and discussions to date; timing and success of the Phase 1 clinical trial of prula-cel in multiple autoimmune indications, including timing and expectations for enrollment and future data releases; expectations regarding the timing and initiation of a pivotal study for prula-cel in SLE patients with or without LN and potential expansion to include non-renal lupus; expectations regarding prula-cel’s potential to transform treatment for patients with lupus; expectations regarding the suitability of prula-cel for outpatient administration; expectations regarding the scalability of the Company’s off-the-shelf manufacturing platform; expectations regarding the pace of enrollment in the pivotal study for prula-cel in SLE patients with or without LN; and estimates for the addressable patient population and commercial opportunity for prula-cel in LN and SLE.

Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including without limitation, the effect of global economic conditions and public health crises on the Company’s business and financial results, including with respect to disruptions to its preclinical and clinical studies, business operations, employee hiring and retention, and ability to raise additional capital; Adicet's ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; that positive results, including interim results, from a preclinical or clinical study may not necessarily be predictive of the results of future or ongoing studies; that clinical studies may fail to demonstrate adequate safety and efficacy of Adicet’s product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization; and regulatory approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; and Adicet’s ability to meet production and product release expectations. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Adicet’s actual results to differ from those contained in the forward-looking statements, see the section titled “Risk Factors” in Adicet’s most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Adicet’s other filings with the U.S. Securities and Exchange Commission, including its quarterly report on Form 10-Q. All disclosure in this Current Report on Form 8-K is as of the date of this filing, and Adicet undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Adicet Bio, Inc. on September 28, 2026, furnished herewith.
99.2	Corporate presentation of Adicet Bio, Inc., furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

ADICET BIO, INC.

Date: September 28, 2026

By: /s/ Nick Harvey
Name: *Nick Harvey*
Title: *Chief Financial Officer*



Adicet Bio Announces Positive Safety and Efficacy Data from Prula-cel (formerly ADI-001) Study in Patients with Systemic Lupus Erythematosus with or without Lupus Nephritis

- Prula-cel shown to be generally well tolerated with no CRS greater than Grade 2 and no IEC-HS or ICANS -

-At 12-months, 54% of evaluable patients achieved DORIS remission and 50% of patients achieved CRR-

-All patients discontinued immunosuppressants –

- All but one patient tapered background steroids to ≤ 5 mg prednisone equivalent per day-

-Rapid reductions in SLEDAI-2K and PGA scores, consistent with autologous alpha beta CAR-T cell therapies-

-Plan to initiate pivotal lupus nephritis trial start-up activities in 4Q/2026; high DORIS remission rate may support expansion of pivotal study to include lupus without nephritis based on regulatory precedent-

-Company to host investor webcast at 8:00am ET today-

REDWOOD CITY, Calif. – September 28, 2026 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical-stage biotechnology company discovering and developing allogeneic gamma delta CAR-T cell and *in vivo* CAR-T therapies for autoimmune diseases, hematologic malignancies and solid tumors, today announced safety and efficacy data from the Phase 1 study evaluating prulacabtagene leucel (prula-cel) as a potential treatment for patients with systemic lupus erythematosus (SLE) with or without lupus nephritis (LN). The data cut as of August 28, 2026 includes 22 efficacy evaluable patients (16 LN patients and 6 extra-renal SLE patients). All patients have follow-up of at least 6 months, and 13 patients have at least 12 months of follow-up. Based on these findings, the Company plans to initiate start-up activities for a pivotal study in LN in the fourth quarter of 2026. Given the high Definition of Remission in Systemic lupus (DORIS) remission rate observed in the study, the pivotal study may expand to include lupus patients without nephritis.

"We are excited to report clinical data for prula-cel reinforcing its potential to deliver meaningful, lasting remission after a single treatment for patients with SLE, including those with lupus nephritis," said Lloyd Klickstein, M.D., Ph.D., Interim Chief Medical Officer and a Member of the Board of Directors. "We observed complete renal responses and DORIS remissions after a single dose of prula-cel in patients who had failed multiple prior therapies. Notably, these remissions were achieved off immunosuppression and were accompanied by biological evidence of an immune reset. In a disease where chronic therapy with limited efficacy and significant tolerability and safety considerations remains the standard of care, the prospect of durable, treatment-free remission after a single treatment could be transformative for individuals living with lupus."

"Today's results mark an exciting step forward for Adicet and for lupus patients with or without nephritis. The data suggests prula-cel has the potential to offer lupus patients a highly differentiated treatment option: a single dose, off-the-shelf therapy, with a favorable safety profile, that may lead to immunosuppressant free remission," said Chen Schor, President and Chief Executive Officer of Adicet Bio "Importantly, the compelling efficacy data observed to date has been accompanied by a generally favorable safety profile with no cases of IEC-HS, no ICANS and no CRS beyond Grade 2 reported in the study. Combined with the FDA's support of outpatient administration of prula-cel, and the scalability of our off-the-shelf manufacturing, these findings support the potential of prula-cel to redefine the treatment expectations for patients living with systemic lupus erythematosus with or without lupus nephritis. We look forward to progressing towards a potentially pivotal study by the end of 2026."

Data highlights as of August 28, 2026, cut-off date were as follows:

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 - **Efficacy endpoints.** Prula-cel treatment yielded high rates of immunosuppressant-free responses in a heavily pretreated population. Patients had a mean baseline of Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) of 13 and those with LN had mean urine protein-to-creatinine ratio (UPCR) of 2.8, and all had received at least three prior therapies (71% received four or more). At the 12-month mark, 50% of evaluable lupus nephritis patients achieved a complete renal response (CRR) and 54% of evaluable patients achieved DORIS remission. All 12-month responses were ongoing at 12 to 21 months of follow-up, except 1 patient with UPCR 0.65 g/g who remains off immunosuppressants. Reductions in mean SLEDAI-2K and Physician's Global Assessment (PGA) were rapid and sustained, consistent with autologous alpha beta CD19 CAR-T therapies, and 85% of patients with 12-month follow-up achieved a PGA score below 0.5.
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For more information about the Phase 1 study, please visit: [Study Details | NCT06375993 | A Phase 1 Study of Prulacabtagene Leucel \(Prula-cel, Formerly ADI-001\) in Autoimmune Disease | ClinicalTrials.gov](#)

Webcast/Conference Call Information Adicet will host a webcast presentation on Monday, September 28, 2026 at 8:00am ET. The live webcast of the presentation can be accessed by registering via this [link](#) or under “Presentations & Events” in the investors section of the Company’s website at <https://www.adicetbio.com>. An archived replay will be available for 30 days following the presentation. The archived webcast will be available on the Company’s website beginning approximately two hours after the event.

About Prulacabtagene leucel (prula-cel)

Prula-cel is an investigational allogeneic gamma delta chimeric antigen receptor (CAR) T cell therapy targeting B-cells via an anti-CD20 CAR. ADI-001 was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of relapsed/refractory class III or class IV lupus nephritis (LN), refractory systemic lupus erythematosus (SLE) with extrarenal involvement and systemic sclerosis (SSc).

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical-stage biotechnology company discovering and developing a broad pipeline of allogeneic gamma delta T cell therapies, engineered with chimeric antigen receptors (CARs), alongside differentiated *in vivo* CAR-T therapies with the potential to redefine treatment across autoimmune diseases, hematologic malignancies and solid tumors. For more information, please visit our website at <https://www.adicetbio.com>.

Forward-Looking Statements

This press release contains “forward-looking statements” of Adicet within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the business and operations of Adicet. The words “anticipate,” “believe,” “continue,” “could,” “estimate,”

“expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: clinical development of Adicet’s product candidates, including future plans or expectations for prula-cel in autoimmune diseases and the potential safety, tolerability and efficacy for the treatment of autoimmune diseases and cancer as well as expectations to achieve a complete immune reset; expectations regarding future alignment with the FDA on regulatory path to approval and discussions to date; timing and success of the Phase 1 clinical trial of prula-cel in multiple autoimmune indications, including timing and expectations for enrollment and future data releases; expectations regarding the timing and initiation of a pivotal study for prula-cel in SLE patients with or without LN and potential expansion to include non-renal lupus; expectations regarding prula-cel’s potential to transform treatment for patients with lupus; expectations regarding the suitability of prula-cel for outpatient administration; expectations regarding the scalability of the Company’s off-the-shelf manufacturing platform; expectations regarding the pace of enrollment in the pivotal study for prula-cel in SLE patients with or without LN; and estimates for the addressable patient population and commercial opportunity for prula-cel in LN and SLE.

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release is as of the date of the release, and Adicet undertakes no duty to update this information unless required by law.

Adicet Bio, Inc.

Investor and Media Contacts

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Prula-cel Clinical Data Update

September 28, 2026

Adicet Bio

Forward-Looking Statements

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Industry and Market Information

Information regarding market share, market position and industry data pertaining to Adicet’s business contained in this presentation consists of estimates based on data and reports compiled by industry professional organizations and analysts and Adicet’s knowledge of their industry. Although Adicet believes the industry and market data to be reliable, this information could prove to be inaccurate. You should carefully consider the inherent risks and uncertainties associated with the market and other industry data contained in this presentation. Forward-looking information obtained from third-party sources is subject to the same qualifications and the additional uncertainties as the other forward-looking statements in this presentation.

Prula-cel Delivered High Rates of Immunosuppression-Free CRRs and DORIS Remissions in Heavily Pre-Treated LN & SLE Patients

50%

12-Month CRR Rate

54%

12-Month DORIS Rate



Favorable Safety Profile

Generally well-tolerated — No IEC-HS,
No ICANS and No > Grade 2 CRS observed



Immunosuppressant-Free

All patients discontinued immunosuppressants



Steroid Taper Achieved

All but one patient tapered background steroids
to ≤5 mg prednisone equivalent



Demonstrated Immune Reset

Complete CD19+ B cell depletion followed by
naïve B cells recovery

Prula-cel Has Established Path to Potential Approval and Large Commercial Opportunity

Pivotal Readiness



Established Pivotal Trial Design

- Aligned with FDA on single arm pivotal study in LN
- Potential to expand pivotal to include non-renal lupus based on regulatory precedent



Strong Enrollment Execution

- Significant interest from investigators and patients to enroll

Compelling Commercial Opportunity



Potential One-Time, Off-the-Shelf, Outpatient Therapy

- Aligned with FDA to make prula-cel available for enrollment in outpatient setting
- Scalable Manufacturing



Significant Addressable Market

- 35,000 organ/life threatening LN¹ (US)
- 35,000 organ/life threatening non-renal SLE² (US)

Anticipated Near-Term Value-Creating Milestones

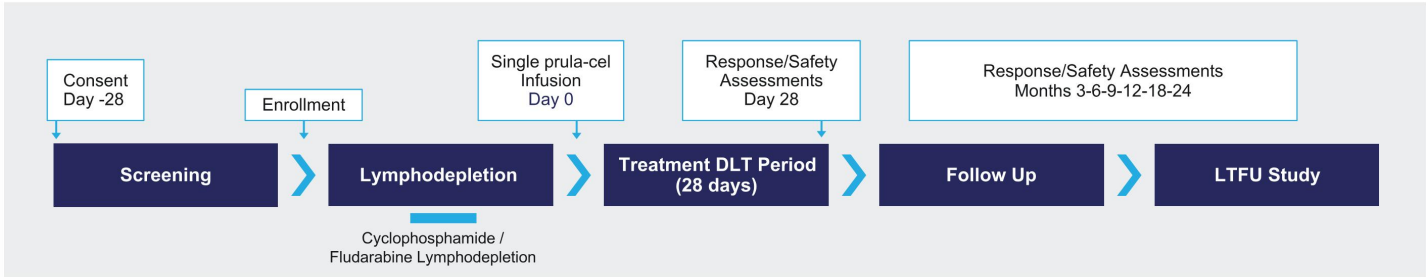
Clinical, regulatory and platform catalysts expected across prula-cel, ADI-212 and in vivo CAR-T programs

	2026	2027	2028	2029
Prula-cel Autoimmune disease LN / SLE / SSc	LN/SLE clinical update LN/SLE Pivotal start-up activities Potential SLE expansion*	SSc clinical update* LN/SLE clinical update*	LN/SLE Interim pivotal data*	LN/SLE Potential pivotal data*
	Progression toward registrational pathway →			
ADI-212 mCRPC	IND Clearance mCRPC Enrollment	mCRPC Clinical update*	mCRPC Clinical update*	
In Vivo CAR-T MM Program	Platform/program update	MM Initiate clinical study*	MM Clinical Update*	
In Vivo CAR-T NHL Program	Platform/program update		Potential clinical data*	
In Vivo CAR-T Solid Tumors Program	Platform/program update		Potential clinical data*	

5 *Achievement and timing of forward-looking milestones subject to clinical progress, regulatory outcomes, financing ability and other business considerations



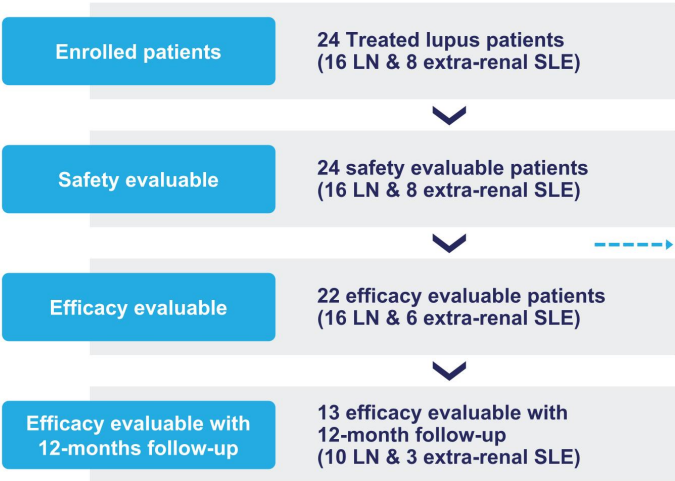
Prula-cel Phase 1 Autoimmune Study Design



Prula-cel SLE/LN Patient Characteristics

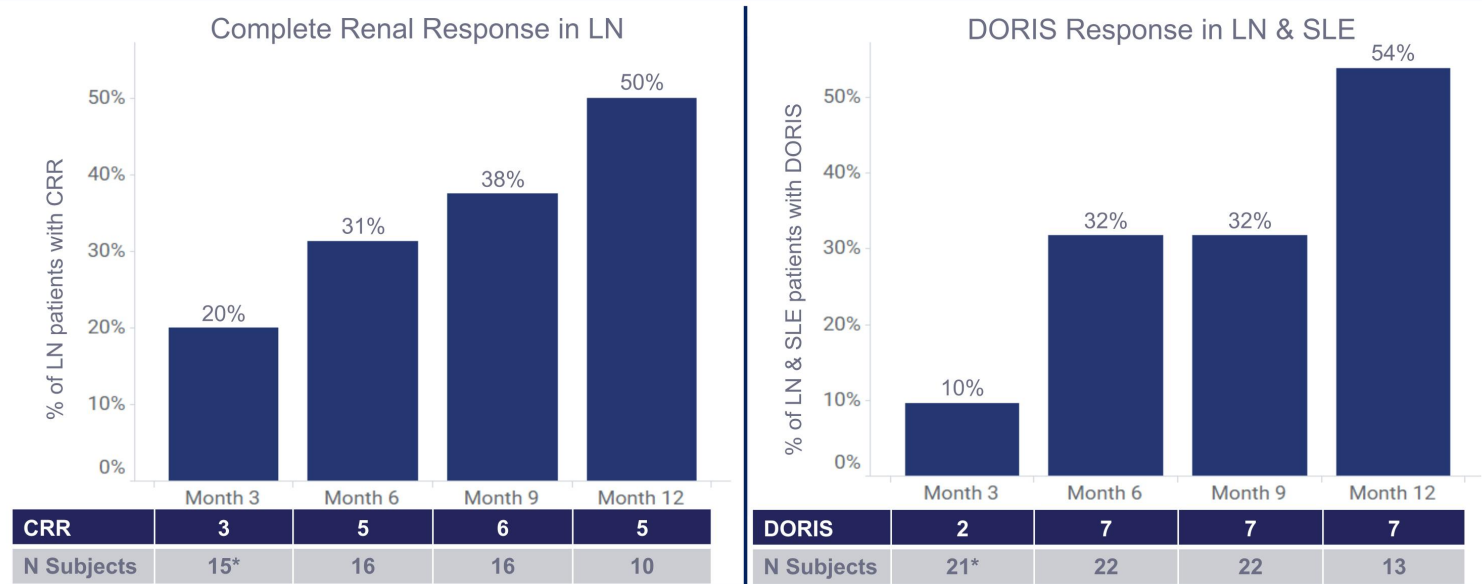
Patient Characteristics

Demographics	
Age (mean yrs)	34.8
Female (%)	87.5%
Duration Since SLE Diagnosis (mean yrs)	7.2
Disease Activity	Mean
Baseline SLEDAI ¹	13
Baseline UPCR ²	2.8
Number of Prior Therapies	N (%)
2 or more	24 (100%)
3 or more	24 (100%)
4 or more	17 (71%)



* One patient with Inclusion Body Myositis (excluded per protocol)
One patient with hypersensitivity reaction was not provided the prula-cel dose

High Rates of Both Complete Renal Response & DORIS Remissions Achieved By 12 Months Post Treatment With Prula-cel



All 12-mo CRRs and DORIS remissions ongoing (12-21 mo. follow up), except 1 pt with UPCr 0.65 g/g off immunosuppressants

8

CRR = UPCr ≤ 0.5 AND EITHER eGFR ≥ 60 mL/min/1.73m² OR no confirmed decrease from baseline in eGFR of $>15\%$ and no treatment or disease related eGFR-associated event; *One subject's M3 UPCr was not evaluable; Cut-off date: August 28, 2026; Data cut included 22 efficacy-evaluable patients

DORIS Remission= Clinical SLEDAI (irrespective of serology) = 0 AND Physician global assessment score < 0.5 ; the subject may be on antimalarials, low-dose glucocorticoids (prednisolone ≤ 5 mg/day), and/or stable immunosuppressives including biologics; An additional 20% of the LN patients had at least a 50% decrease in proteinuria from their baseline levels at mo. 12, which is defined as partial renal response per protocol.

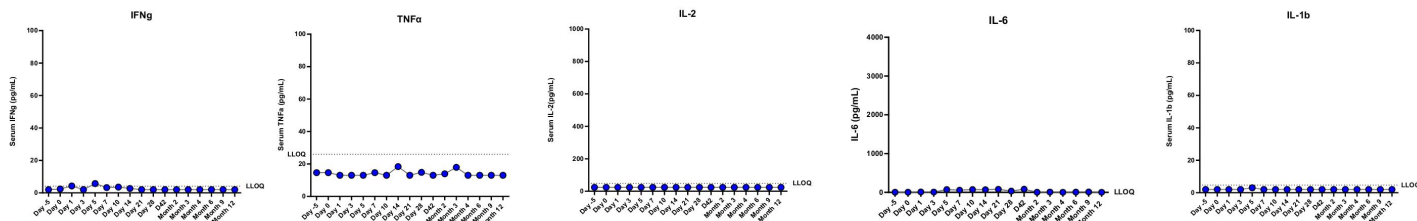
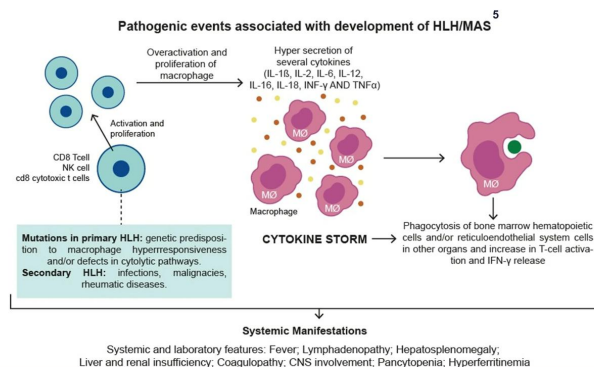
Generally Well-Tolerated Safety Profile: No DLT Observed, No IEC-HS, No ICANS, No Gr >2 CRS

Adverse events of interest	Prulacabtagene leucel (prula-cel) <i>LN/SLE, all dose levels</i>	Rapcabtagene autoleucel (rap-cel) ¹	Zolacabtagene autoleucel (zola-cel) ²	Obecabtagene autoleucel (obe-cel) ³
No. of Patients (n)	24	21	26	6
CRS (any / Gr 3+) (%)	25% / —	57% / --	77% / 4%	50% / --
ICANS (any Gr) (%)	--	5%	4%	--
Infections (any / Gr3+) (%)	13 (54%) / 2 (8.3%)	71% / 10%	15% any grade (Gr3+ rate not disclosed)	100% / 33%

- Favorable safety profile with No IEC-HS, No ICANS and No Gr >2 CRS consistent across all autoimmune indications (48 patients dosed to date)
- Per alignment with FDA, prula-cel may be administered to SLE and LN patients in the outpatient setting
- γδ CAR-T are generally well tolerated compared to αβ CAR-T, likely due to different cytokine profile secreted upon activation as compared αβ CAR-T

Prula-cel's Favorable Safety Profile in Autoimmune Compared to a Autologous $\alpha\beta$ CAR-T is Rooted in the Biology of $\gamma\delta 1$ T Cells

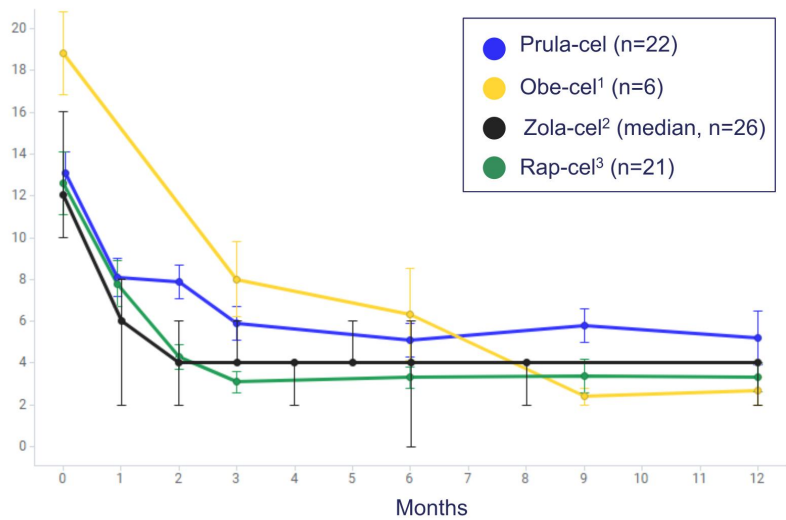
- $\gamma\delta 1$ T cells are defined by a clearly differentiated cytokine profile compared to $\alpha\beta$ T cells¹⁻⁴
- IEC-HS is primarily related to hyperproliferation of $\alpha\beta$ CAR-T and associated with secretion of $\text{IFN}\gamma$, $\text{TNF}\alpha$, IL-2, IL6, and IL18⁵
- Prula-cel did not lead to meaningful increase in these systemic markers in SLE/ LN patients



1. Nishimoto, K.P. et al. (2020). Allogeneic CD20-targeted γ T cell bispecific innate and adaptive antitumor activities in preclinical B-cell malignancy models. *Clin Transl Immunol* 9, 1: e1373.
2. Nishimoto KP et al. ADI-207: an armored allogeneic gamma delta T cell therapy designed to target CD20+ expressing solid and hematologic malignancies in combination with immune checkpoint inhibitors. *Journal of Cancer Therapy and Cancer Research* 2020; 13:1601-1704.
3. Herman, M, Altsh, B, et al. presented at: Prostate Cancer Foundation Scientific Retreat: September 2026.
4. Perez XB, CAR Signaling Informs Mechanisms to Enhance Metabolism and Function in γ T Cells. *Res Sq [Preprint]* 2026.
5. Sztajnberg, F. et al. Hemophagocytic lymphosyndrome and macrophage activation syndrome: two rare sides of the same devastating coin. *Adv Rheumatol* 64, 28 (2024).
6. Carfagna, C et al. Safety evaluation of CAR-T cells in patients with relapsed and refractory diffuse large B-cell lymphoma: 22 efficacy-evaluable and 24 safety-evaluable patients. *Onco Targets Ther* 2026; 19: 1-12. <https://doi.org/10.2147/ott.s428222>
7. Carfagna, C et al. Safety evaluation of CAR-T cells in patients with relapsed and refractory diffuse large B-cell lymphoma: 22 efficacy-evaluable and 24 safety-evaluable patients. *Onco Targets Ther* 2026; 19: 1-12. <https://doi.org/10.2147/ott.s428222>

SLEDAI Decline With Prula-cel In-Line With That Observed With Autologous $\alpha\beta$ CD19 CAR-T Therapies

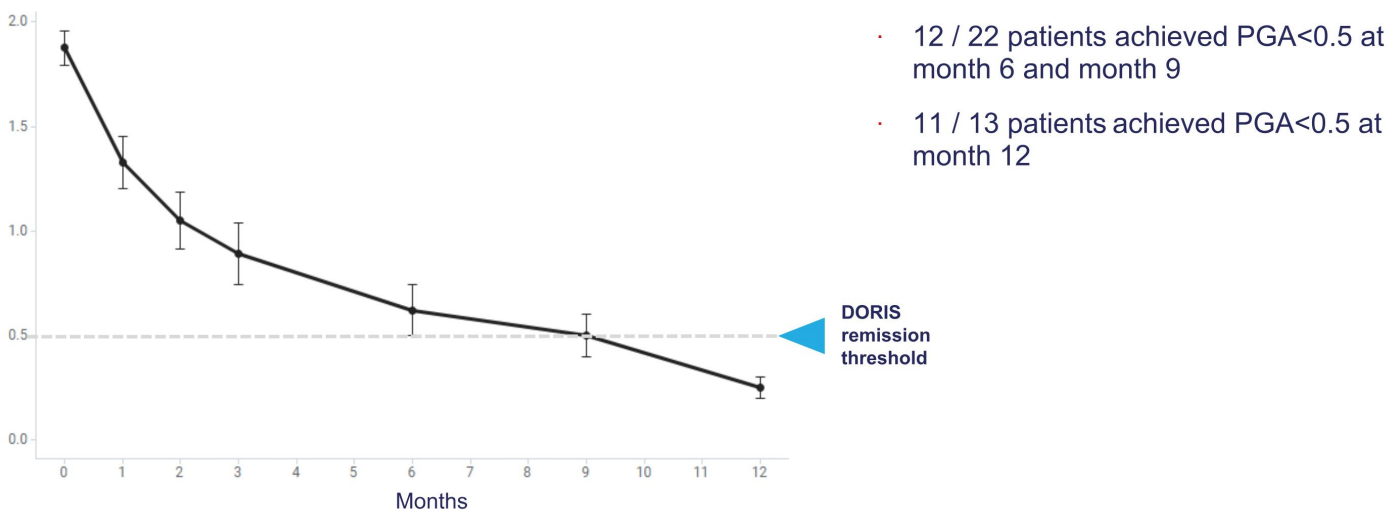
SLEDAI-2K over time (mean)



- Rapid and substantial decline in SLEDAI scores consistent with autologous CAR-T therapies
- Reductions in SLEDAI stable beyond 12 months

85% of Evaluable Patients with 12-Month Follow-Up Achieved PGA score of <0.5

Physician Global Assessment over time (mean)



Patients Discontinued Immunosuppressants and Tapered Steroids to ≤ 5 mg Prednisone Equivalent

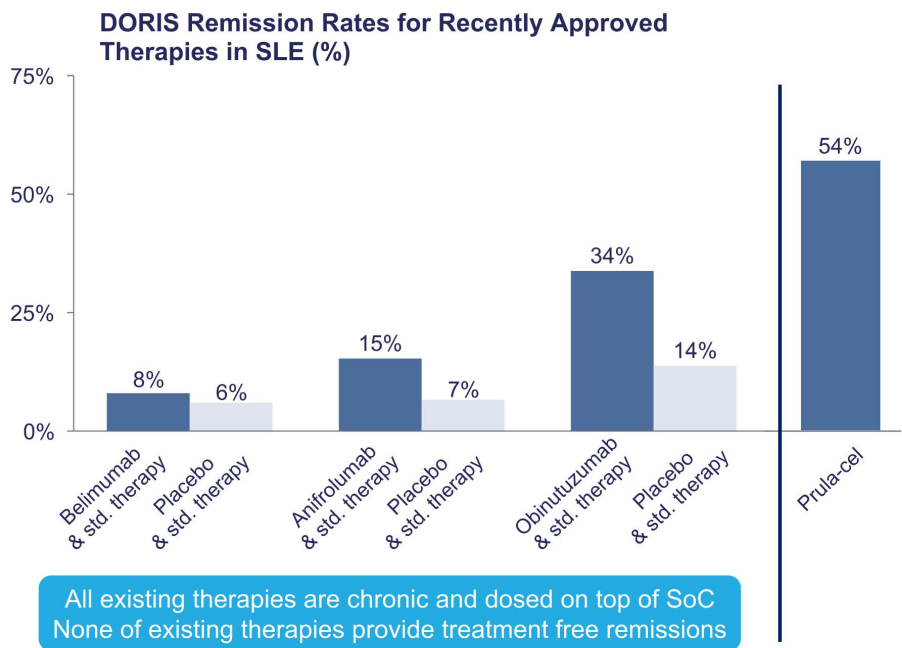
Immunosuppressants

All patients discontinued immunosuppressants

Steroids

Background steroids tapered to ≤ 5 mg prednisone in all patients but one

Recently Approved Therapies for SLE Are Delivered On Top of Standard Therapy & Have Not Shown High DORIS Remission Rates



Anticipated Pivotal Design

Single-arm study in LN per alignment with FDA

- Double-digit number of patients
- Key inclusion criteria
 - ☐ Participants must meet EULAR/ACR 2019 criteria for SLE
 - ☐ Biopsy-proven proliferative Class III or IV LN, with or without concomitant Class V involvement
 - ☐ Inadequate clinical response to at least two immunosuppressants
- Endpoint for LN Patients:
 - ☐ Complete renal response (LN) @ 12 months

Next steps

- Potential to expand study to include SLE
 - ☐ Consistent with regulatory precedent
 - ☐ Expected study size: Up to 90 patients
- Endpoint for SLE: DORIS remission
- Pivotal study start up activities in Q4; interim data anticipated 2028; pivotal readout in 2029

Major Unmet Needs in LN/SLE Remain

Limited disease control with existing therapies

- **Treatment-free remissions are rare**
- **Flares are common** despite chronic therapy, reflecting ongoing disease activity
- **Increased early mortality** due to organ damage, cardiovascular disease, infections, renal disease and other causes

Significant side effects associated with chronic therapies

- **Current chronic therapy with high dose corticosteroids and immunosuppressants associated with serious side effects** - infections, bone fractures and diabetes
- Disease and chronic therapies **negatively impact patients' QoL** - fatigue, emotional problems, rash, pain and ability to work



Need for one-time therapy with favorable safety profile that can deliver treatment-free remissions

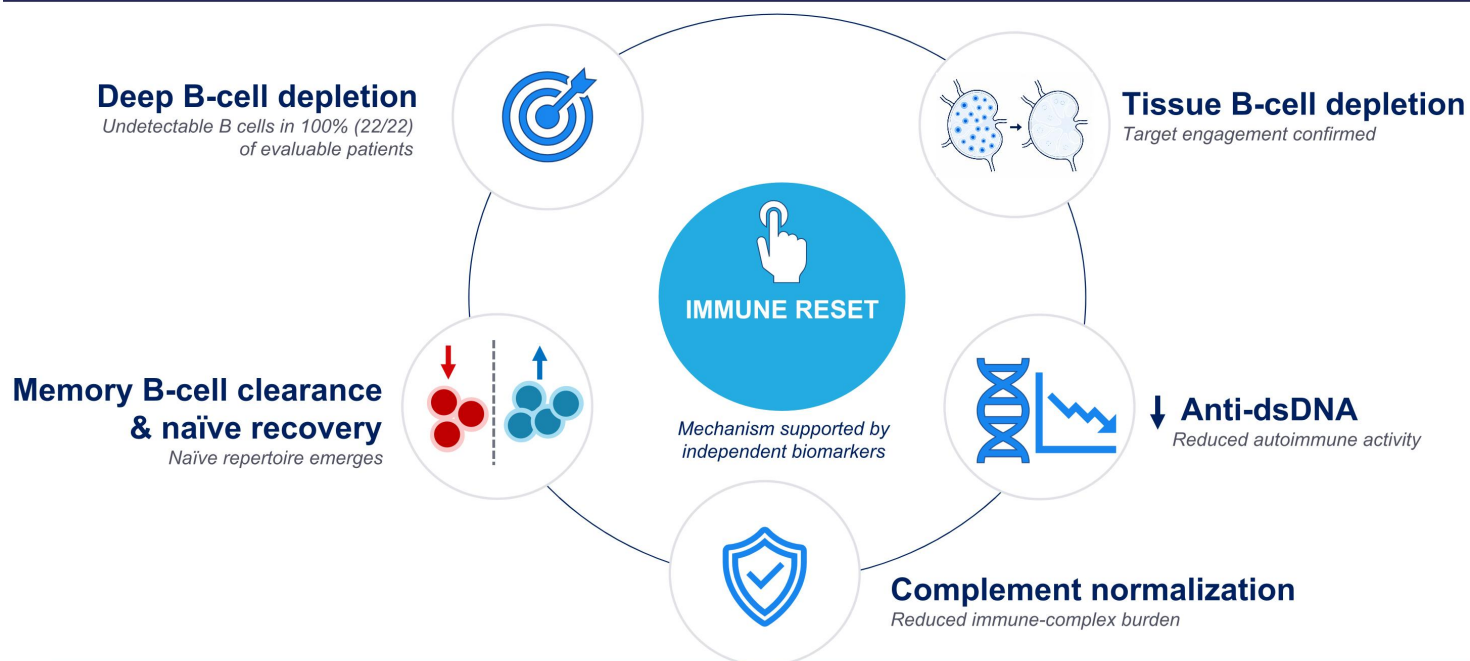
Prula-cel: Potential to Transform the SLE and LN Patient Journey

Potential for Strong Adoption

- ✓ One time treatment approach
- ✓ Off-the-shelf
- ✓ Favorable safety profile
- ✓ Potential for outpatient therapy and accessibility in non-academic medical centers
- ✓ Potential for durable immunosuppressant-free clinical benefit
- ✓ Reduced steroid burden

Potentially shifting treatment paradigm to “treat once and monitor patient”

Multiple Independent Biomarkers Support Immune Reset



Deep B-cell Depletion with Naïve Recovery

KEY TAKEAWAY



Deep B-cell depletion



Naïve dominant Recovery ~1-3 months



Kinetics aligned with leading CAR-T data



Immune reset

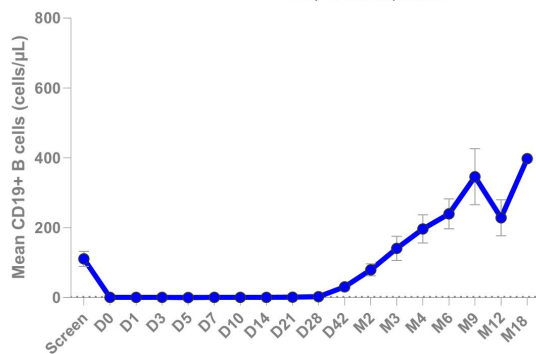


100%
(22/22)
evaluable patients

Achieved Undetectable CD19+ B cells

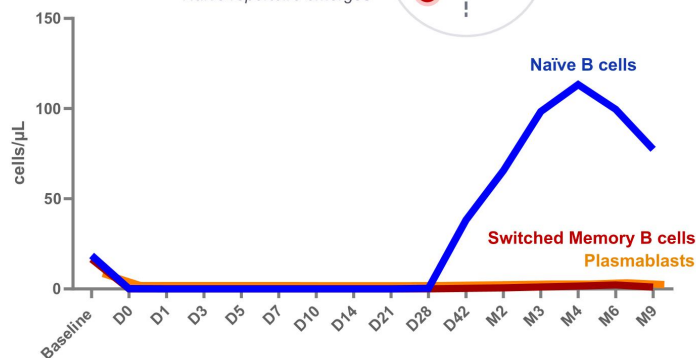
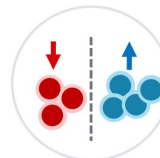
CD19+ B cell Depletion

Deep B cell depletion



Memory B-cell clearance & naïve recovery

Naïve repertoire emerges



CD19+ B-cell counts are presented as mean $\pm$ SEM. Naïve B-cell, switched memory B-cell, and plasmablast data are presented as median values at each study visit. B cells are considered undetectable when below the assay lower limit of detection (LLD; <2 cells/ μ L). D = day; M = month. CD19+ B cells = CD3+CD19+CD16/CD56; naïve B cells = CD19+CD20+IgD+CD27-; switched memory B cells = CD19+CD20+IgD-CD27+; plasmablasts = CD19+CD20+IgD-CD27+CD38+CD138-.

Prula-cel Achieved Deep CD19+ B-cell Depletion in Tissues

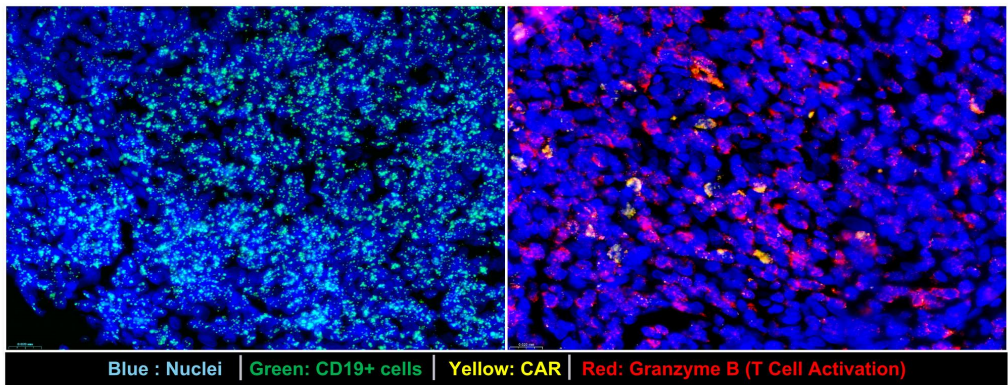


POC: *Prula-cel rapidly depleted CD19+ B cells within secondary lymphoid tissue*

MCL PATIENT LYMPH NODE BIOPSIES

Baseline

Day 10 Post Dose



Robust tissue infiltration by prula-cel and complete depletion of CD19+ B cells
observed at day 10 within secondary lymphoid tissue

Reduction in Anti-dsDNA Titers and Immune Complex Burden Supports an Emerging Immune Reset

Key Findings

91% (10/11)

of evaluable baseline anti-dsDNA-positive patients demonstrated **reductions in anti-dsDNA titers**

90% (9/10)

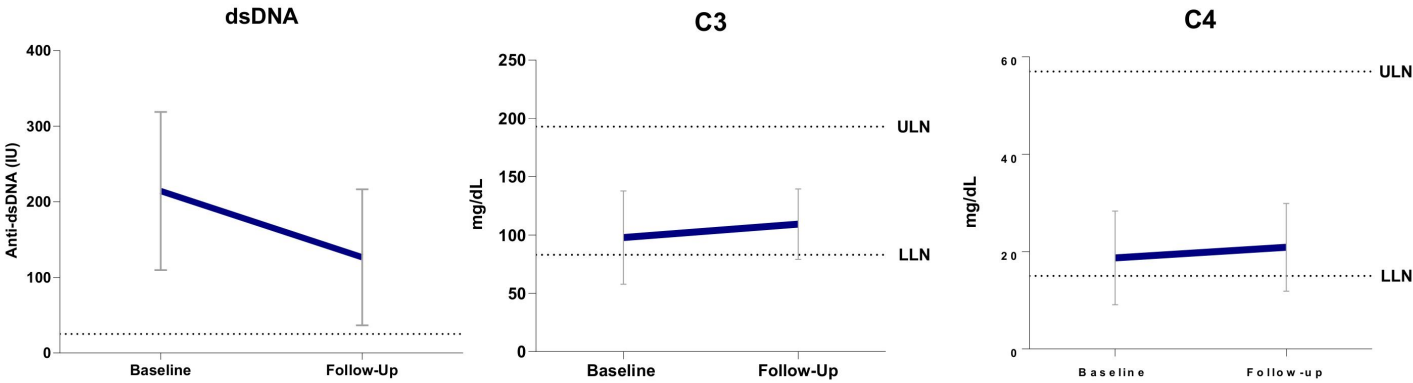
of patients with low baseline C3 and/or C4 demonstrated **complement recovery** (normalized or increased levels)

70% (7/10)

achieved **normalization** of at least one complement parameter



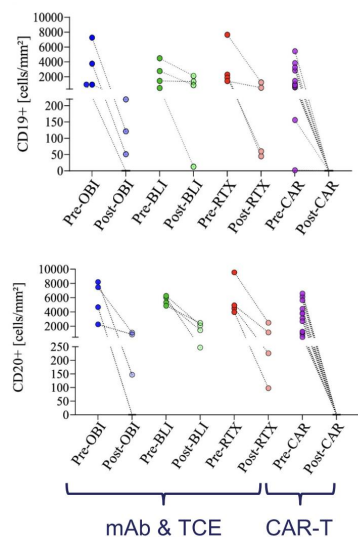
Findings are consistent with **reduced immune-complex burden** and support an emerging **immune reset mechanism**.



Prula-cel: Designed for Broad Adoption and Scalable Commercialization

	Autoimmune CAR-T	
	AUTOLOGOUS CAR-T <i>Current paradigm</i>	Prula-cel <i>Allogeneic / bank-ready γδ1 CAR-T</i>
Treatment Workflow	✗ Physician withdraws immunosuppression, schedules leukapheresis weeks later; product manufactured per patient	✓ Readily available product — no leukapheresis or personalized manufacturing
Time to Treatment	✗ Several weeks vein-to-vein time for individual manufacturing and frequent need for bridging therapy	✓ Immediate dosing from cryopreserved inventory
Safety Profile	✗ Meaningful IEC-HS, ICANS and CRS risk requiring intensive monitoring	✓ No IEC-HS, No ICANS and No Gr>2 CRS
Site-of-Care Access	✗ Higher safety burden generally restricts use to specialized centers	✓ Well suited to community rheumatology and infusion settings
Manufacturing Cost & Scale	✗ Custom batch per patient drives high COGS & impedes scalability for prevalent autoimmune diseases	✓ Centralized batch production intended to lower cost & improve scalability

Incomplete B-Cell Depletion With Protein-based Approaches (mAbs & TCEs) Associated With Less Robust Clinical Responses in Patients With Autoimmune Diseases



	mAb & TCE				CAR-T							
	OBI 1	OBI 2	OBI 3	OBI 4	BLI 1	BLI 2	BLI 3	BLI 4	RTX 1	RTX 2	RTX 3	RTX 4
LN Clearance	SLE	IIM	SLE	SLE	RA	RA	RA	RA	RA	RA	IIM	IIM
Clinical response												
Remission												
Drug-Free State												
	CAR 1				CAR 2				CAR 3			
	SLE	SSc	SLE	SSc	SLE	SSc	SLE	SSc	SLE	SSc	SLE	SSc
LN Clearance												
Clinical response												
Remission		n.a.		n.a.				n.a.	n.a.	n.a.		n.a.
Drug-Free State												

Patients treated with mAbs and TCEs do not consistently achieve remissions and drug-free states in contrast to patients treated with CAR-T

Incomplete B-cell depletion in lymph nodes with mAbs and TCE approaches in contrast to complete depletion in all CAR-T treated patient samples

Prula-cel Potential Competitive Positioning in Lupus With and Without Nephritis

Autologous CAR-T

- Proven immunosuppressant free DORIS/CRR
- Safety Challenges: IEC-HS, ICANS, CRS
- Require leukapheresis & personalized manufacturing

Bi-Specifics

- Have not demonstrated efficacy comparable to autologous CAR-T
- Likely require semi-chronic dosing (immune dimming)
- Chronic immunosuppression may lead to high infection rate

Prula-cel Target Product Profile

- One time, off-the-shelf therapy, available in outpatient setting
- Delivers immunosuppressant free remissions & steroids tapered to ≤ 5 mg prednisone equivalent comparable to autologous CAR-T
- Favorable safety profile: No IEC-HS, No ICANS, No CRS $> \text{Gr}2$
- Does not require leukapheresis or personalized manufacturing
- Delivers immune-reset with no permanent gene therapy

mRNA in vivo CAR-T

- Deliver transient expression CAR-T in patients
- Have not demonstrated complete B cell depletion & immune reset in patients
- Have not demonstrated efficacy comparable to autologous CAR-T

Lentivirus based in vivo CAR-T

- Deliver gene therapy to stay "forever" with unknown risk (e.g. insertional mutagenesis)
- May experience similar safety challenges to autologous CAR-T
- Have not demonstrated efficacy comparable to autologous CAR-T

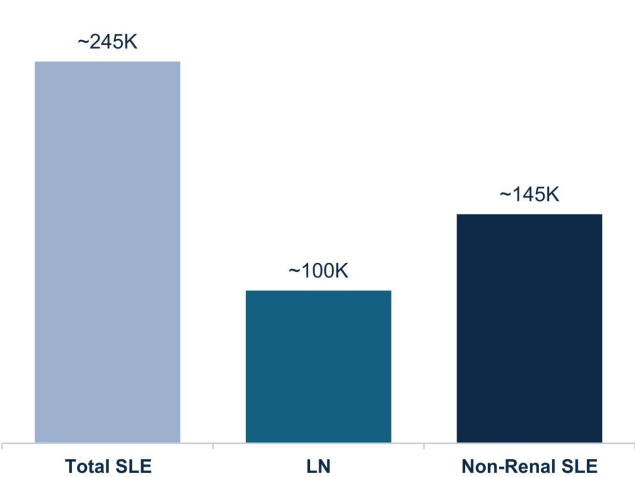
Modality Comparison

	Potency / durability	Potential for IS-free remissions	Safety	Logistics	Scalability
Prula-cel target product profile	 Efficacy in-line with auto CAR-T	 Phase I data supports	 Favorable safety profile	 No leukapheresis & available out-patient	 Low cost of manufacturing as off-the-shelf
Autologous αβ CAR-T	 High remission rates with evidence of durability	 Phase I data supports	 Noted IEC-HS, ICANS & CRS risk	 Leukapheresis required	 N=1 manufacturing
T-cell engaging antibodies	 Preliminary efficacy not in-line with auto CAR-T	 May require chronic dosing, 'immune-dimming' approach	 Safety of chronic dosing unclear	 Dosing schedules remain to be worked out	 Highly scalable
mRNA/LNP-based <i>in vivo</i> CAR-T	 Transient CAR-exposure and B-cell depletion limited	 Incomplete B-cell depletion	 Early favorable safety data	 Dosing schedules remain to be worked out	 Highly scalable
Viral-based <i>in vivo</i> CAR-T	TBD	TBD	 Gene therapy Insertional mutagenesis risk & similar safety risks to auto CAR-T	 Potentially single dose without LD	 Highly scalable

Commercial Potential

~70K-Patient Organ-Threatening SLE Opportunity in the US

US Prevalence of SLE & Non-Renal SLE (thousands of patients)



Lupus Nephritis (LN)

~100K prevalent patients in the US

Roughly 25–45% of LN patients fail to achieve remission after 24 months of SoC treatment

→ ~35K addressable organ/life-threatening LN patients



Non-Renal SLE

145K prevalent patients in the US

An estimated 25% of non-renal SLE patients have organ/life-threatening disease on current SoC (Adicet estimate; analyst reports)

→ ~35K addressable organ/life-threatening non-renal SLE patients

70K patients in the US alone have organ/life-threatening SLE, with or without nephritis

Helmick CG et al. Arthritis & Rheumatism (2007) | Morales E et al. Nephron (2021)

Developing Broad Pipeline of Allogeneic $\gamma\delta 1$ CAR-T Cell and Best In Class Differentiated In Vivo CAR-T Therapies

Off-The-Shelf $\gamma\delta 1$ CAR-T					
Program	Indication	Research	IND-Enabling	Clinical	Potential Key Differentiation
Prula-cel Target: CD20	LN/SLE				- Off-the-shelf, outpatient dosing — no leukapheresis or personalized manufacturing - Quick, easy administration - Favorable safety profile; reduced IEC-HS, ICANS, CRS risk - Efficacy comparable to autologous CAR-T
	SSc				
ADI-212 Target: PSMA (gene-edited w/ armor)	mCRPC				- Validated target (PSMA) - Armoring enhances tumor-cell killing - Improved anti-tumor activity in the tumor microenvironment

In Vivo CAR-T – Cell-specific delivery via novel homing and VSV-G fusogen technology					
Program	Indication	Research	IND-Enabling	Clinical	Potential Key Differentiation
Multiple Myeloma Target: BCMA Mono / Dual CAR	MM	PRE-CLINICAL			- Differentiated CAR design with effective BCMA targeting - Decreased susceptibility to immune-mediated inactivation and clearance
NHL Target: CD19 Dual CAR	NHL	PRE-CLINICAL			Differentiated dual-CAR design
Solid Tumors Target: Not disclosed	NA	PRE-CLINICAL			Multiple armoring technologies designed to enhance efficacy in solid tumors

Anticipated Near-Term Value-Creating Milestones

Clinical, regulatory and platform catalysts expected across prula-cel, ADI-212 and in vivo CAR-T programs

	2026	2027	2028	2029
Prula-cel Autoimmune disease LN / SLE / SSc	LN/SLE clinical update LN/SLE Pivotal start-up activities Potential SLE expansion*	SSc clinical update* LN/SLE clinical update*	LN/SLE Interim pivotal data*	LN/SLE Potential pivotal data*
	Progression toward registrational pathway →			
ADI-212 mCRPC	IND Clearance mCRPC Enrollment	mCRPC Clinical update*	mCRPC Clinical update*	
In Vivo CAR-T MM Program	Platform/program update	MM Initiate clinical study*	MM Clinical Update*	
In Vivo CAR-T NHL Program	Platform/program update		Potential clinical data*	
In Vivo CAR-T Solid Tumors Program	Platform/program update		Potential clinical data*	

Prula-cel Delivered High Rates of Immunosuppression-Free CRRs and DORIS Remissions in Heavily Pre-Treated LN & SLE Patients

50%

12-Month CRR Rate

54%

12-Month DORIS Rate



Favorable Safety Profile

Generally well-tolerated — No IEC-HS,
No ICANS and No > Grade 2 CRS observed



Immunosuppressant-Free

All patients discontinued immunosuppressants



Steroid Taper Achieved

All but one patient tapered background steroids
to ≤5 mg prednisone equivalent



Demonstrated Immune Reset

Complete CD19+ B cell depletion followed by
naïve B cells recovery



Adicet Bio