CASI Pharmaceuticals

# Developing a Potential Best-in-Class, CD38-targeting mAb for Autoimmune Diseases and Organ Transplant Rejection

November 2025

# Disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act with respect to the outlook for expectations for future financial or business performance, strategies, expectations and goals. Forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Forward-looking statements speak only as of the date they are made, and no duty to update forward-looking statements is assumed. Actual results could differ materially from those currently anticipated due to a number of factors. Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition. Additional information about the factors and risks that could affect our business, financial condition and results of operations, are contained in our filings with the U.S. Securities and Exchange Commission, including, but not limited to, our Annual Reports on Form 20-F and our Quarterly Reports on Form 6-K, which are available at www.sec.gov.

# Investment Highlights

## CID-103: Targeting CD38 in Autoimmune Diseases and Organ Transplant Rejection

### Potential Best-in-Class Asset

- Fully human IgG1 anti-CD38 monoclonal antibody targeting a unique epitope
- Encouraging preclinical efficacy and clinical safety profile compared to other anti-CD38 mAb
- Patent protection thru mid-2038
- Progressing multiple technology platforms in development of a CID-103 subcutaneous injection ready for registration studies

### Clinical Catalysts

- Immune thrombocytopenic purpura (ITP)
  - Phase 1 study ongoing
  - Abstract accepted for presentation of Phase 1 results at ASH 2025
- Renal allograft antibody-mediated rejection (AMR)
  - Phase 1 study initiating in U.S.
    - First patient planned in Q1 2026
  - Proposed Phase 1/2 study in China
    - CTA submission planned
    - Feedback expected Q4 2025

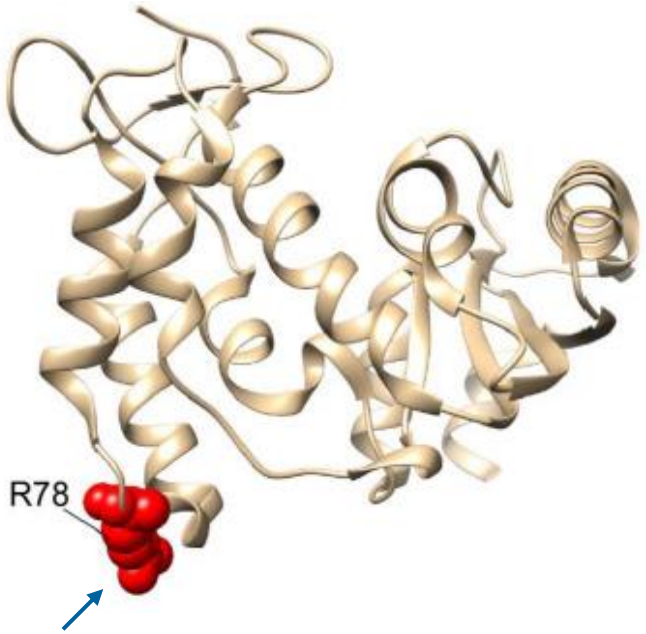
### U.S. Operating Plan

- U.S. HQ has been established in South San Francisco, California
- Focus on capitalization and executing CID-103 development
- U.S. operating team to oversee and execute global development
- Divestiture of CASI China business planned in Q2 2026

# CID-103 Recognizes a Unique Epitope on CD38

## Differentiated Profile

### CD38




CID-103 binds to unique binding epitope on CD38

- CID-103 binds to a unique epitope on CD38
- CID-103 selected for:
  - Increased ADCC (antibody-dependent cellular cytotoxicity)
  - Increased ADCP (antibody-dependent cellular phagocytosis)
  - Less CDC (complement-dependent cytotoxicity)
    - Potential to translate into less infusion-related reaction (IRR)
    - ~18% IRR, all low-grade AEs
- Strong IP through mid-2038 (before extensions)

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# Targeting CD38 in Diseases Driven by Pathological Antibodies

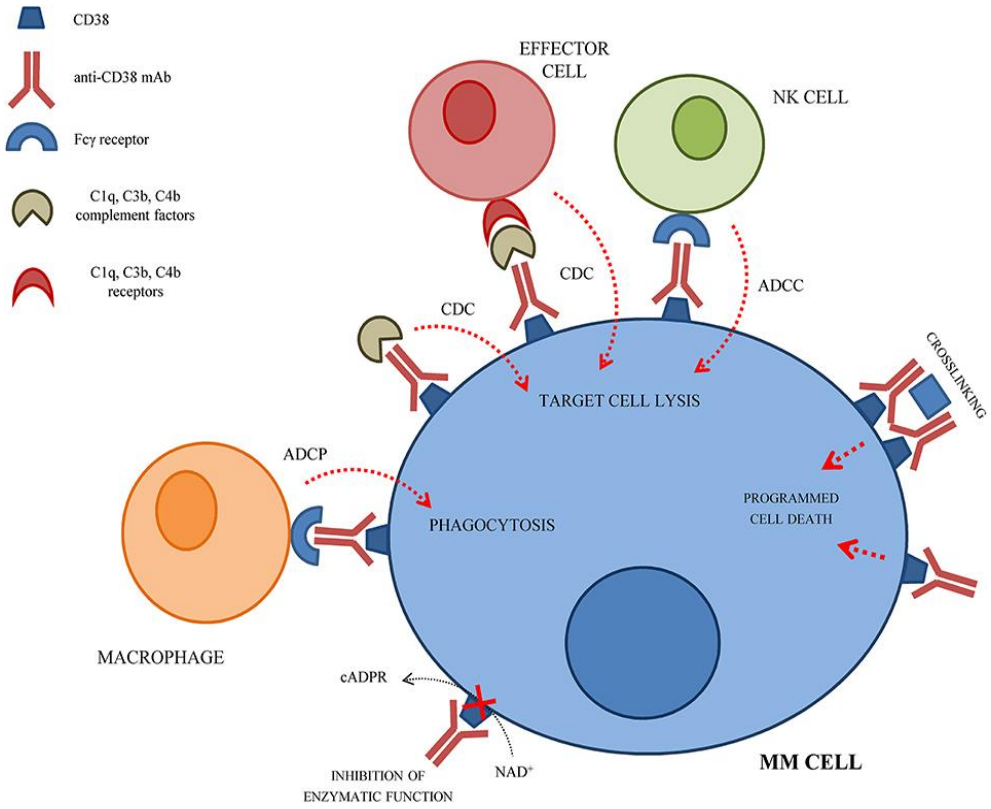
## Inducing Plasma Cell Death by Binding to CD38

### CD38 is Highly Expressed on Plasma and NK Cells

- Plasma cells are responsible for production of autoantibodies and donor-specific antibodies

### Mechanism of Action

- Selectively deplete CD38⁺ plasma cells to block production of donor-directed and pathologic autoantibodies
- Reduce number of NK cells which cause microvascular inflammation and damage

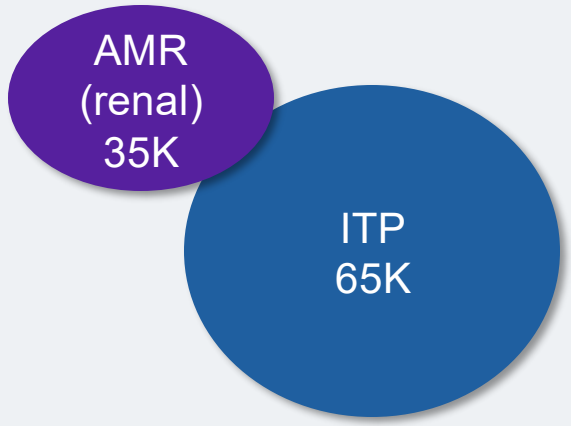



ADCP = antibody-dependent cellular phagocytosis; CDC = complement-dependent cytotoxicity;DCC = antibody dependent cell-mediated cytotoxicity.

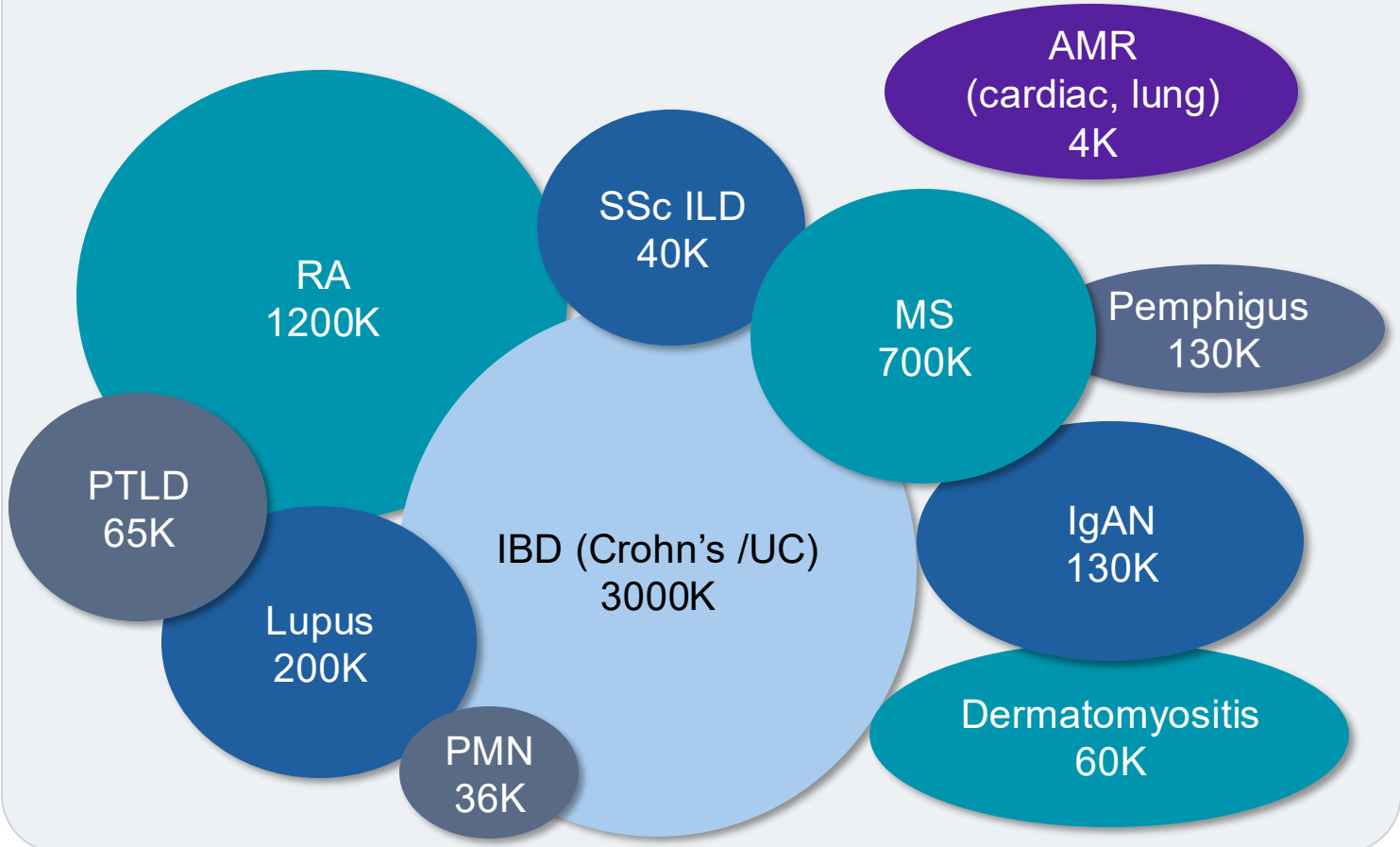
# CID-103: Franchise-in-a-Product

## Expansive Unmet Medical Needs in Future Potential Indications

### CID-103 In Development




### Future Potential Indications




U.S. patient prevalence

# Anti-CD38 Therapeutic Landscape

## CID-103 Positioned for Success

| Asset | Company | Route of Administration | Status |
|---|---|---|---|
| Darzalex (daratumumab) | J&J | IV and SQ | Approved in 2015 (U.S.) for MM<br>Annual sales in 2024 nearly $12B |
| Sarclisa (isatuximab-irfc) | Sanofi | IV | Approved in 2020 (U.S.) for MM<br>Annual sales in 2024 > $300M |
| Felzartamab | Biogen | IV | Biogen acquired HI-Bio for $1.8B<br>Phase 3 in AMR initiated |
| Mezagitamab | Takeda | IV and SQ | Phase 3 in ITP initiated |
| **CID-103** | CASI | **IV** | **Phase 1 data in ITP to be presented at ASH 2025**<br>**Phase 1 in AMR first patient planned Q1 2026**<br>**SQ formulation development in process** |

# CID-103 Development Plan

# Clinical Development Plan for CID-103

## Targeting Pathological Auto-Antibody Production

| Indication | Phase 1 | Phase 2 | Status & Upcoming Catalysts |
|---|---|---|---|
| **ITP**<br>Immune Thrombocytopenic Purpura | | | • Generating POC for CID-103<br>• Phase 1 enrolling and dosing at 900 mg dose cohort<br>• 67th ASH® Annual Meeting and Exposition DECEMBER 6-9, 2025 \| ORLANDO, FLORIDA |
| **AMR**<br>Antibody-Mediated Rejection in Renal Allograft | | | • Phase 1 study initiating<br>• First patient planned in Q1 2026 |
| **AMR**<br>Antibody-Mediated Rejection in Renal Allograft | | | • Phase 1/2 CTA submission planned<br>• Anticipate feedback in Q4 2025 |

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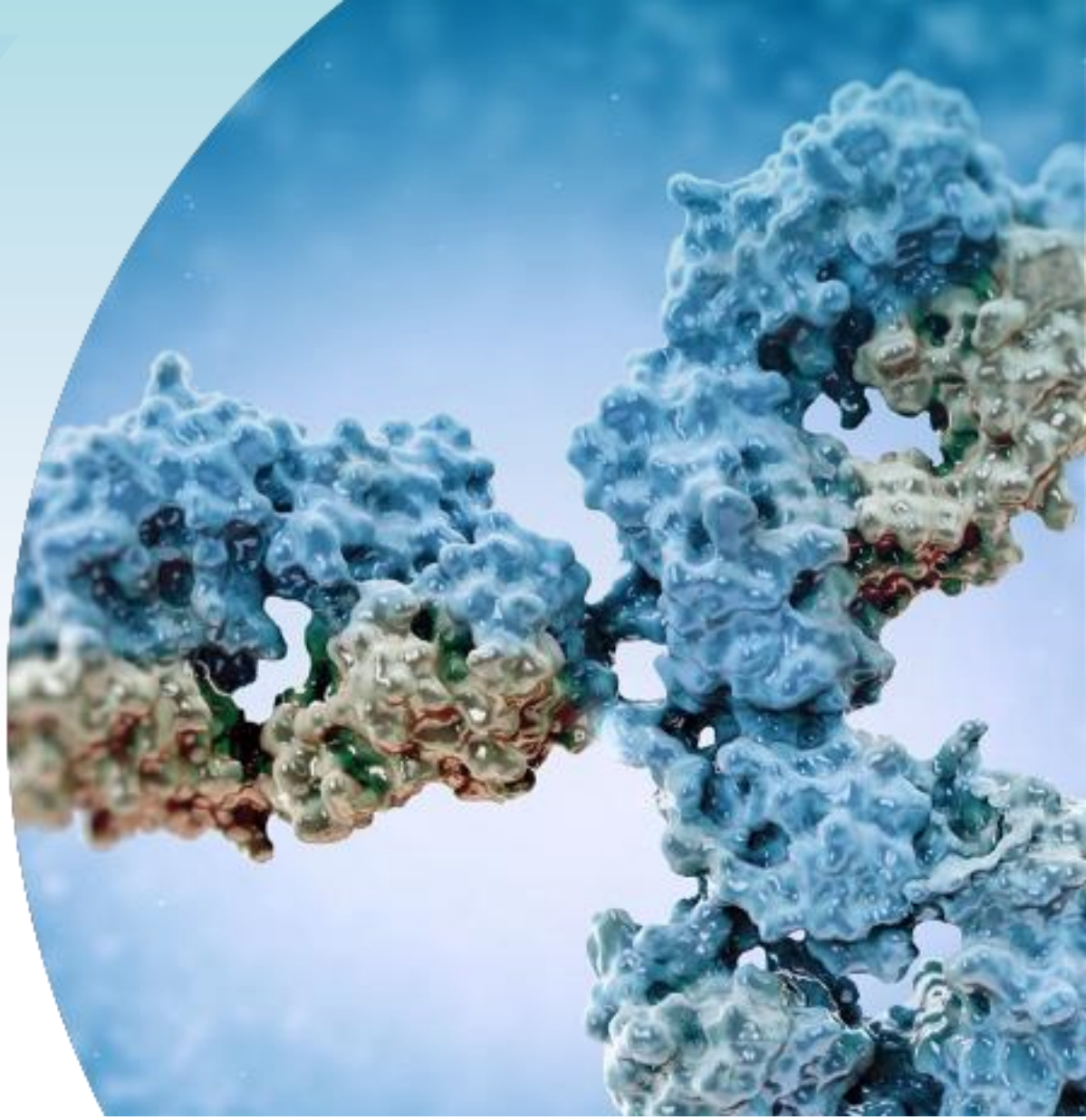
# Immune Thrombocytopenic Purpura (ITP)

- Ongoing Phase 1 Study



# CID-103: Phase 1 Dose-Escalation Study in ITP

## Accepted for Presentation at ASH 2025

**Primary Efficacy Endpoint**

Platelet count ≥ 50 x $10^9$/L and ≥ 20 x $10^9$/L above baseline, achieved on at least 2 consecutive measurements at ≥ 7 days apart within the first 12 weeks of treatment

1+3 design
CID-103
30 mg / 30 mg IV
n = 1-6
Priming / Target Dose

1+3 design
CID-103
30 mg / 150 mg IV
n = 1-6

1+3 design
CID-103
150 mg / 300 mg IV
n = 1-6

3+3 design
CID-103
150 mg / 600 mg IV
n = 3-6

CID-103
150 mg / 900 mg IV
n = 3-6

67th ASH® Annual Meeting and Exposition
DECEMBER 6-9, 2025 | ORLANDO, FLORIDA

*Accepted for Poster Presentation at ASH 2025*

- Dosing duration: 24 Weeks (QW for Week 1-6; Q2W for Week 7-12; Q4W for Week 13-24)
- After at least 6 doses, subjects may escalate to next dose at investigator and SMC discretion

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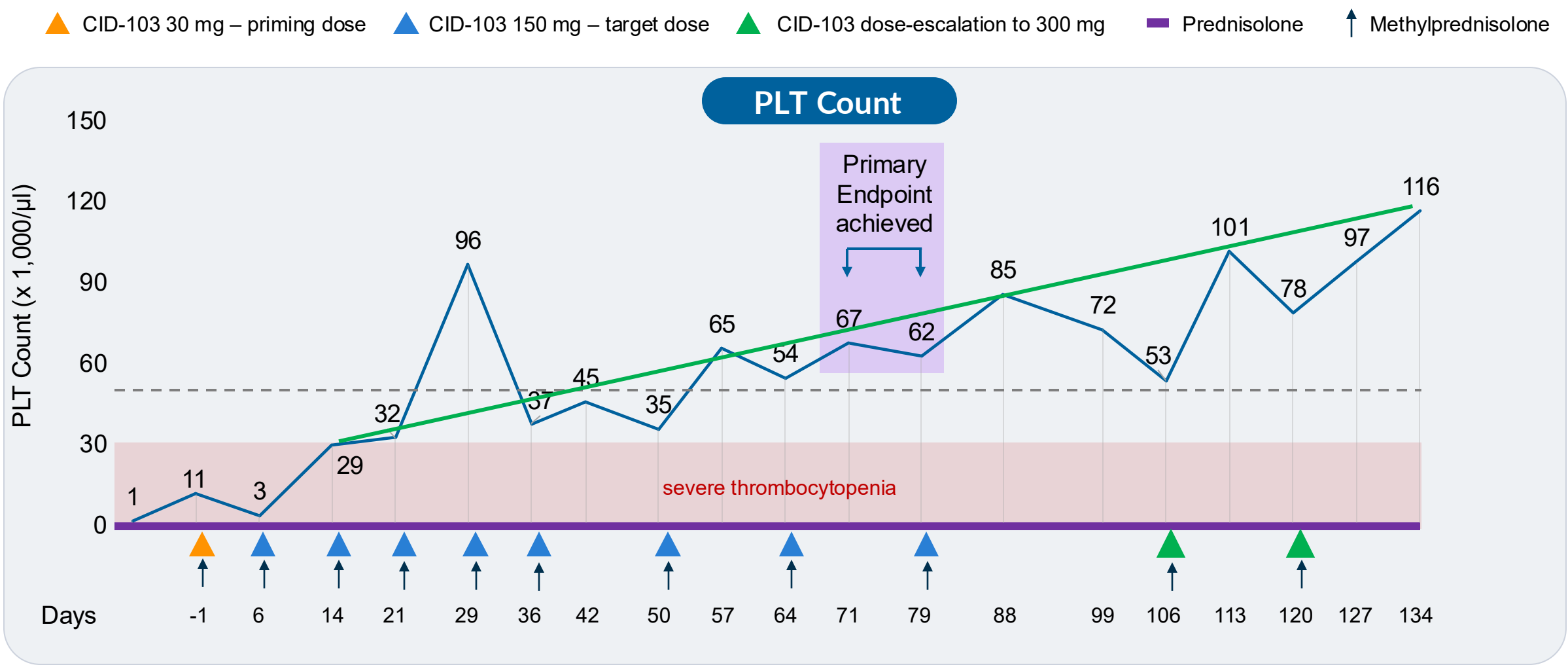
# Patient 8601003 (30mg/150mg of CID-103)

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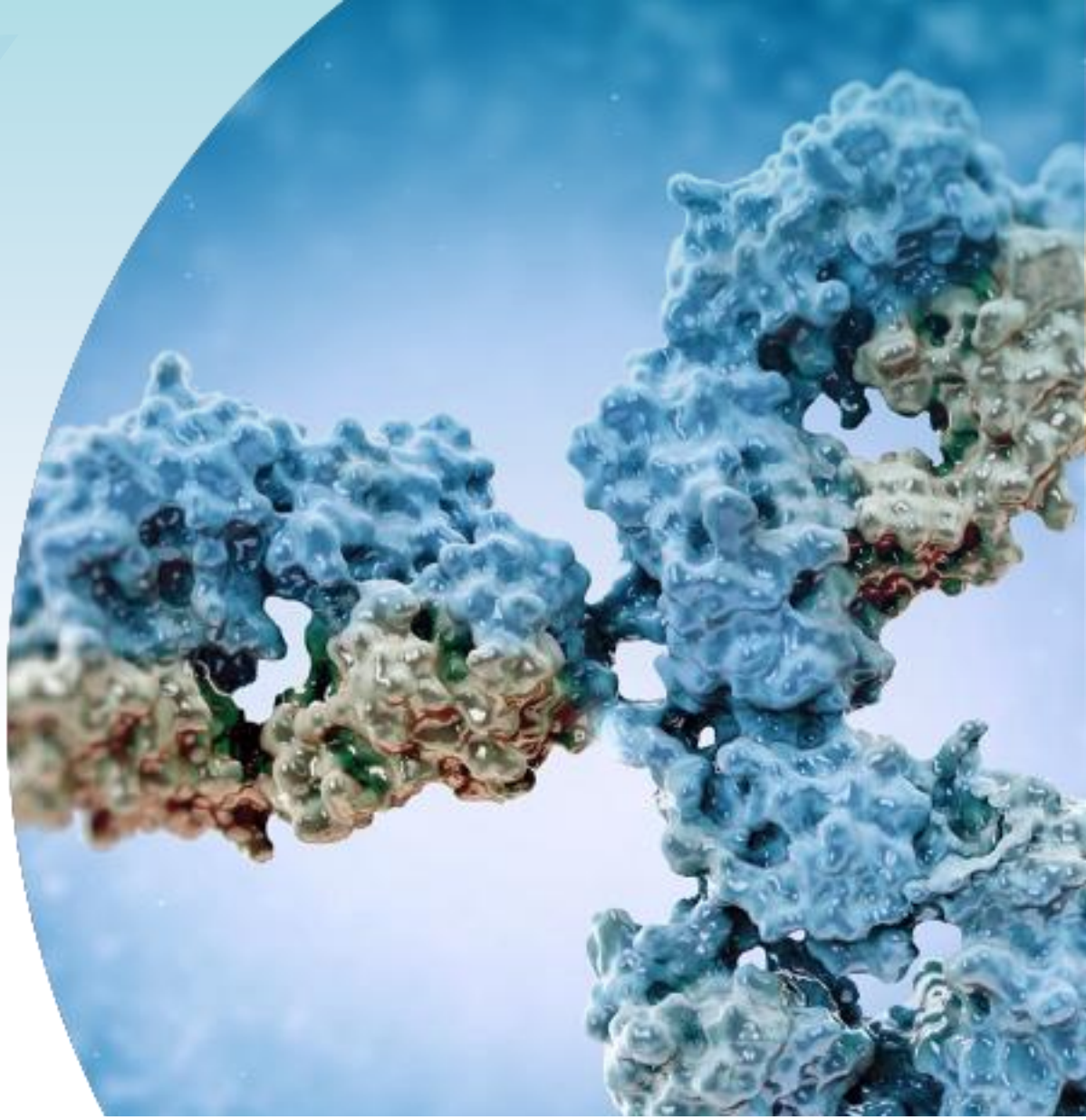
Data presented at CASI May 2025 Investor Call

# Antibody-Mediated Rejection (AMR) in Renal Allografts

- Phase 1 Study Initiating in U.S.
- Proposed Phase 1/2 Study in China
  - CTA Submission Planned
  - Feedback expected in Q4 2025



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# Antibody-Mediated Rejection (AMR) of Renal Allografts

## Leading Cause of Late Graft Loss in Kidney Transplant Recipients

**35K** transplants/yr

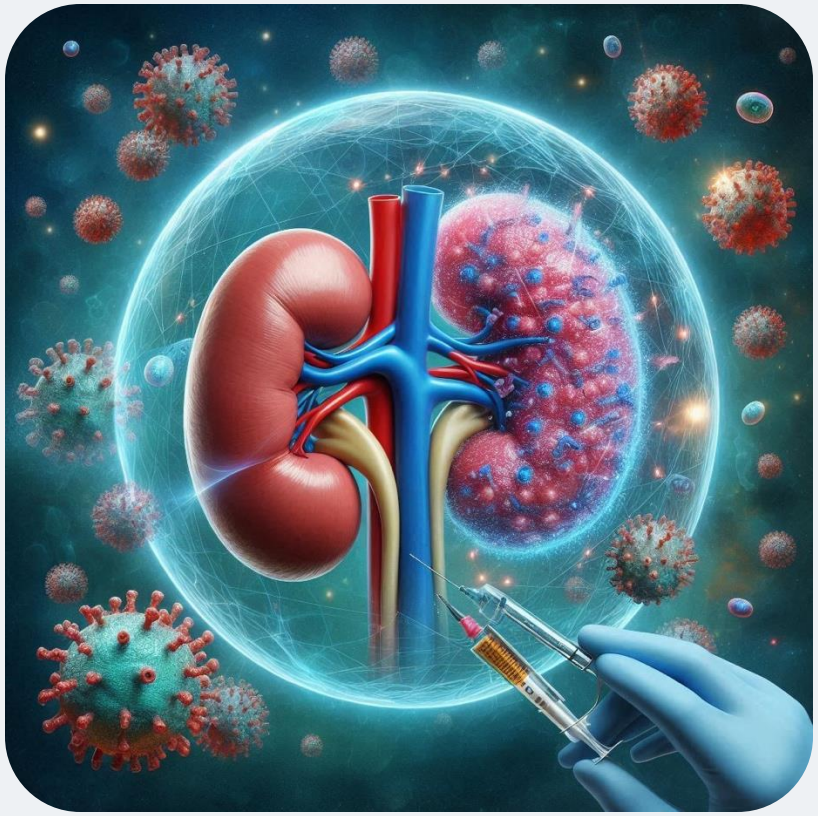
AMR contributes significantly to both acute and chronic rejection and ultimately leads to graft loss

**~25%**

of patients develop *de novo* donor-specific anti-HLA antibodies (dnDSA) 10 years post kidney transplant

**~60%**

of renal transplant recipients in a multicenter cohort study suffered from allograft dysfunction post-transplant due to antibody-mediated damage



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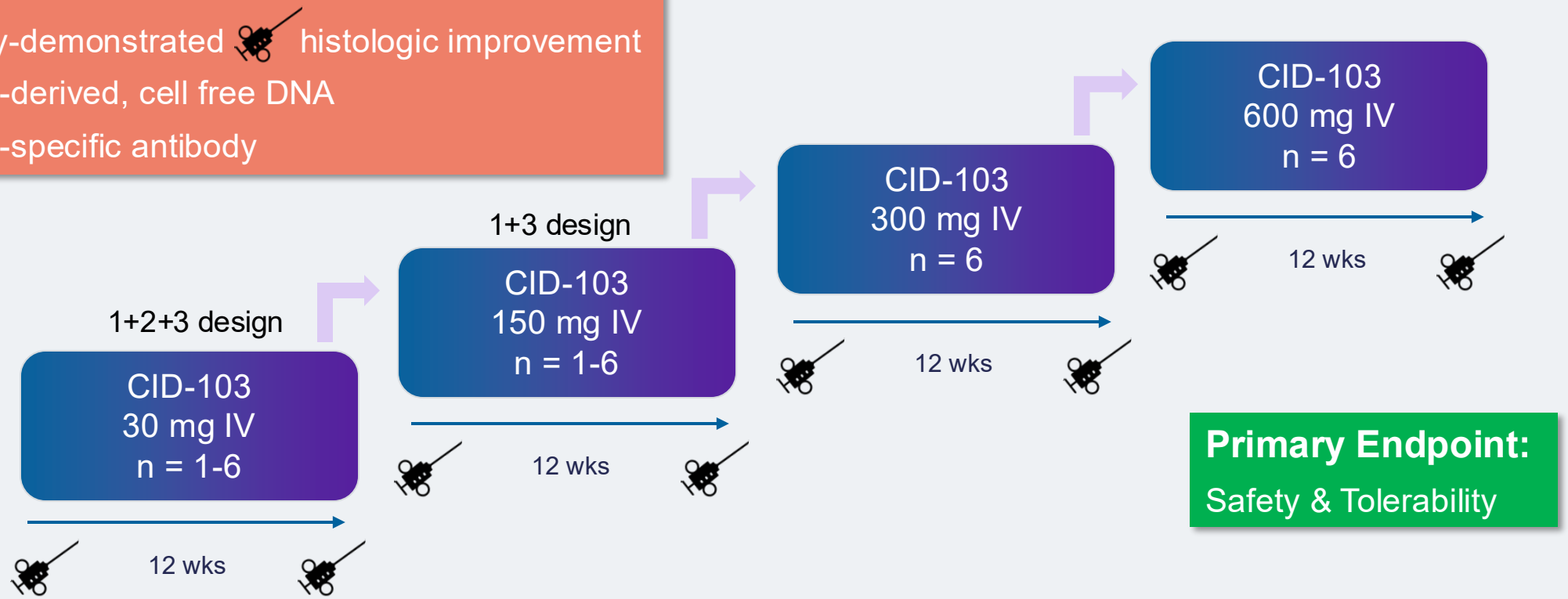
Schinstock, CA, et al, "Recommended Treatment for Antibody-mediated Rejection After Kidney Transplantation: The 2019 Expert Consensus From the Transplantation Society Working Group", *Transplantation* 2020;104: 911–922

# Approved U.S. Phase 1 Dose-Escalation Study in AMR

## First Patient Planned in Q1 2026

**Efficacy Assessment:**

- Biopsy-demonstrated histologic improvement
- Donor-derived, cell free DNA
- Donor-specific antibody




Priming Dose in all cohorts

- All patients on standard background immunosuppression therapy
- 12-week safety observation period before each dose escalation (QW for Week 1-5; Q2W for Week 6-11)
- Open-label study allows for interim data reporting as early as 2026

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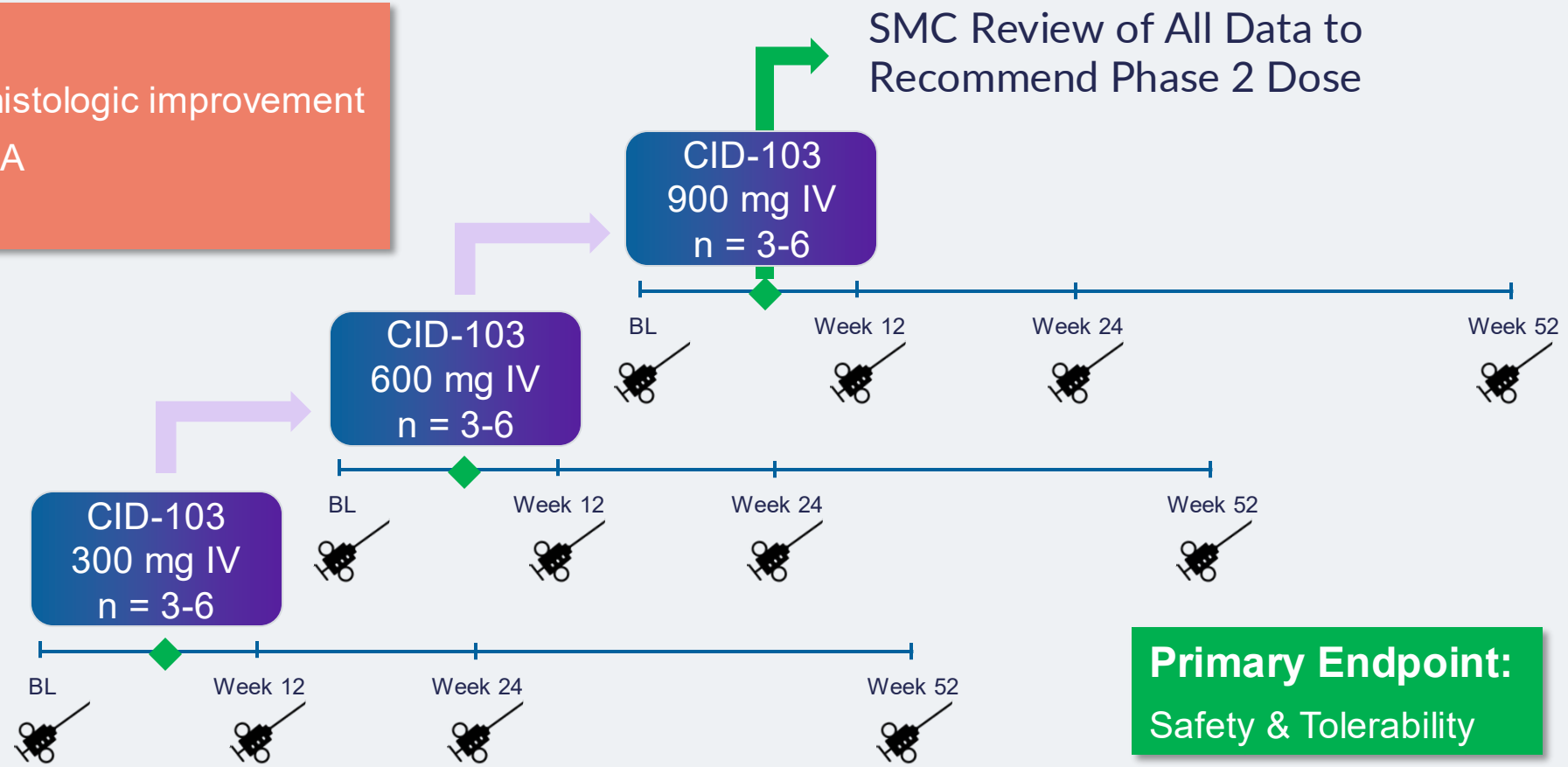
# Planned Phase 1 AMR Study in China

## Conducted Under China CTA: Allows for Efficient Path to Phase 2

**Efficacy Assessment:**

- Biopsy-demonstrated histologic improvement
- Donor-derived, cell free DNA
- Donor-specific antibody




Priming Dose in all cohorts

- QW for Week 1-5; Q2W for Week 7-13; Q4W for Week 17-49
- 6-week safety observation period ◆ before each dose escalation
- Open-label study allows for interim data reporting as early as 2026

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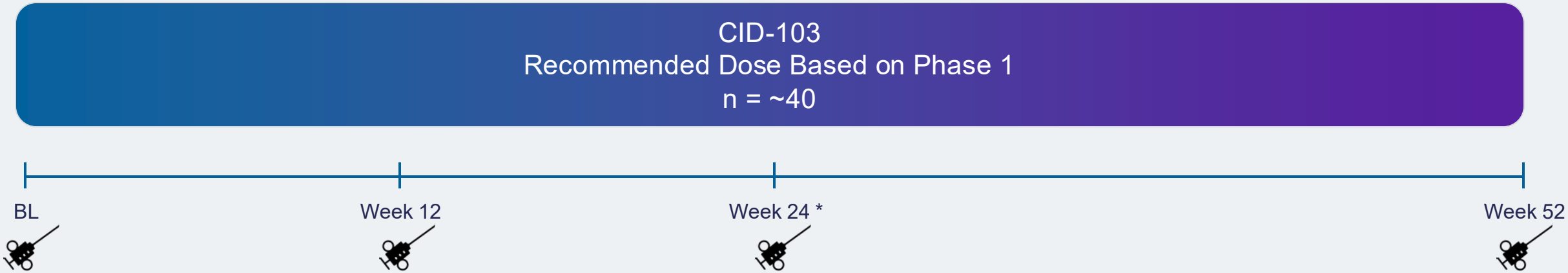
# Planned Phase 2 AMR Study in China

## Conducted Under China CTA

**Primary Endpoint*** :
Resolution of AMR on biopsy at Week 24




- QW for Week 1-5; Q2W for Week 7-13; Q4W for Week 17-49
- Open-label study allows for interim data reporting as early as 2026

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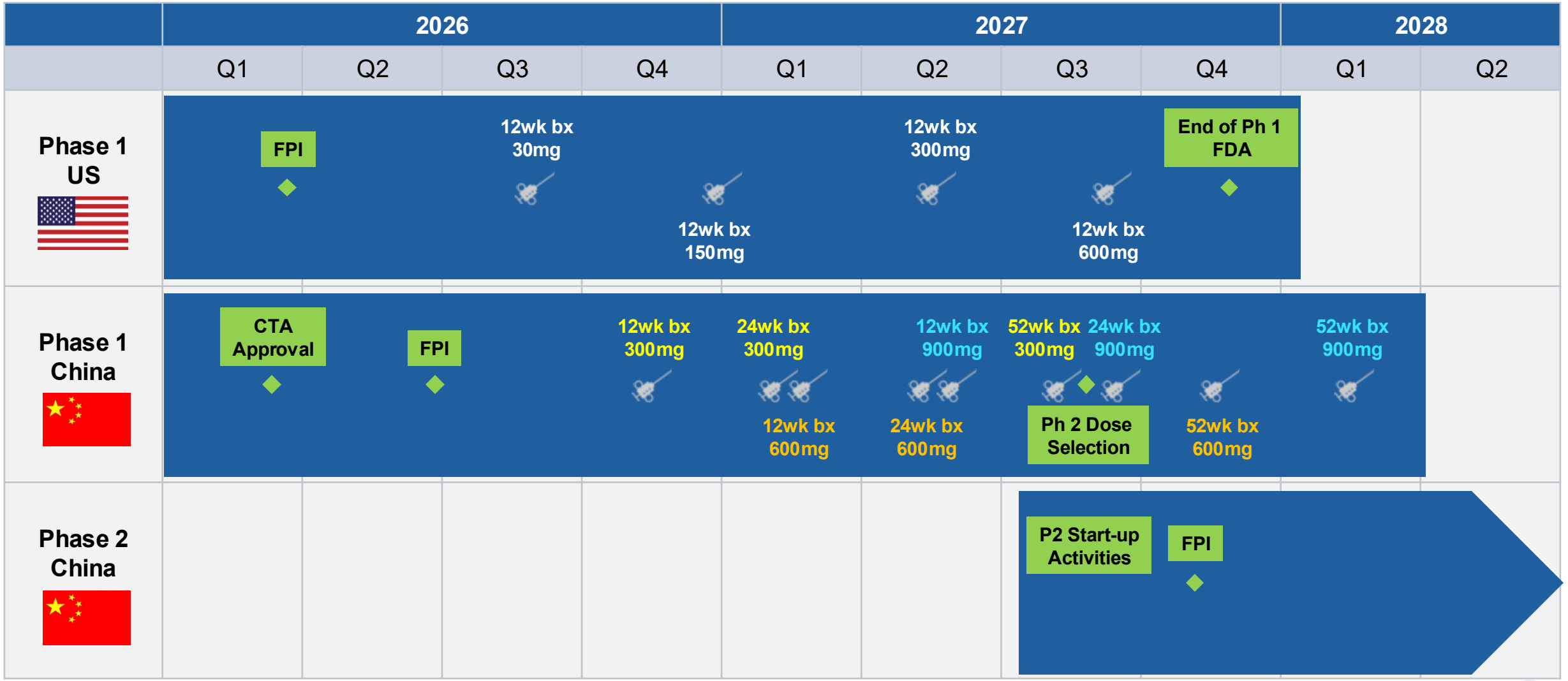
# AMR Program Timelines and Key Milestones*

## Biopsy / PD Marker Data Available for Scientific Conference Presentations Beginning 2H2026




* Capitalization and Use of Proceeds available under CDA

# Subcutaneous Formulation Development for CID-103

## Developing a High Concentration Protein (HCP) Solution

- Subcutaneous formulation of CID-103 to provide self-administration convenience for patients
- Progressing multiple technologies toward a high concentration, stable protein solution for SQ delivery*
  - Customized blends of amino acids and synergistic excipients to reduce viscosity
    - Enabled by high throughput formulation platform
  - Non-aqueous technology
  - Hyaluronidase enzyme technologies
  - High volume autoinjectors
- Targeting Phase 3 AMR study start with subcutaneous CID-103 formulation

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* Details available under CDA

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# Thank You

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