CASI Pharmaceuticals

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

December 2025

Nasdaq: CASI

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Investment Highlights

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

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 POC results at ASH 2025
- Antibody-mediated rejection (AMR) in renal allograft
  - U.S. FDA IND approved
    - Phase 1 initiating in U.S. planned in Q1 2026
  - Proposed Phase 1/2 study in China
    - CTA submitted Q4 2025

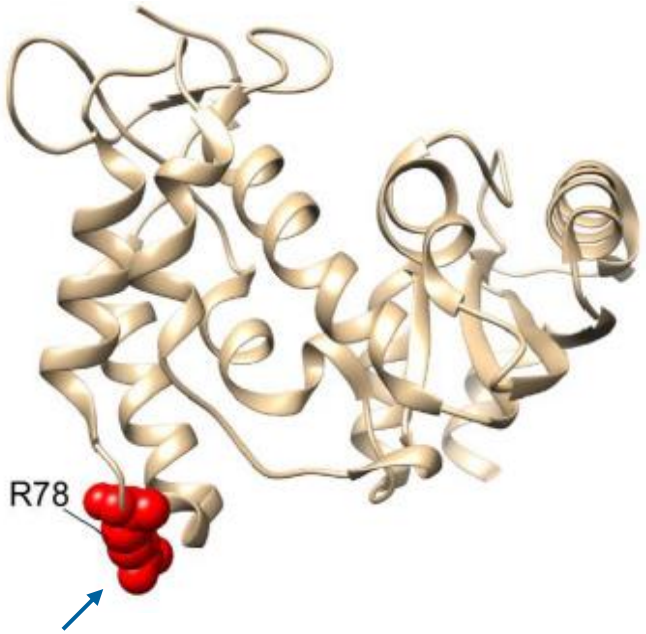
U.S. Operating Plan

- U.S. HQ has been established in South San Francisco, California
- New CEO and New Chairman
- 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

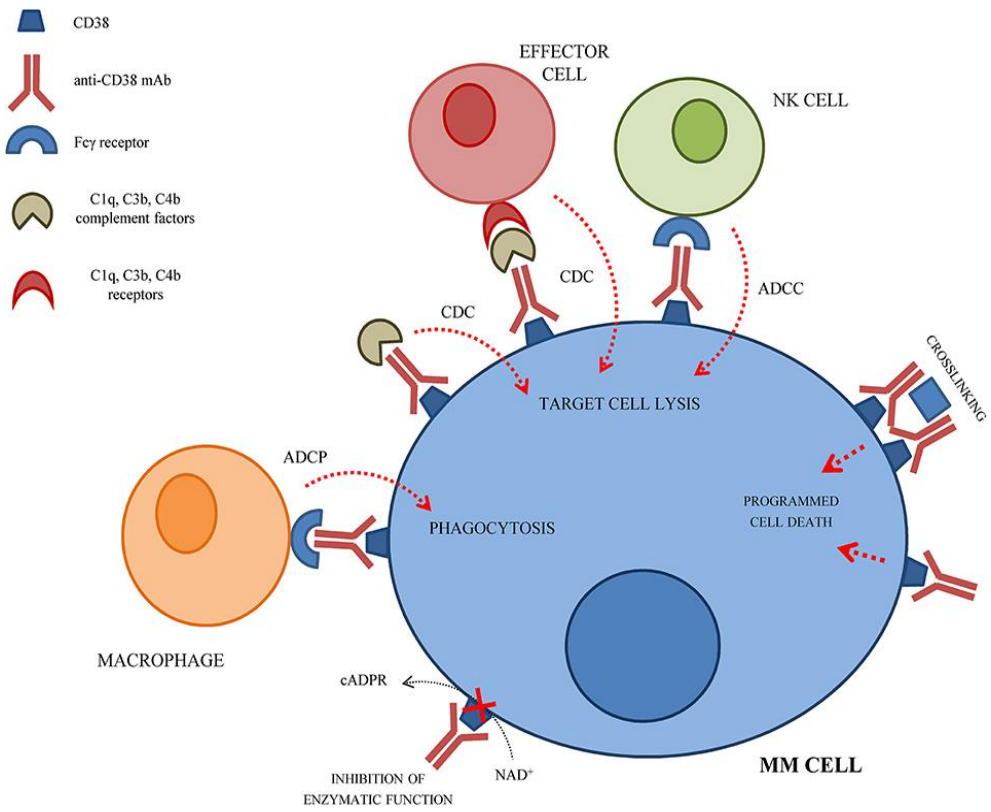
Inducing Plasma Cell Death by Binding to CD38

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

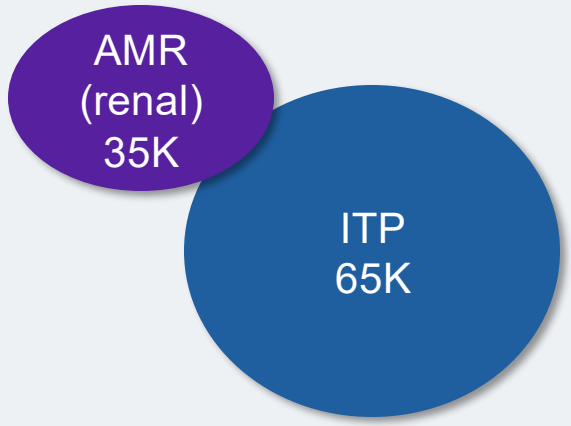


ADCP = antibody-dependent cellular phagocytosis; CDC = complement-dependent cytotoxicity; DCC = antibody dependent cell-mediated cytotoxicity.

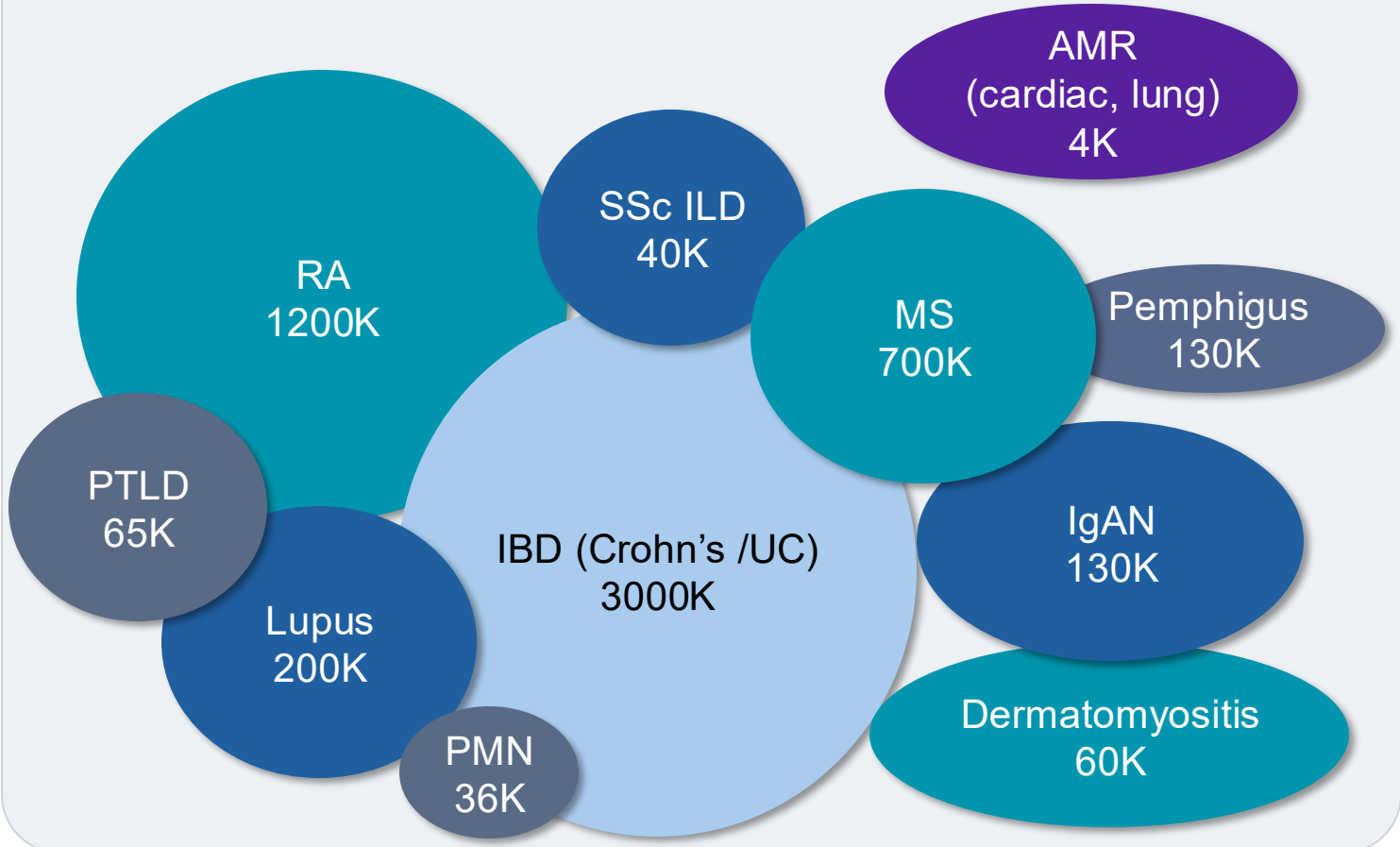
CID-103: Franchise-in-a-Product

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 Annual sales in 2024 nearly $12B
Sarclisa (isatuximab-irfc)	Sanofi	IV	Approved in 2020 (U.S.) for MM Annual sales in 2024 > $300M
Felzartamab	Biogen	IV	Biogen acquired HI-Bio for $1.8B Phase 3 in AMR initiated
Mezagitamab	Takeda	IV and SQ	Phase 3 in ITP initiated
CID-103	CASI	**IV**	**Phase 1 data in ITP presented at ASH 2025** **Phase 1 in AMR study initiation planned in Q1 2026** **SQ formulation development in process**

CID-103 Development Plan

Clinical Development Plan for CID-103

Financing to Fund U.S. AMR Study Start and Subcutaneous Formulation Development

Indication	Phase 1	Phase 2	Status & Upcoming Catalysts
ITP Immune Thrombocytopenic Purpura			• Generating POC for CID-103 • Phase 1 enrolling and dosing at 900 mg dose cohort • 67th ASH® Annual Meeting and Exposition DECEMBER 6-9, 2025 | ORLANDO, FLORIDA
AMR Antibody-Mediated Rejection in Renal Allograft			• Phase 1 study initiation planned in Q1 2026
AMR Antibody-Mediated Rejection in Renal Allograft			• CTA submitted Q4 2025

Pursuing multiple subcutaneous development technologies for Phase 3 readiness

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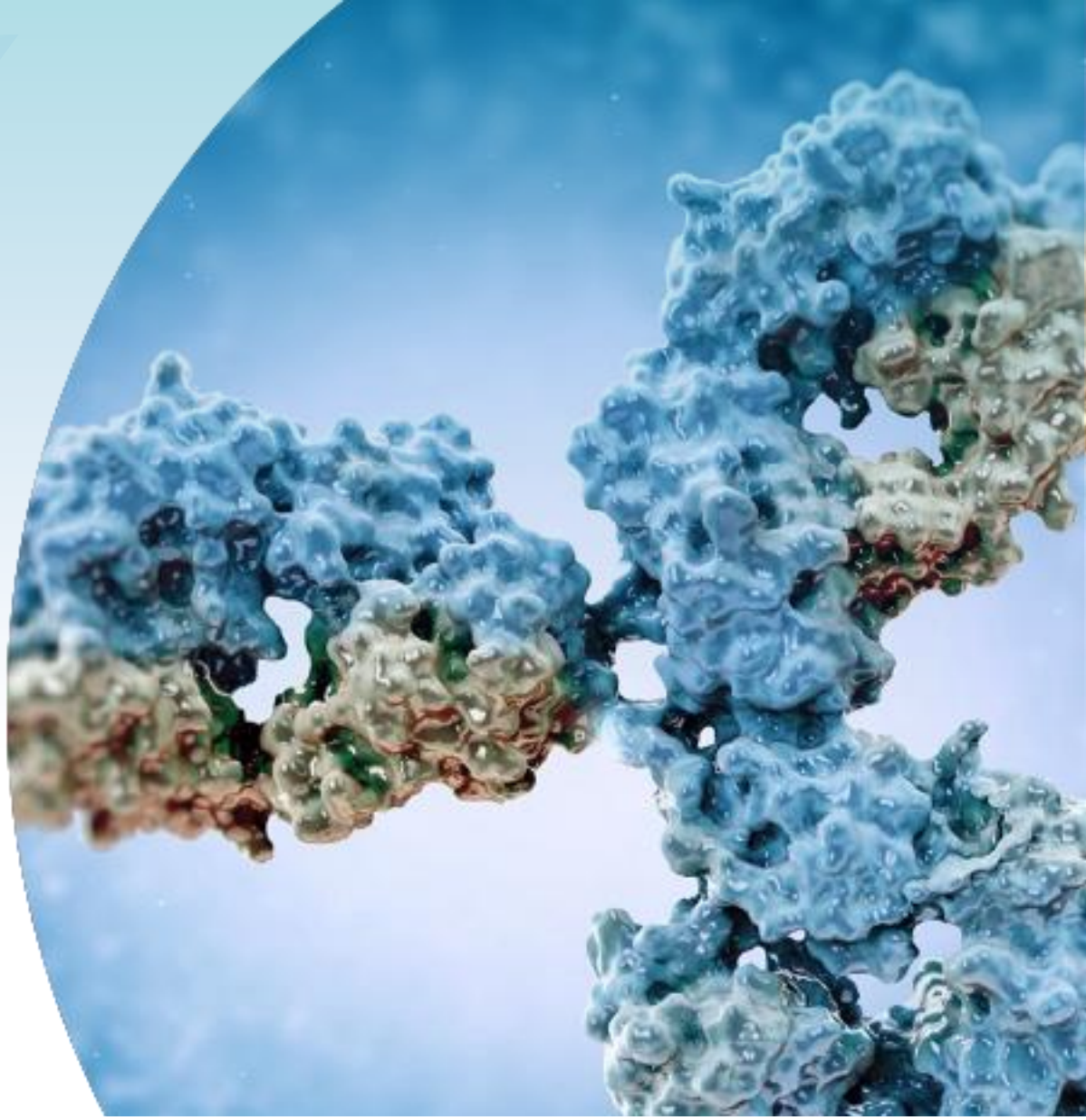
Antibody-Mediated Rejection (AMR) in Renal Allograft

- Phase 1 Study Initiation in U.S. planned in Q1 2026
- Proposed Phase 1/2 Study in China
  - CTA Submitted 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

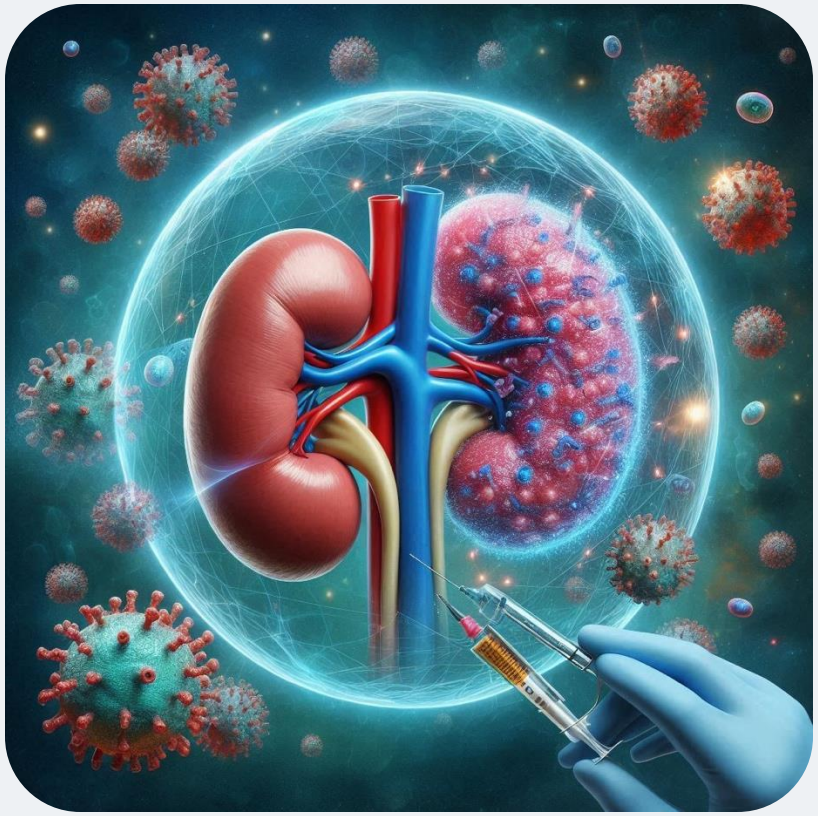
AMR contributes significantly to both acute and chronic rejection and ultimately leads to graft loss

~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

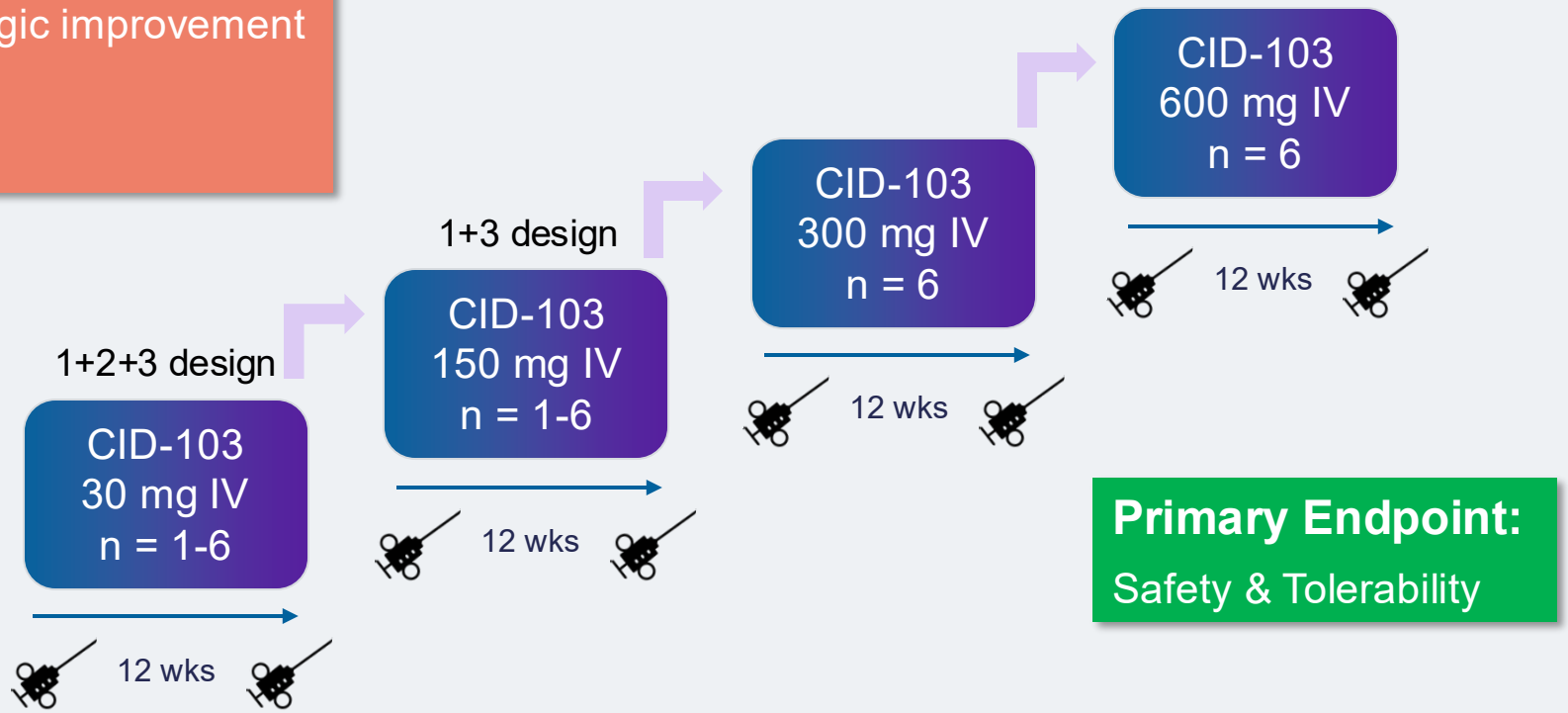
Approved U.S. Phase 1 Dose-Escalation Study in AMR

Study Start Planned in Q1 2026

Efficacy Assessment:

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

Open-label study allows for interim data reporting potentially as early as 2026



Primary Endpoint:
Safety & Tolerability

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)

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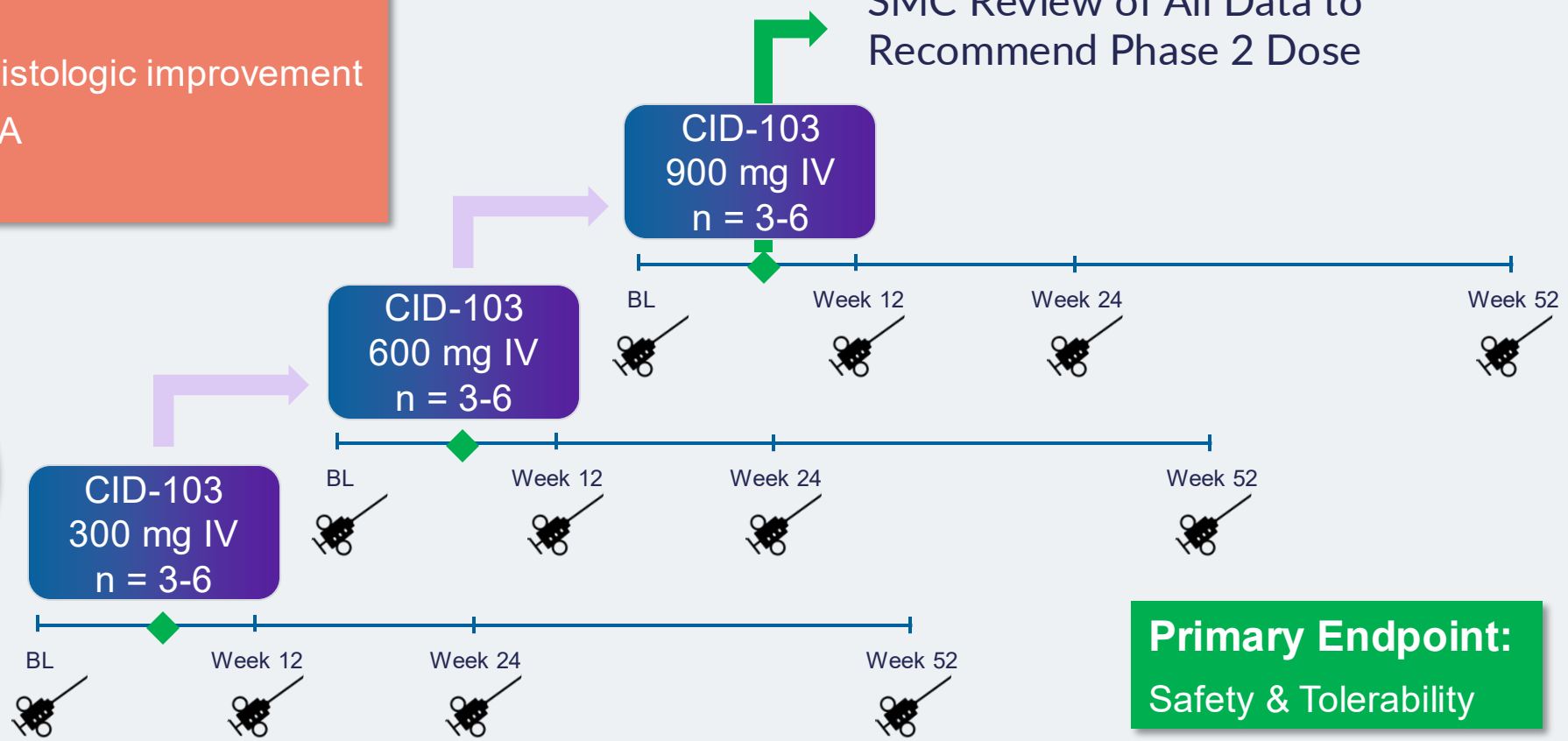
Proposed Phase 1 AMR Study in China

Efficient Path to Phase 2

Efficacy Assessment:

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

Open-label study allows for interim data reporting potentially as early as 2027



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

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Proposed Phase 2 AMR Study in China

Allows for Potentially Fast Transition from Phase 1 to Phase 2

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

CID-103
Recommended Dose Based on Phase 1
n = ~40

- QW for Week 1-5; Q2W for Week 7-13; Q4W for Week 17-49
- Open-label study allows for interim data reporting of biopsy and PD results

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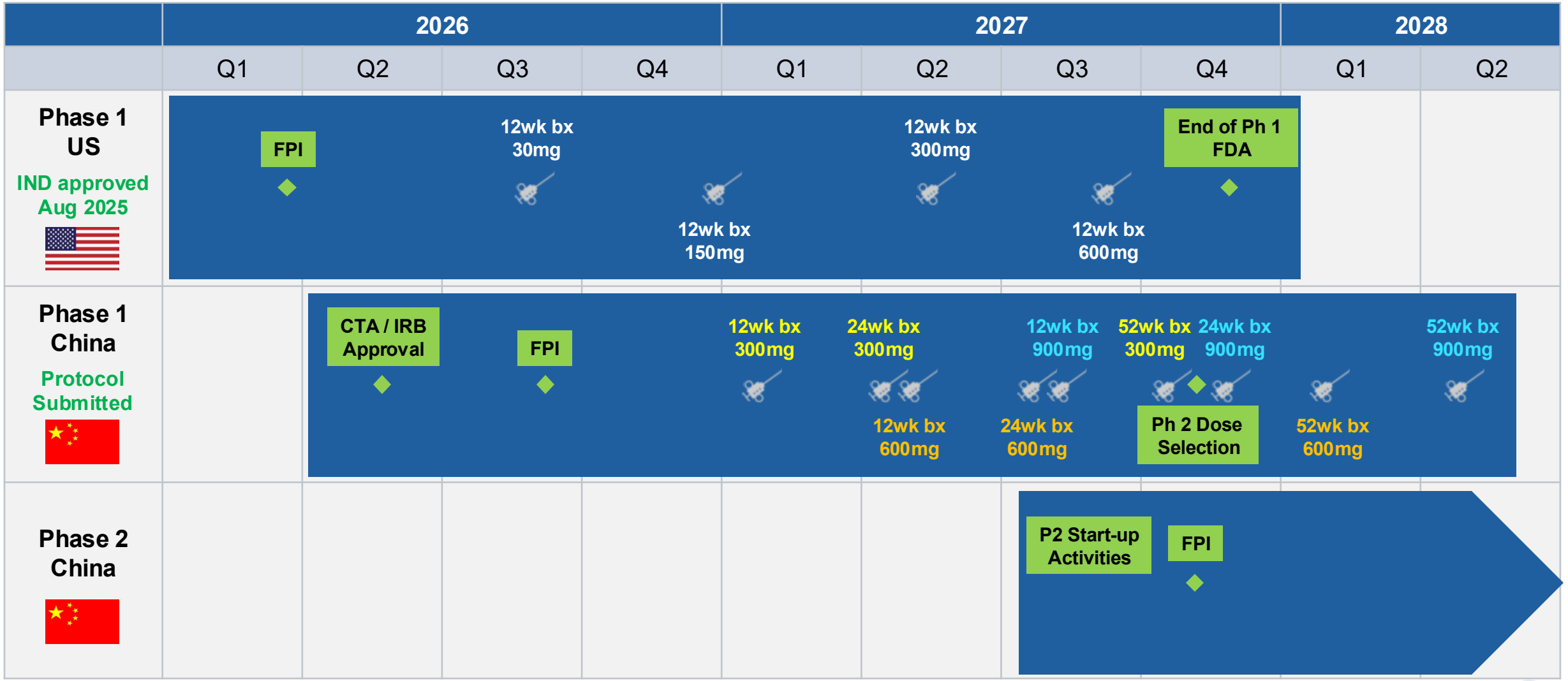
AMR Program Timelines and Anticipated Key Milestones

U.S. Biopsy / PD Marker Data Available for Public Presentation as Early as 2H2026



- U.S. study ready to initiate upon financing
- China study initiation subject to China CDE feedback and negotiation

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
- Option to progress multiple technologies to deliver a high concentration, stable protein solution
  - Customized blends of amino acids and synergistic excipient combinations to reduce the viscosity
  - Non-aqueous technology
  - Hyaluronidase enzyme technology
  - High volume autoinjectors
- Targeting Phase 3 AMR study start with subcutaneous CID-103 formulation
- Ready to initiate at least two technologies post financing

Assessing Multiple Technologies

Plan to Pursue Parallel SQ Formulation Programs to Ensure Success

curia
Sterile Drug Product

- Excelse™ technology: Utilizes customized blends of amino acids to stabilize formulation
- Significantly reduces viscosity; allows for concentrations of up 300 mg/mL
- Uses stabilizers that are non-active and FDA approved

WuXi Biologics
Global Solution Provider

- Multiple technologies
- WuXiHigh™: Synergistic excipient combinations to reduce viscosity in high concentration protein solutions
- Generic hyaluronidase co-formulation
- High volume autoinjectors

xeris™
BIOPHARMA

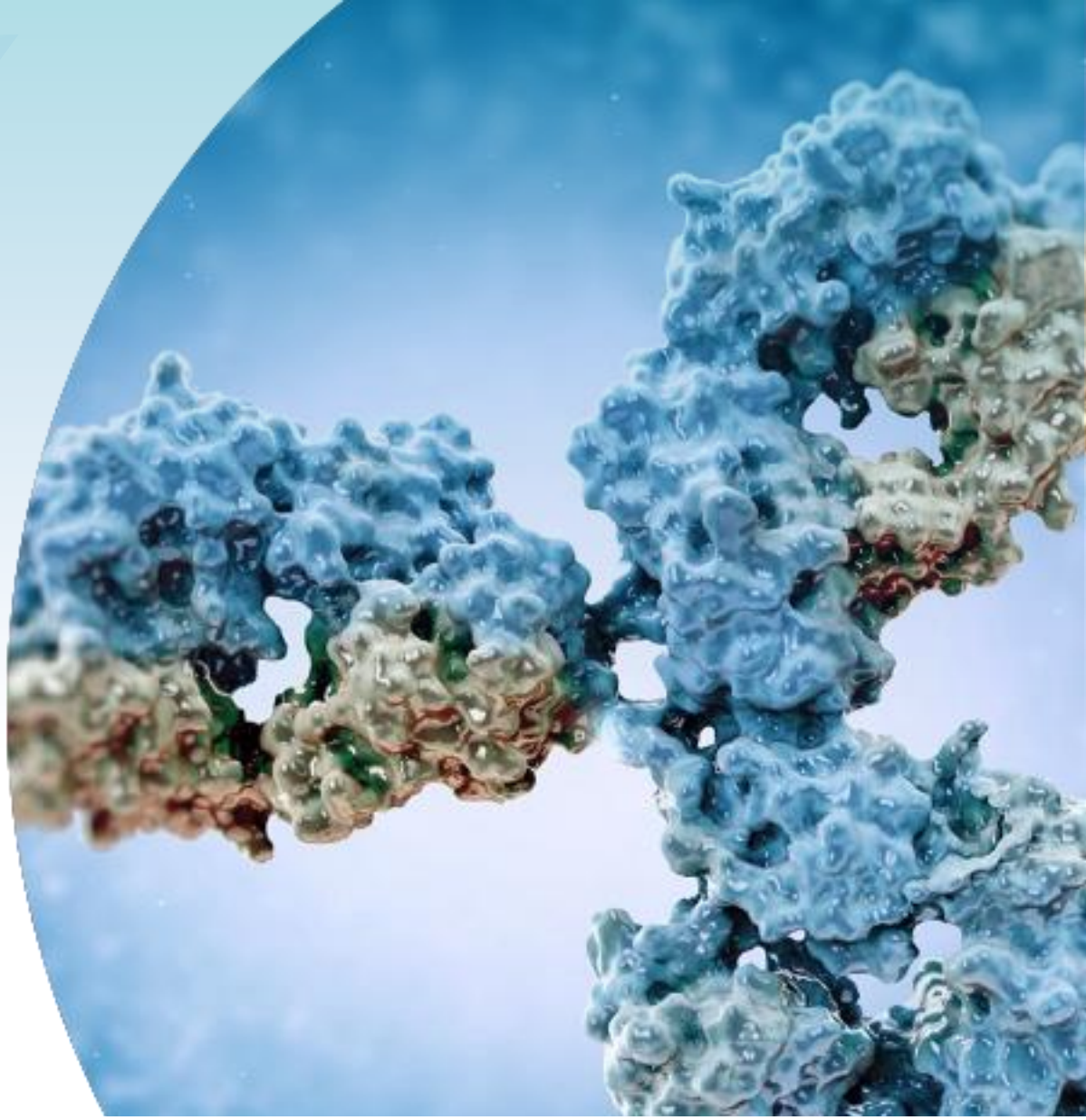
- XeriJect®: Non-aqueous technology
- Drug substance is reduced to a powder which is “wetted” with biocompatible diluents
- Creates an ultra-concentrated, ready-to-use, injectable, viscoelastic suspension

ALTEOGEN Inc.

- Hybrozyme™ technology: Proprietary recombinant human hyaluronidase enzyme technology
- Temporarily hydrolyzes hyaluronan in extracellular matrix, increasing its permeability
- Enables large volume subcutaneous administration of drugs

Immune Thrombocytopenic Purpura (ITP)

- Ongoing Phase 1 Study



CASI Pharmaceuticals Announces Upcoming Presentation of Clinical Results for CID-103 at the 67th American Society of Hematology (ASH) Annual Meeting

- CID-103 is a potential best-in-class, anti-CD38 monoclonal antibody
- Phase 1 dose escalation study in Immune Thrombocytopenia (ITP) results and update

South San Francisco, California / November 3, 2025 / ACCESS NEWSWIRE / -- CASI Pharmaceuticals, Inc. (NASDAQ: CASI), a clinical-stage biopharmaceutical company developing CID-103, a potential best-in-class, clinical stage anti-CD38 monoclonal antibody, for patients with organ transplant rejection and autoimmune diseases, today announced that data will be presented from its Phase 1 open-label study of CID-103 in adult patients with immune thrombocytopenia (ITP) at the 67th American Society of Hematology Annual Meeting and Exposition being held December 6-9, 2025, in Orlando, Florida.

Poster Presentation Details

Title: *A dose-escalation and safety study of CID-103 followed by a randomized, open-label, parallel-arm multi-dose study evaluating the efficacy and tolerability of CID-103 in adults with persistent or chronic immune thrombocytopenia*

Authors: *Chen Yunfei, ZePing Zhou, Hu Zhou, Ruibin Huang, Zhenyu Yan, Jun Peng, Ming Hou, James Bussel, Alexander Zukiwski, Junping Chen, Lei Zhang*

Session Name: *311. Disorders of Platelet Number or Function: Clinical and Epidemiological: Poster II*

Session Date and Time: *Sunday, December 7, 2025, 6:00 p.m. – 8:00 p.m. ET*

Location: *Orange County Convention Center – West Halls B3-B4*

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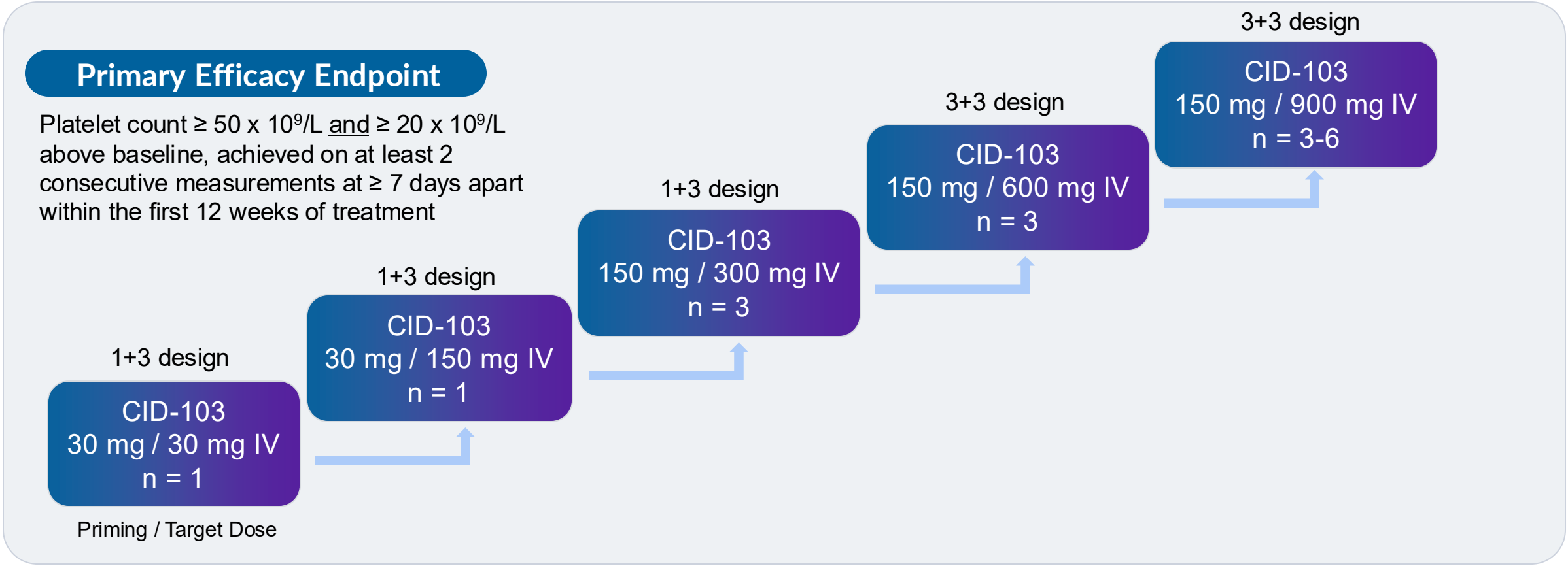
CID-103: Phase 1 Dose-Escalation Study in ITP



- Dosing duration: 24 Weeks (QW for Week 1-6; Q2W for Week 7-12; Q4W for Week 13-24)
- Multiple adaptative design elements including intra-patient dose escalation

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Demographic and Disease Characteristics

Demographic and Disease Characteristics	30 mg N=1	150 mg N=1	300 mg N=3	600 mg N=3	900 mg N=3	Total N=11
Median age, y (range)	32	29	39 (26-49)	34 (33-55)	47 (25-52)	34 (25-55)
Gender, n (%)						
Female, n (%)	1	0	1	1	2	5 (45.5%)
Male, n (%)	0	1	2	2	1	6 (54.5%)
Median duration of ITP prior to study enrollment, months (range)	14	44	27 (9-43)	89 (27-93)	14 (4-24)	27 (4-93)
Median baseline platelet count,$\times 10^9$/L (range)						
$<10\times10^9$/L	0	0	2	1	0	3
10 to $<30\times10^9$/L	1	1	1	2	3	8
Median # of prior ITP therapies (range)*	5	6	2 (2-3)	7 (5-10)	4 (3-4)	4 (2-10)
Karnofsky Performance Status (KPS)	100	100	100	100	100	100
Bleeding (with ITP-BAT bleeding score)						
S0M0O0	1	1	3	3	2	10
S0M0O1**	0	0	0	0	1	1
Concomitant medications, n						
Glucocorticoids	1	1	2	1	1	6
Thrombopoietin-receptor agonists	1	0	2	1	2	6

* Including Glucocorticoids, IVIg, TPO-RA, and others, ** Menorrhagia was observed in Patient 01010 in 900 mg cohort

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Preliminary Safety Data

Preliminary Safety Data	30 mg N=1	150 mg N=1	300 mg N=3	600 mg N=3	900 mg N=3	Total N=11
	n [m]*	n [m]	n [m]	n [m]	n [m]	n [m]
Any AE	1 [13]	1 [6]	3 [14]	3 [11]	3 [14]	11 [58]
DLT	0	0	0	0	0	0
Any TEAE	1 [13]	1 [6]	3 [14]	3 [11]	3 [14]	11 [58]
≥G3 TEAE	1 [2]	0	0	1 [1]	1 [2]	3 [5]
Any TRAE	1 [4]	1 [3]	3 [11]	2 [5]	3 [10]	10 [33]
≥G3 TRAE	1 [2]**	0	0	0	1 [2]***	2 [4]
SAE	0	0	0	0	0	0
IRR**	0	0	1 [1]	1 [1]	3 [3]	5 [5]
TEAEs leading to:						
Treatment delay	0	0	0	0	1[1]	1[1]
Dose reduction	0	0	0	0	0	0
Treatment discontinuation	0	0	0	0	0	0
Death	0	0	0	0	0	0

* n, number of patients; m, number of events
** Grade 3 anemia was reported twice on Patient 01001 but was deemed a lab error by Safety Monitoring Committee (SMC)
*** Grade 3 neutropenia and Grade 3 leukopenia were reported on Patient 01011 in Week 4 which led to a treatment delay
**** Mild IRR events, four Grade 2 (Pt 01005, 01007, 01009, and 01010) and one Grade 1 (Pt 01011), were all reported during the administration of the priming dose

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Efficacy

Platelet Count (x 1000/μL)				
ORR = 73%		Primary Endpoint	Complete Response	No Response
		PLT ≥ 50 & ≥ 20 above baseline	≥ 100	
30 mg	8601001	√		
150 mg	8601003	√	√*	
300 mg	8601004			√
	8601007	√	√	
	8601008	√	√	
600 mg	8601005	√	√	
	8603001			√
	8601006			√
900 mg	8601009	√	√	
	8601010	√	√	
	8601011	√		
TOTAL	**11**	**8 / 11**	**6 / 11**	**3 / 11**

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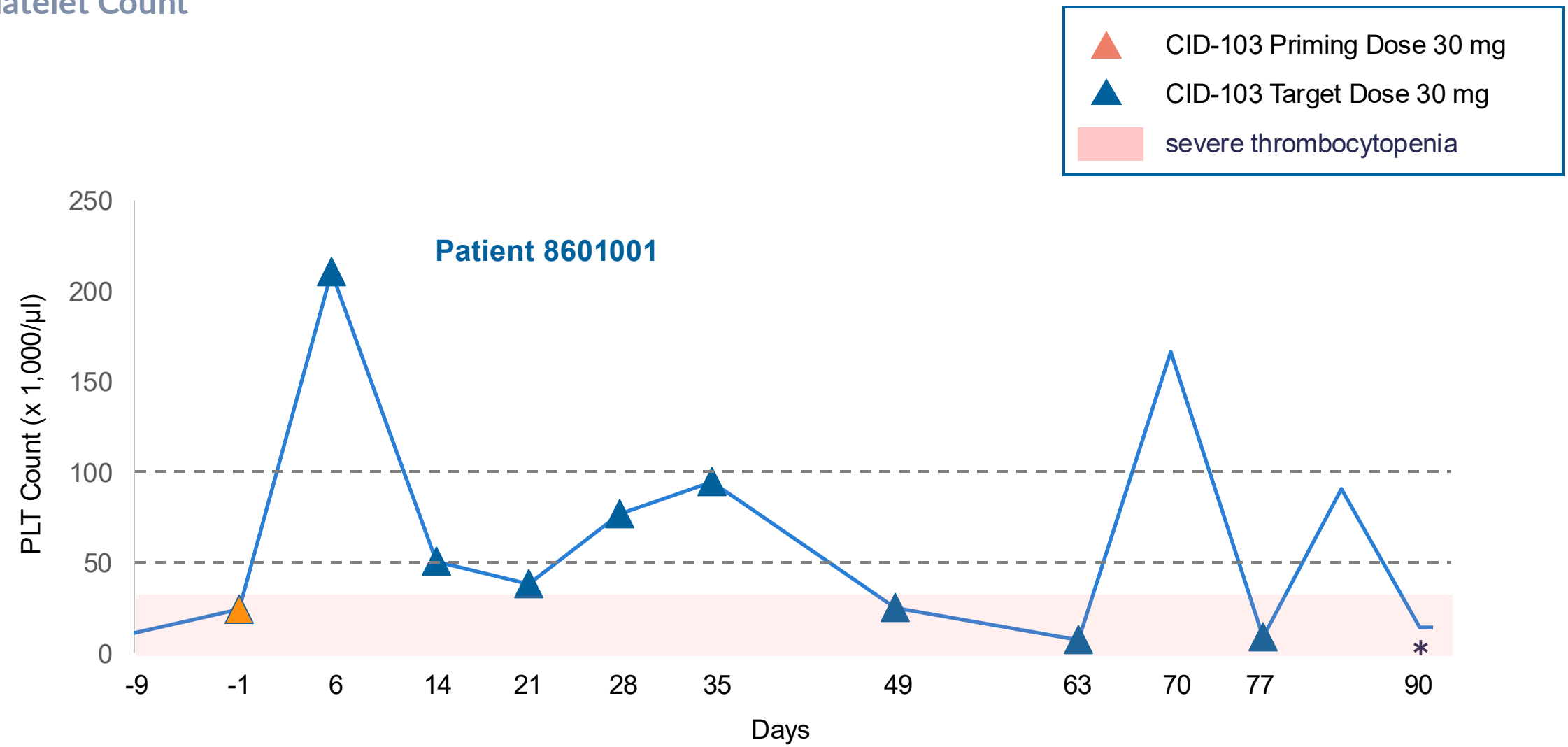
* with dose escalation

Cohort 1 (N=1): 30 mg Target Dose

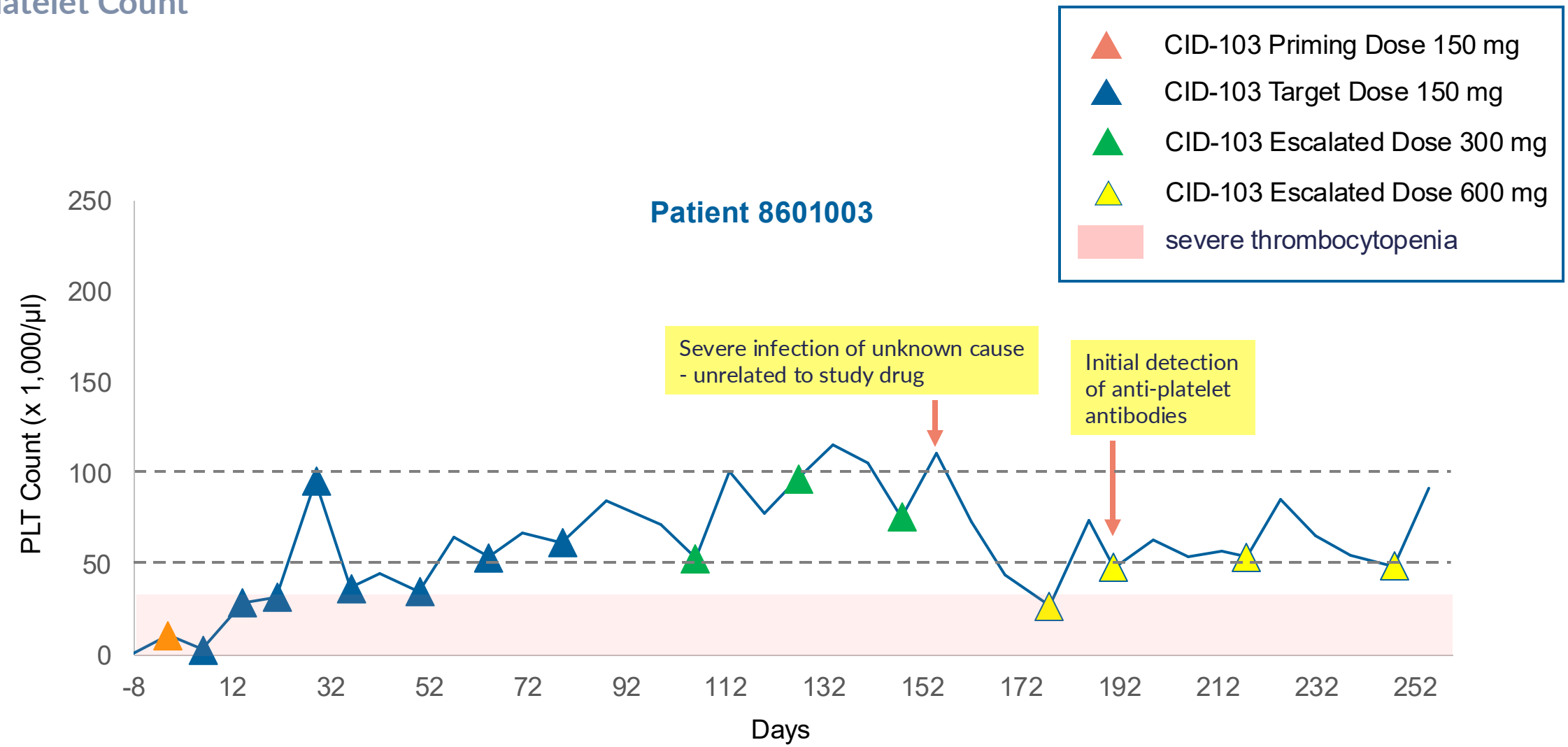
Platelet Count



* = EOT

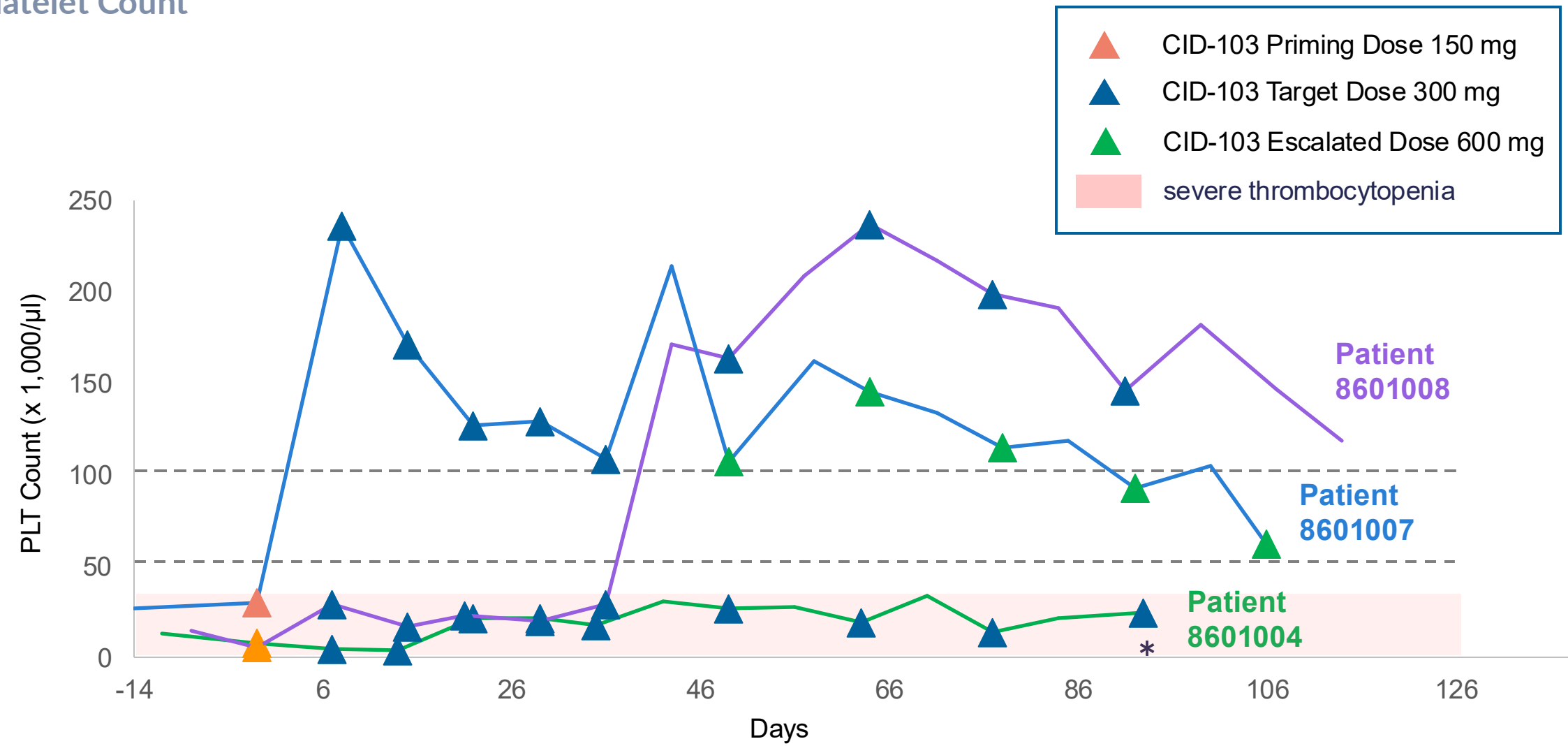
Cohort 2 (N=1): 150 mg Target Dose

Platelet Count



Cohort 3 (N=3): 300 mg Target Dose

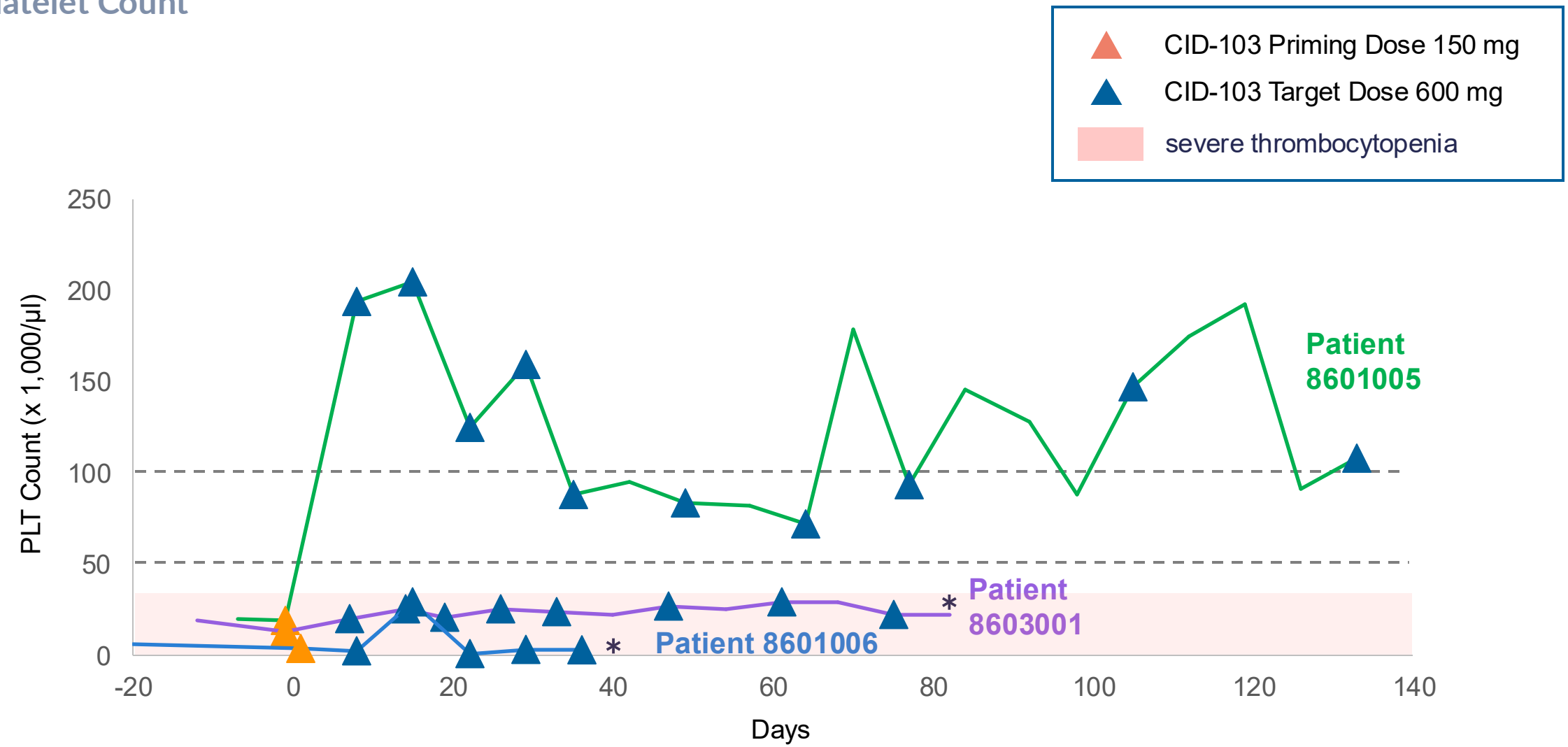
Platelet Count



* = EOT

Cohort 4 (N=3): 600 mg Target Dose

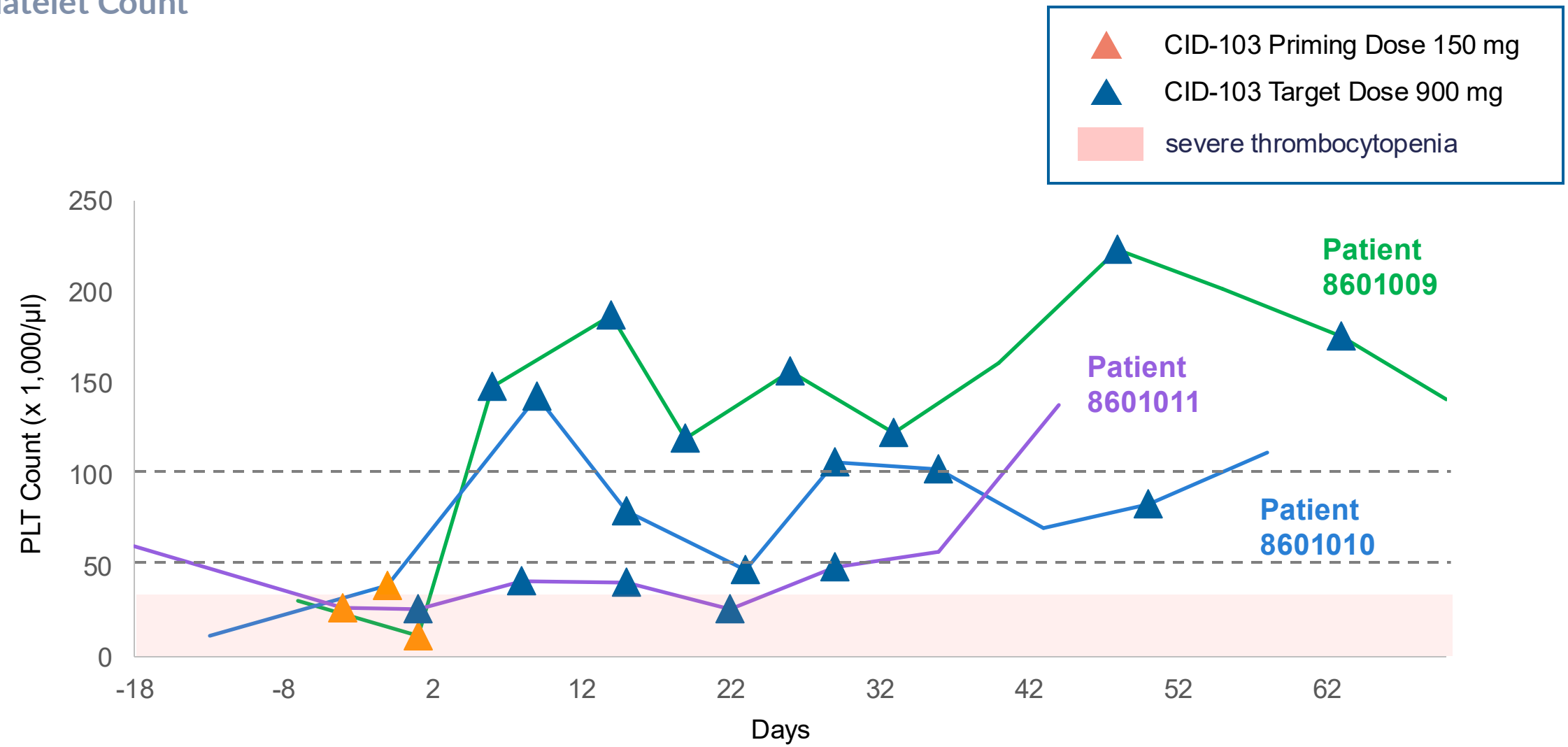
Platelet Count



* = EOT

Cohort 5 (N=3): 900 mg Target Dose

Platelet Count



Pharmacodynamics / Pharmacokinetics

- Anti-Platelet Antibodies
  - At baseline (BL), 4 patients had detectable anti-platelet Ab (A-PA)
    - 2 patients (01005 CR, 01009 CR) reduced A-PA to non-detectable
    - 2 patients (01006 NR, 01008 CR) substantially reduced A-PA
  - 1 patient (01003) had non-detectable A-PA at BL and developed detectable A-PA after an infection assumed to be of viral origin at Day 191 (Week 28)
- % Change of plasma cell number from BL measured in 900 mg cohort
  - All 3 patients decreased from BL as follows:
    - Week 3: -52%, -82%, and -94%; Week 5: -73%, -84%, and –92%
- NK cell reduction in peripheral blood observed in all doses tested
  - Maximum reduction (~80-100%) achieved at ≥ 300 mg dose
- Reductions in IgG, IgA and IgM observed at all doses; plateau in 300 mg cohort
- Mean receptor occupancy 58% (300 mg), 72% (600 mg), 77% (900 mg)
- $T_{1/2}$ > 60 hours (dose proportional)

Summary & Conclusions

- This Phase 1 ITP study demonstrates proof-of-concept for CID-103 as a promising anti-CD38 targeted monoclonal antibody and rationale for future clinical development in diseases involving donor-directed and pathological autoantibodies
- Manageable safety profile; only two Grade 3 treatment-related events, no DLTs
- All IRRs occurred with priming dose and are due to low grade AEs
- Primary Efficacy Endpoint achieved in 8 of 11 (73%) patients
    - 6 of 8 (75%) patients achieved Complete Response (CR) with platelet improvement observed as early as one week post dose
- Reduction of PD markers (decreased anti-platelet antibodies, immunoglobulins, NK and plasma cells) is consistent with the presumed CID-103 MOA resulting in the observed platelet response
- Additional patients to be enrolled in 600 and 900 mg cohorts to expand safety / efficacy data for CID-103 in an autoimmune disease population

Preparing for Success

Key Events in 2025

- Announced Agreement for Divesture of Business in China
- Appointed Industry Veteran – David Cory – as New Operating Chief Executive Officer
- Received FDA IND Clearance for Phase 1 Renal Allograft AMR Study in U.S.
- Appointed Former Morphosys Chief Business Officer – Barbara Krebs-Pohl – to Board of Directors
- Appointed Seasoned New Non-Executive Chairman – James Huang
- Presented Positive Proof of Concept Results from CID-103 Phase 1 ITP Study at ASH 2025

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Thank You

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