CASI Pharmaceuticals

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

January 2026

Nasdaq: CASI

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Investment Highlights

Developing CID-103: Anti-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 profile emerging from clinical proof of concept data
- Multiple Sub Q technology platforms being pursued toward a CID-103 Sub Q injection for use in registration program
- Patent protection thru mid-2038 (before extensions)

Clinical Catalysts

- Immune thrombocytopenic purpura (ITP)
  - Phase 1 POC results at ASH 2025
  - Additional data update planned
- Antibody-mediated rejection (AMR) in renal allograft
  - IND approved by U.S. FDA
    - Phase 1 in U.S. planned
  - CTA approved by China NMPA
    - Phase 1 / 2 study planned

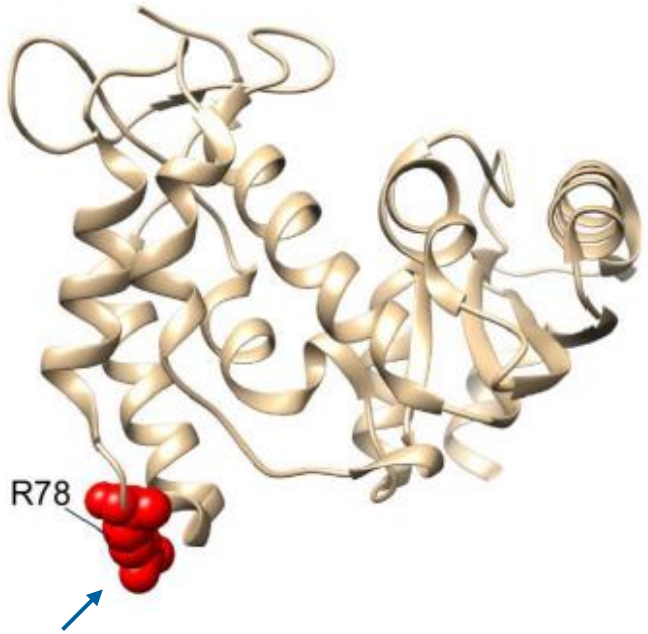
U.S. Operating Plan

- 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

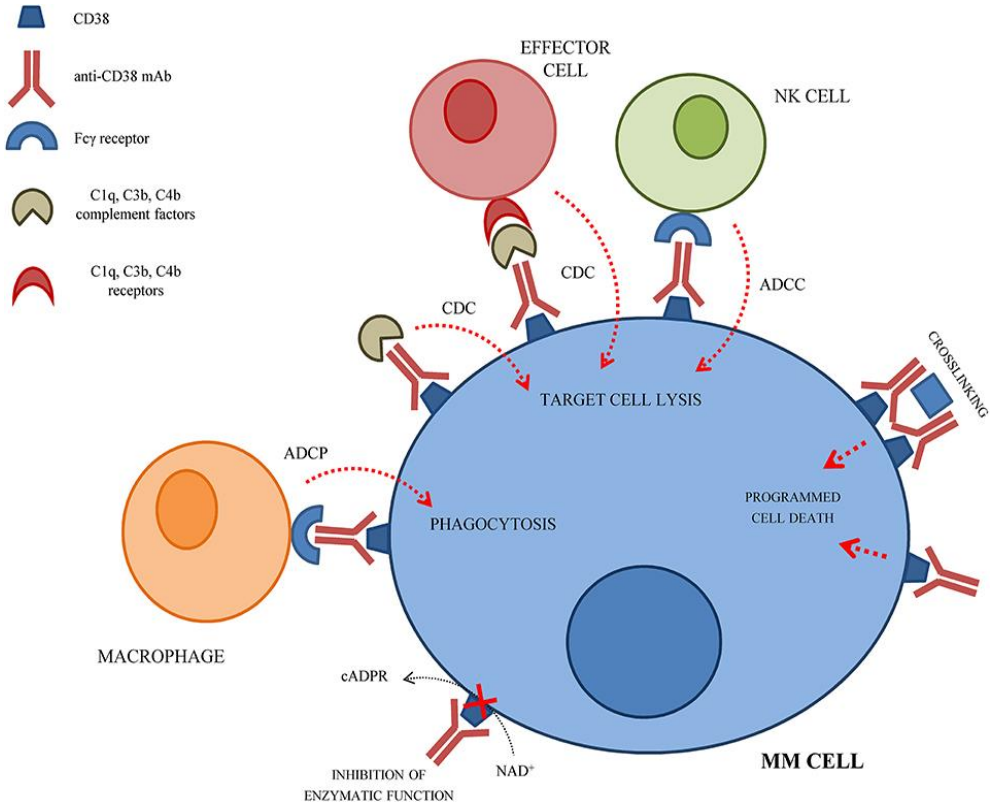
Inducing Plasma Cell Death by Binding to CD38

CD38 is Highly Expressed on Plasma and NK Cells

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

Mechanism of Action

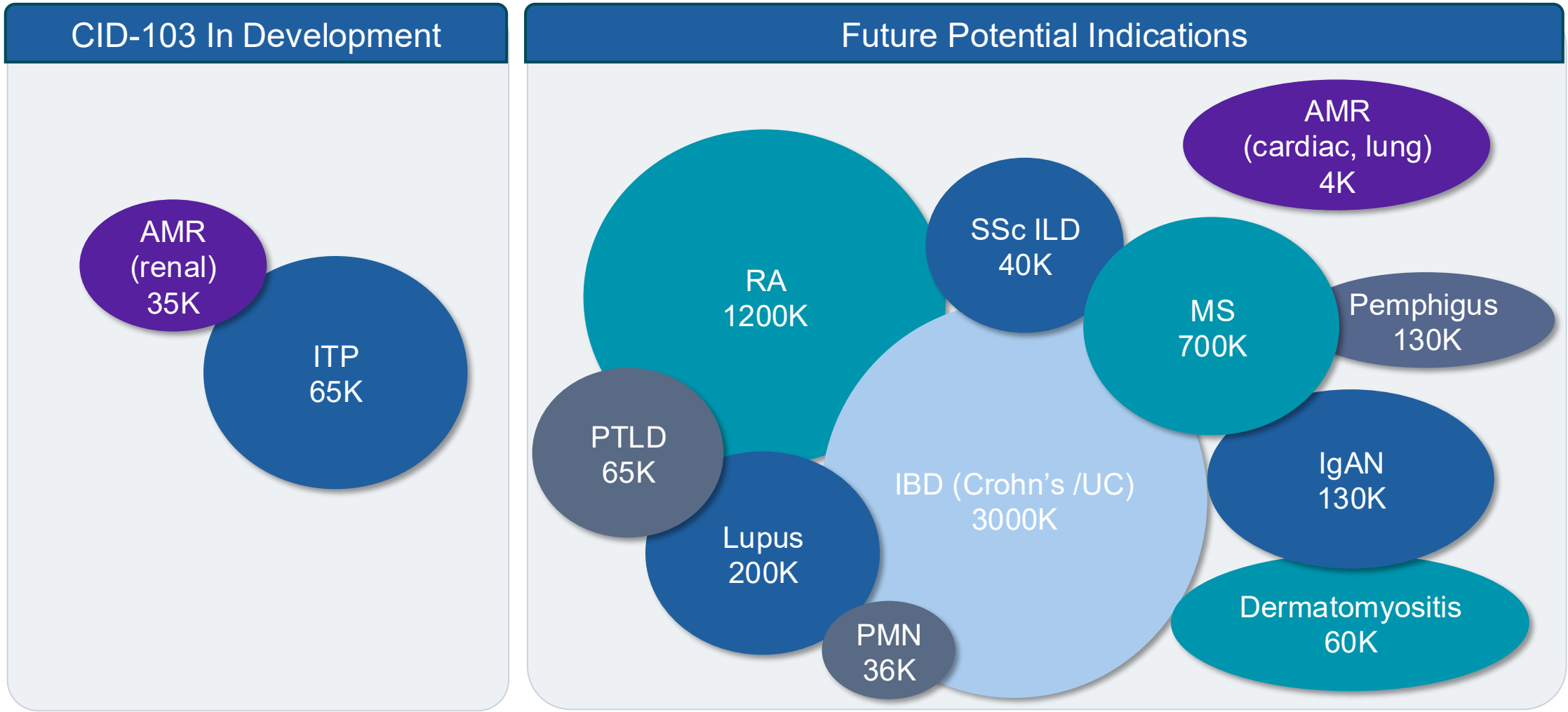
- Selectively deplete CD38^{+} plasma cells to block production of donor-directed and pathologic autoantibodies
- Reduce number of NK cells which cause microvascular inflammation and damage



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



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 dosing at 600 & 900 mg dose cohort • 67th ASH® Annual Meeting and Exposition DECEMBER 6-9, 2025 | ORLANDO, FLORIDA
AMR Antibody-Mediated Rejection in Renal Allograft			• IND approved by U.S. FDA • Phase 1 study planned
AMR Antibody-Mediated Rejection in Renal Allograft			• CTA approved by China NMPA • Phase 1 / 2 study planned

Pursuing multiple subcutaneous development technologies for Phase 3 readiness

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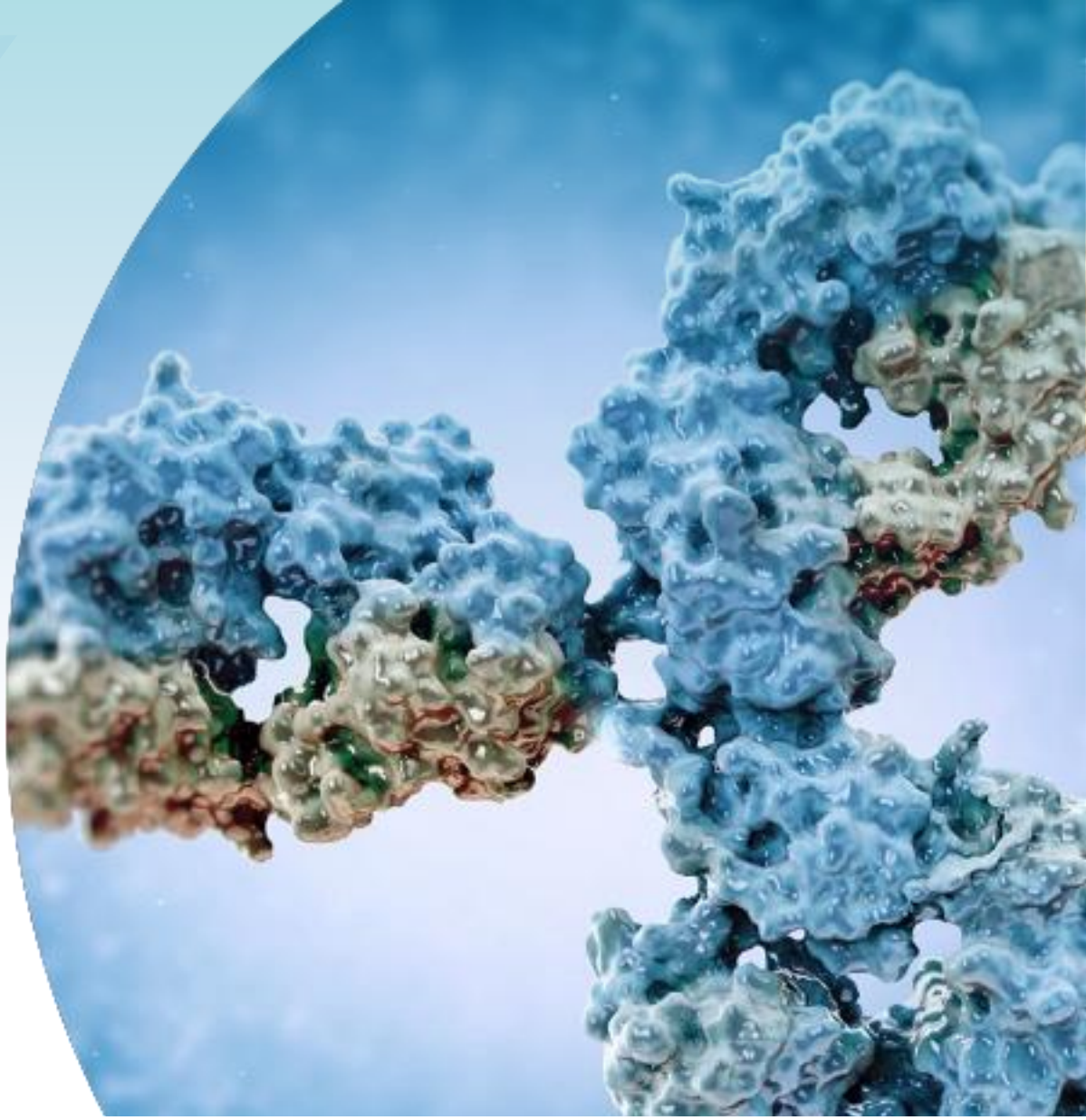
Antibody-Mediated Rejection (AMR) in Renal Allograft

- Phase 1 Study Approved by U.S. FDA
- Phase 1 / 2 Study Approved by China NMPA



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Antibody-Mediated Rejection (AMR) of Renal Allografts

Leading Cause of Late Graft Loss in Kidney Transplant Recipients

35K transplants/yr

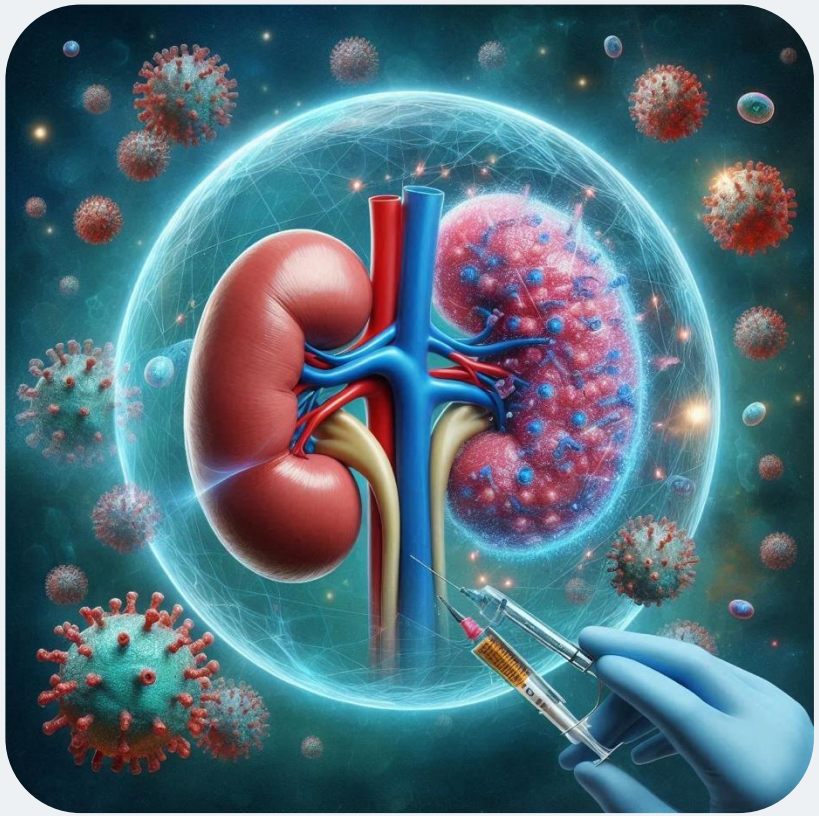
AMR contributes significantly to both acute and chronic rejection and ultimately leads to graft loss

~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

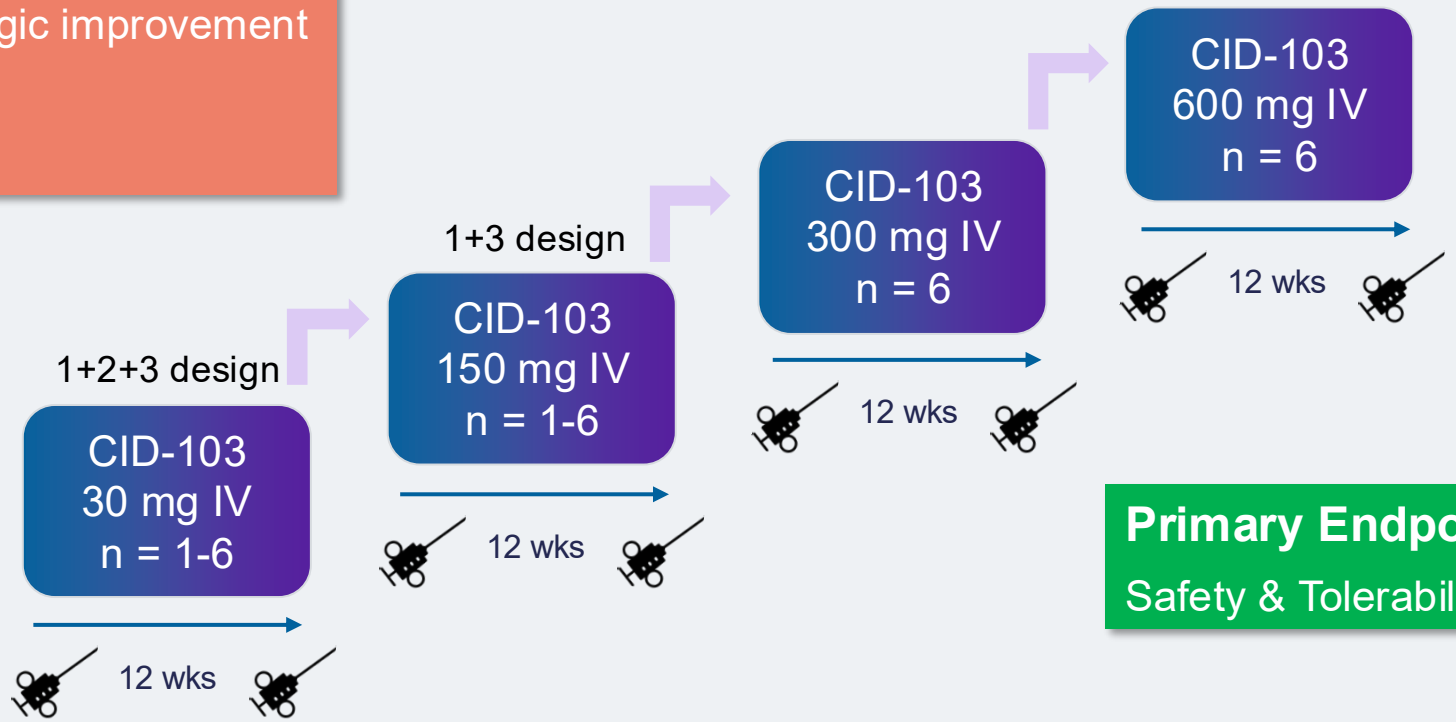
Approved U.S. Phase 1 Dose-Escalation Study in AMR

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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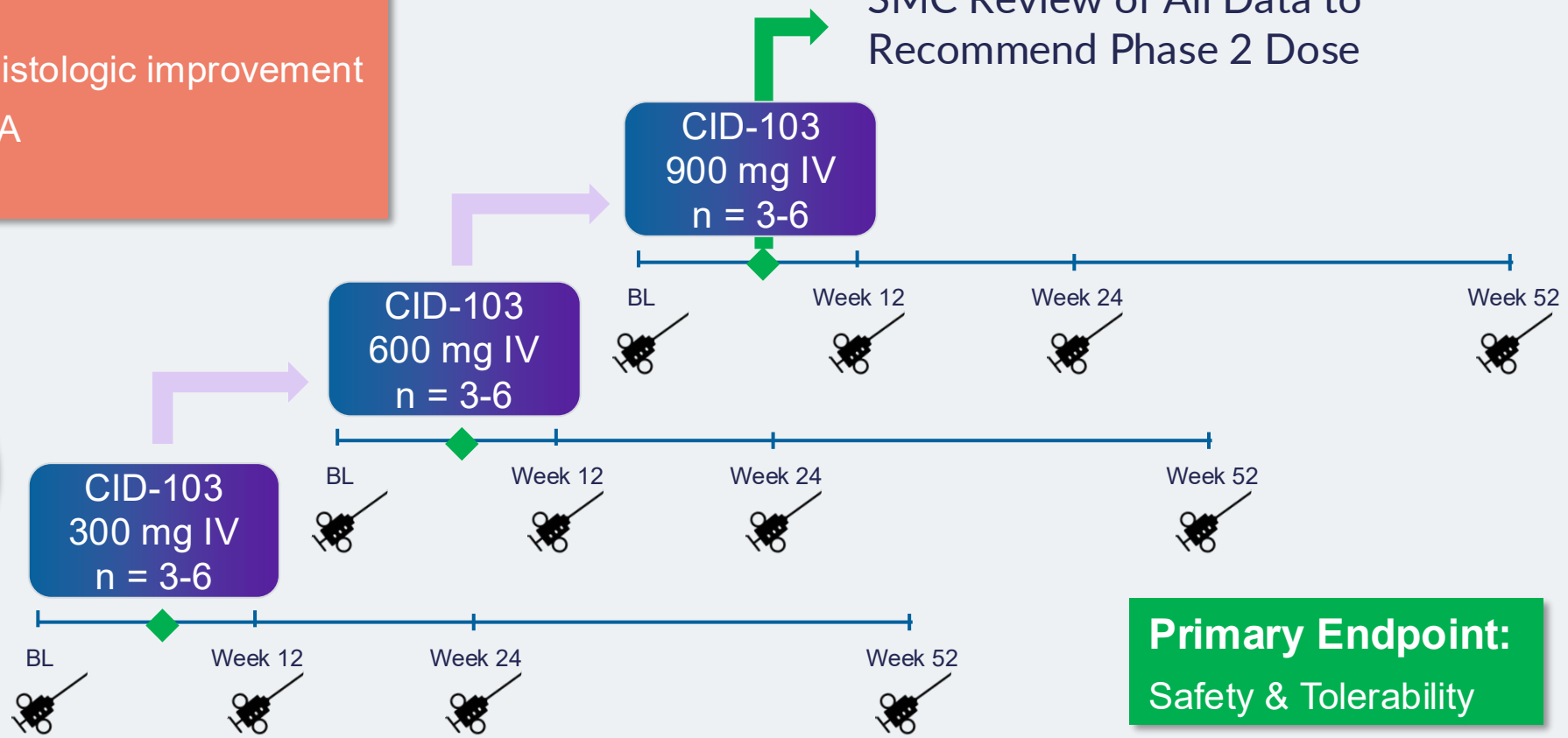
Approved China Phase 1 Dose-Escalation Study in AMR

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 2027



Primary Endpoint:
Safety & Tolerability

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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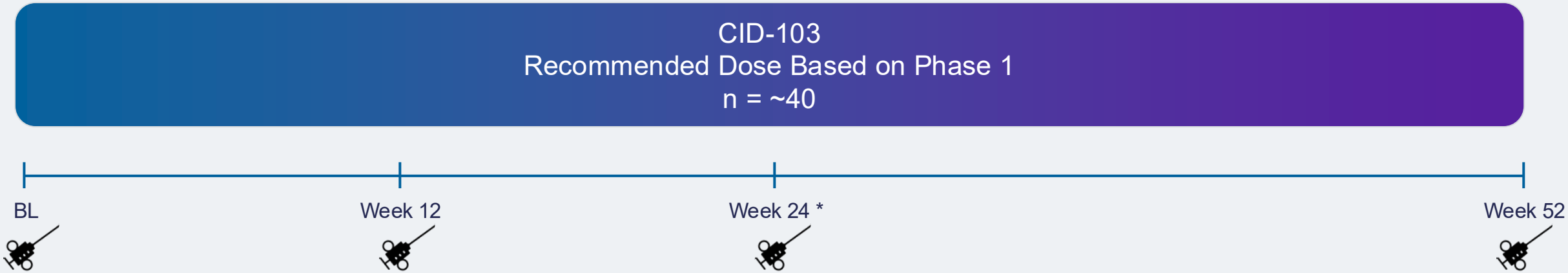
Approved Phase 2 AMR Study in China

Option Following Phase 1 Results

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 of biopsy and PD results

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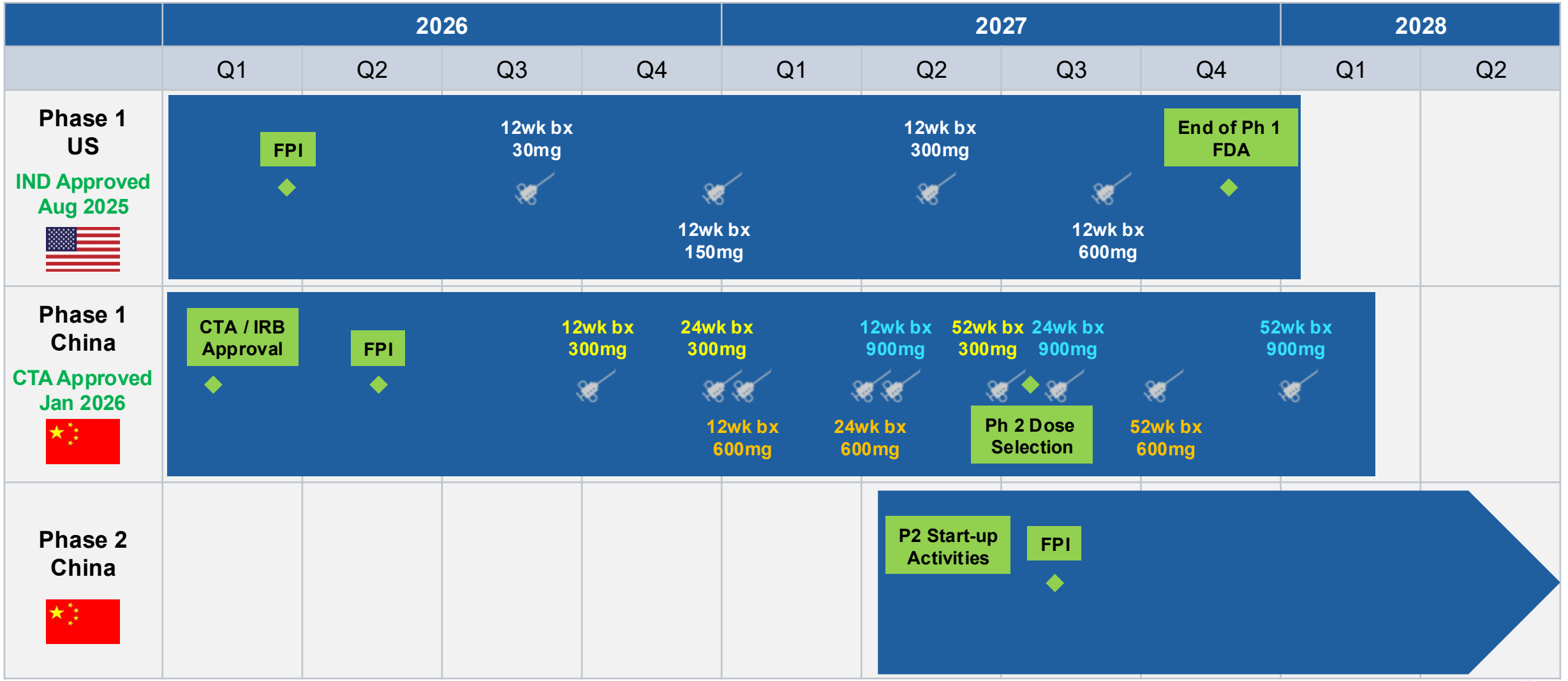
AMR Program Timelines and Anticipated Key Milestones

Biopsy / PD Marker Data Available for Public Presentation Beginning 2026



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

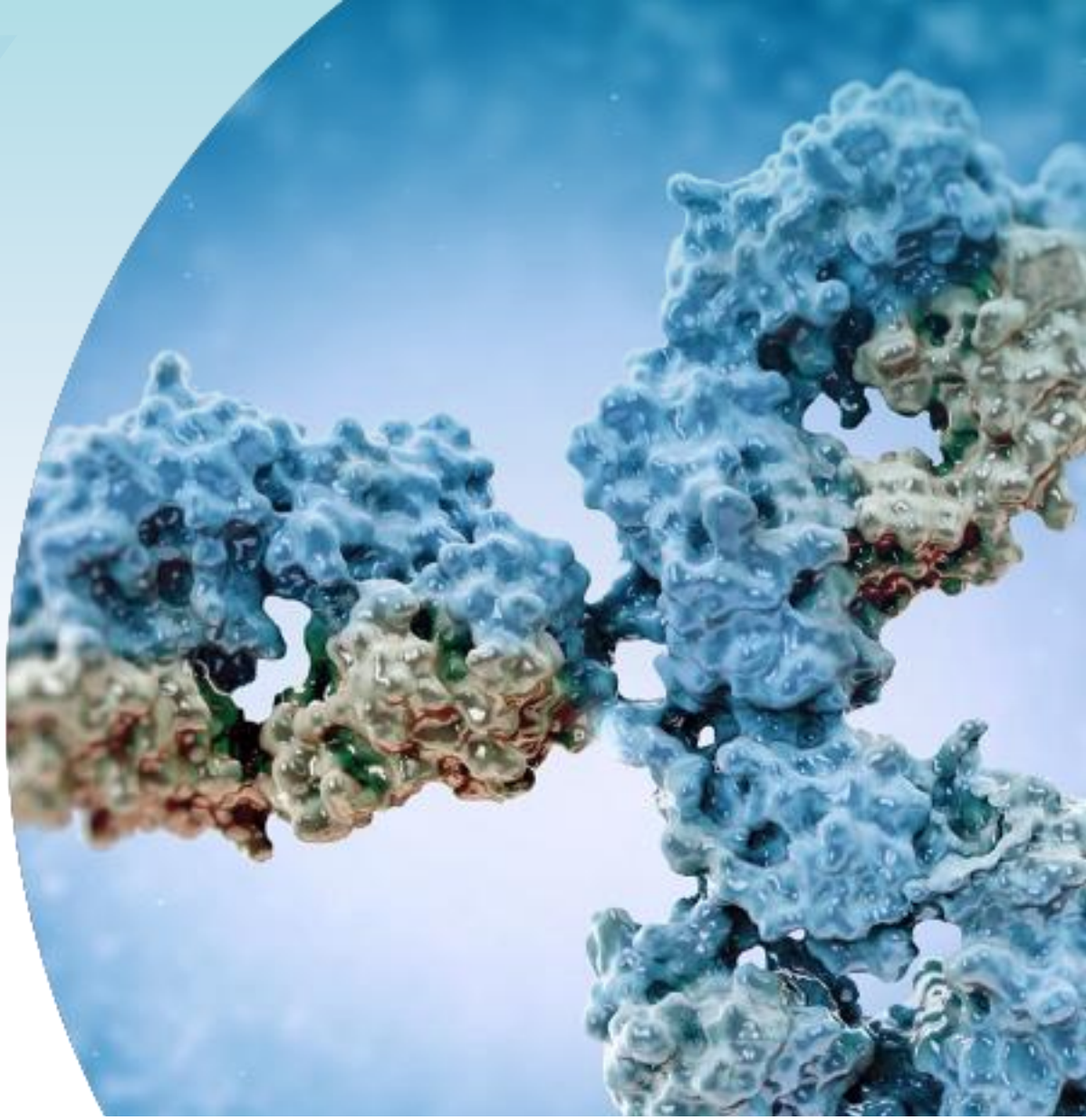
- XeriJect®: Non-aqueous technology
- Drug substance is reduced to a powder which is “wetted” with biocompatible diluents
- Creates an ultra-concentrated, ready-to-use, injectable, viscoelastic suspension

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
- Interim data presented at ASH 2026, Dec 7, 2025
- Additional interim data released Jan 12, 2026

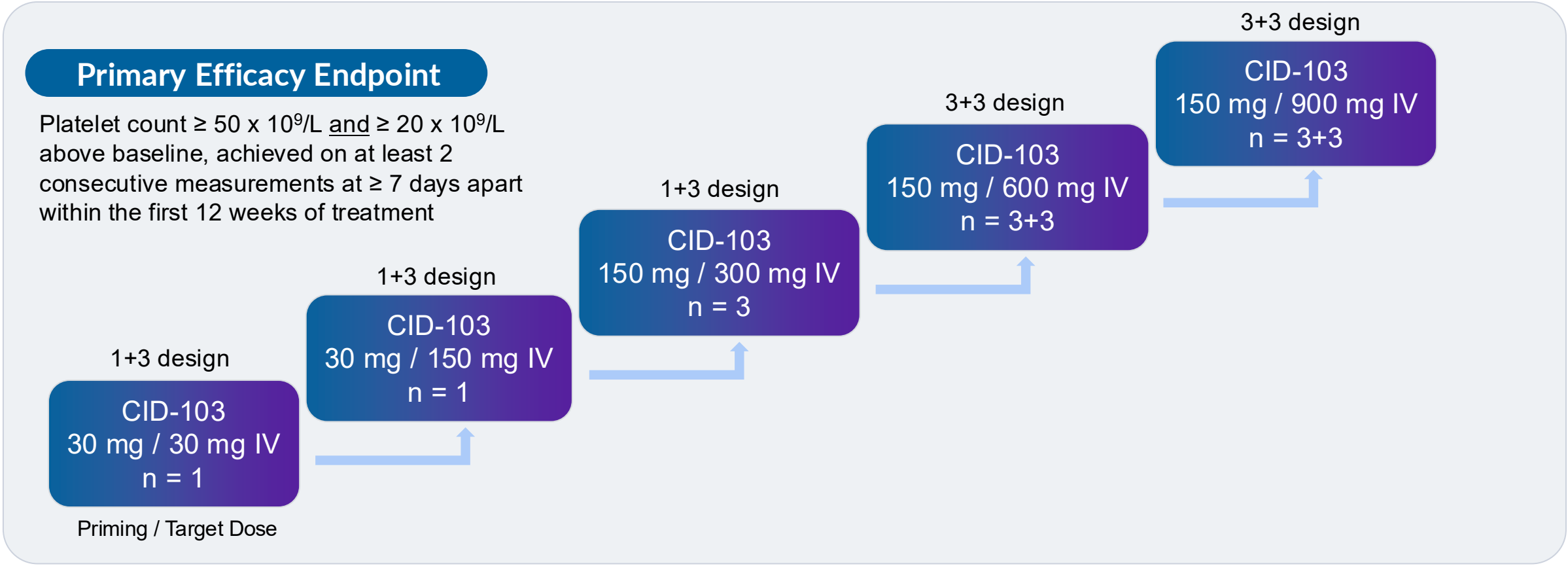


CASI Pharmaceuticals Announces Upcoming Presentation of Clinical Results for CID-103 at the 67th American Society of Hematology (ASH) Annual Meeting

- 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.

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

CID-103 ITP Phase 1 Demographic and Disease Characteristics

Demographic and Disease Characteristics	30mg / 30mg	30mg / 150mg	150mg / 300mg	150mg / 600mg	150mg / 900mg	Total
	N=1	N=1	N=3	N=5	N=6	N=16
Median age, y (range)	32	29	39（26-49）	34（33-55）	45（25-52）	36.5 (25-55)
Gender, n (%)						
Female, n (%)	1	0	1	2	4	8 (50%)
Male, n (%)	0	1	2	3	2	8 (50%)
Median duration of ITP, m (range)	14	44	27 (9-43）	27 (10-93）	28.5 (4-179）	27 (4-179）
Median baseline platelet count,$\times 10^9$/L (range)						
$<10\times10^9$/L	0	0	2	1	2	5
10 to $<30\times10^9$/L	1	1	1	4	4	11
Median # of Prior ITP therapies[&]	5	6	2 (2-3)	5 (3-10)	6 (3-10)	5 (2-10)
Karnofsky Performance Status (KPS)	100	100	100	100	100	100
Bleeding (with ITP-BAT bleeding score）						
S0M0O0	1	1	3	3	1	9
S1M0O0 *	0	0	0	0	1	1
S0M1O0 ⁎	0	0	0	0	1	1
S1M1O0 #	0	0	0	0	2	2
S2M1O0 ‡	0	0	0	1	0	1
S0M0O1 §	0	0	0	0	1	2
Concomitant medications — no. (%)						
Glucocorticoids	1	1	2	1	2	7
Thrombopoietin-receptor agonists	1	0	2	2	4	9
Danazol	0	0	0	1	0	1

& Including Glucocorticoids, IVIg, TPO-RA, and others
§ Menorrhagia was observed in subjects in the 600mg and 900 mg dose cohort respectively (1006 and 1010)
⁎Gum bleeding was observed in one subject in the 900 mg dose cohort (1012)
*Petechiae was observed in one subject in the 900 mg dose cohort (1011)
#Gum bleeding, petechiae and ecchymoses was observed in two subjects in the 900 mg dose cohort (1013 and 3003)
‡Gum bleeding and petechiae was observed in one subjects in the 600 mg dose cohort (3002)

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CID-103 ITP Phase 1 Preliminary Safety Data

Preliminary Safety Data	30 mg N=1	150 mg N=1	300 mg N=3	600 mg N=5	900 mg N=6	Total N=16
	n [m]*	n [m]	n [m]	n [m]	n [m]	n [m]
Any AE	1 [13]	1 [6]	3 [10]	3 [14]	5 [28]	13 [71]
DLT	0	0	0	0	0	0
Any TEAE	1 [13]	1 [6]	3 [10]	3 [14]	5 [28]	13 [71]
≥G3 TEAE	1 [2]	0	0	1 [1]	1 [2]	3 [5]
Any TRAE	1 [4]	1 [3]	3 [9]	2 [8]	4 [16]	12 [40]
≥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 [4]	5 [6]
TEAEs leading to:						
Treatment interruption	0	0	0	0	0	0
Dose reduction	0	0	0	0	1[2]	1[2]
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 1001 but was deemed a lab error by Safety Monitoring Committee (SMC)
*** Grade 3 neutropenia and Grade 3 leukopenia were reported on Patient 1011 in Week 4 which led to a treatment delay
**** Mild IRR events, four Grade 2 (Pt 1005, 1007, 1009, and 1010) and one Grade 1 (Pt 1011), were all reported during the administration of the priming dose

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CID-103 ITP Phase 1 Efficacy

Platelet Count (x 1000/μL)				
ORR = 80% Evaluable patients		Primary Endpoint	Complete Response	No Response
		PLT ≥ 50 & ≥ 20 above baseline	≥ 100	
30 mg	1001	✓		
150 mg	1003	✓	✓	
300 mg	1004			✓ *
	1007	✓	✓	
	1008	✓	✓	
600 mg	1005	✓	✓	
	3001			✓ *
	1006			✓
	3003	✓	treatment ongoing	
	5002	✓	✓	
900 mg	1009	✓	✓	
	1010	✓	✓	
	1011	✓	✓	
	1012	✓	✓	
	3002	treatment ongoing	treatment ongoing	
	1013	✓	✓	
Evaluable for Efficacy	**15 / 16**	**12 / 15**	**10 / 15**	**3 / 15**

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* Refractory to multiple prior treatments

CID-103 ITP Phase 1 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)

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CID-103 ITP Phase 1 Summary & Conclusions

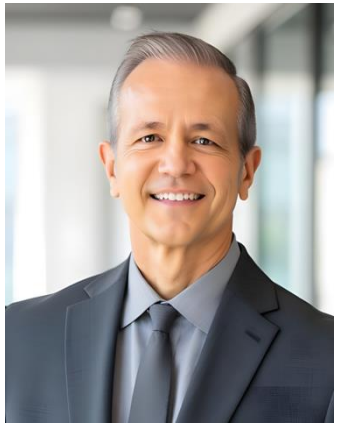
- Demonstrates proof-of-concept for CID-103 as a promising anti-CD38 targeted monoclonal antibody and rationale for future clinical development in diseases involving donor-directed and pathological autoantibodies
- Manageable safety profile; only two Grade 3 treatment-related events, no DLTs
- All IRRs occurred with priming dose and are due to low grade AEs
- To date, within the evaluable patients, primary endpoint achieved in 12 of 15 (80%) patients
    - To date, 10 of 15 (67%) 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 enrolled in 600 mg and 900 mg cohorts to expand safety / efficacy data for CID-103

CASI Corporate: Key Recent Milestone Announcements

- Divesture Agreement of Business in China
- Appointment of New Operating Chief Executive Officer – David Cory
- FDA IND Approval for Phase 1 Renal Allograft AMR Study in U.S.
- Appointment of Former Morphosys CBO – Barbara Krebs-Pohl – to Board of Directors
- Appointment of New Non-Executive Chairman – James Huang
- Positive Proof of Concept Results from CID-103 Phase 1 ITP Study at ASH 2025 / JPM 2026
- China NMPA Approval for Phase 1 / 2 Renal Allograft AMR Study in China

CASI U.S. Management Team

Proven Track-Record in Bringing Innovative Therapies to Market



David Cory, RPh, MBA
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Thank You

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