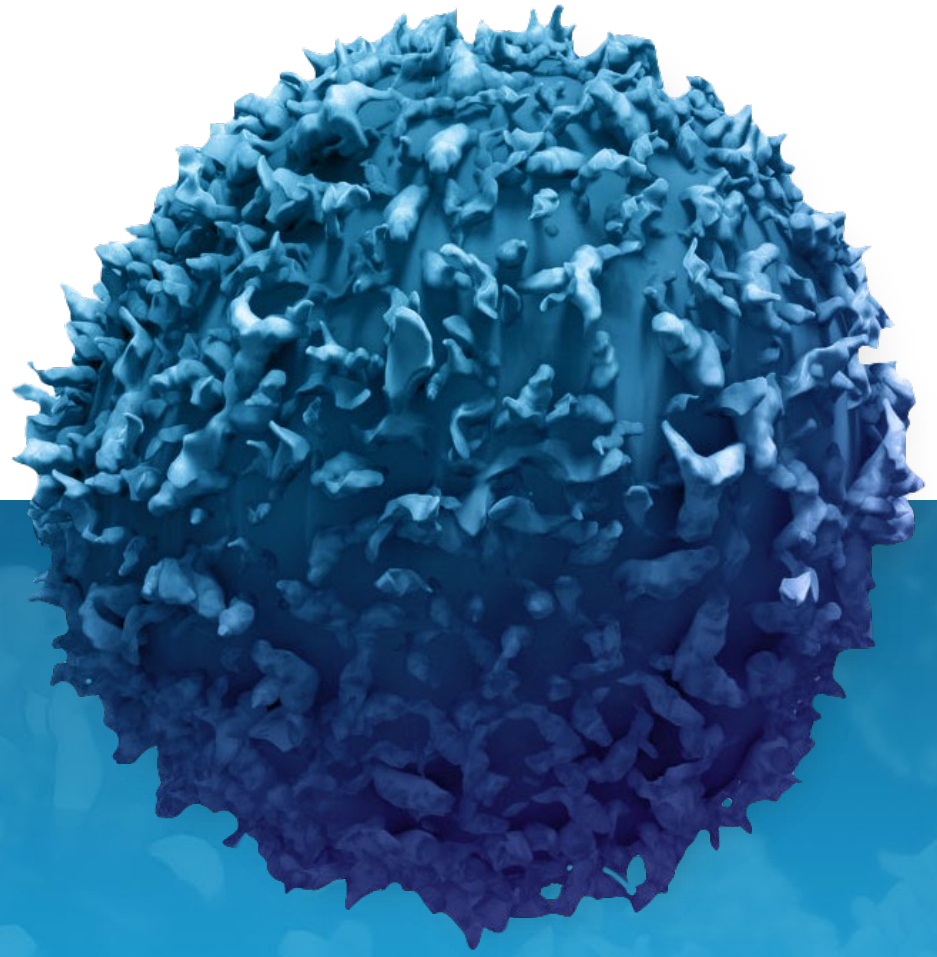


equillium®

Phase 3 EQUATOR Data Presentation

March 27, 2025

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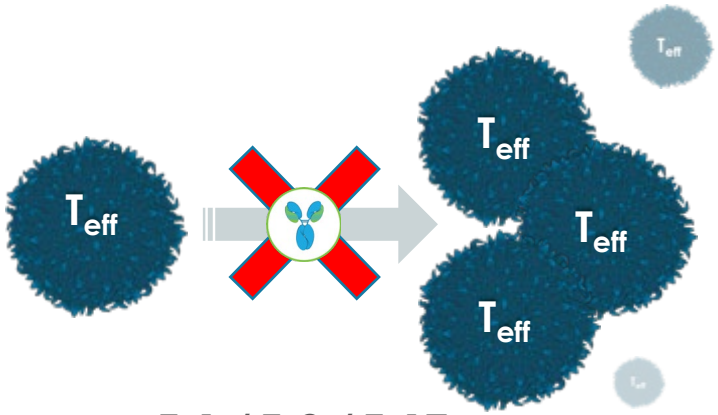
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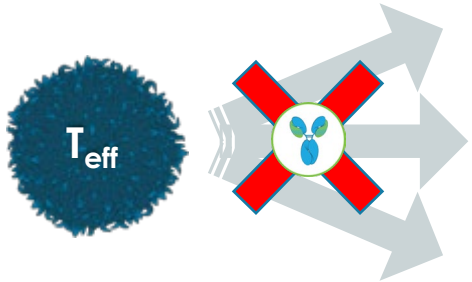
A Differentiated Approach to Treating Immuno-Inflammatory Disease

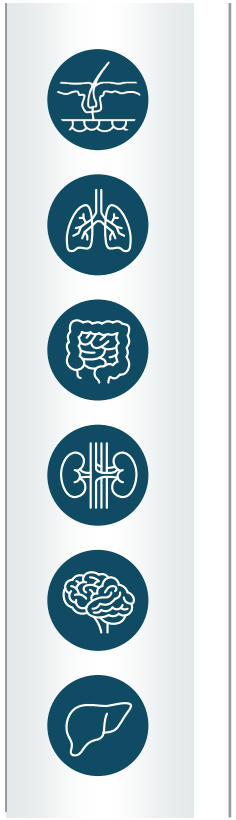
Selectively targets auto-reactive effector T cells, while sparing regulatory T cells to **promote immune tolerance and homeostasis, resulting in durable disease remission**

Synergistic inhibition of multiple T_{eff} cells and cytokines*

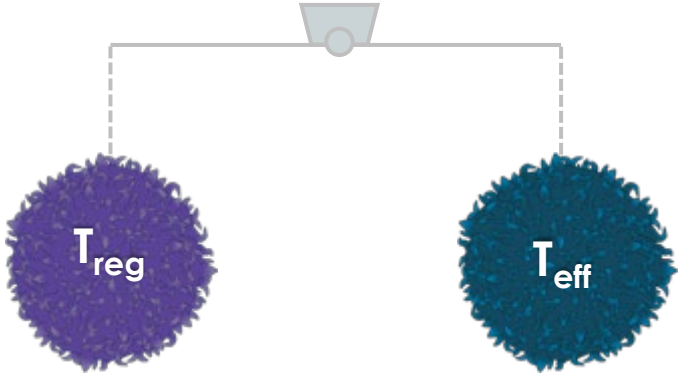


Inhibition of T_{eff} trafficking into key target organs





Restoration of immune regulation without broad immunosuppression



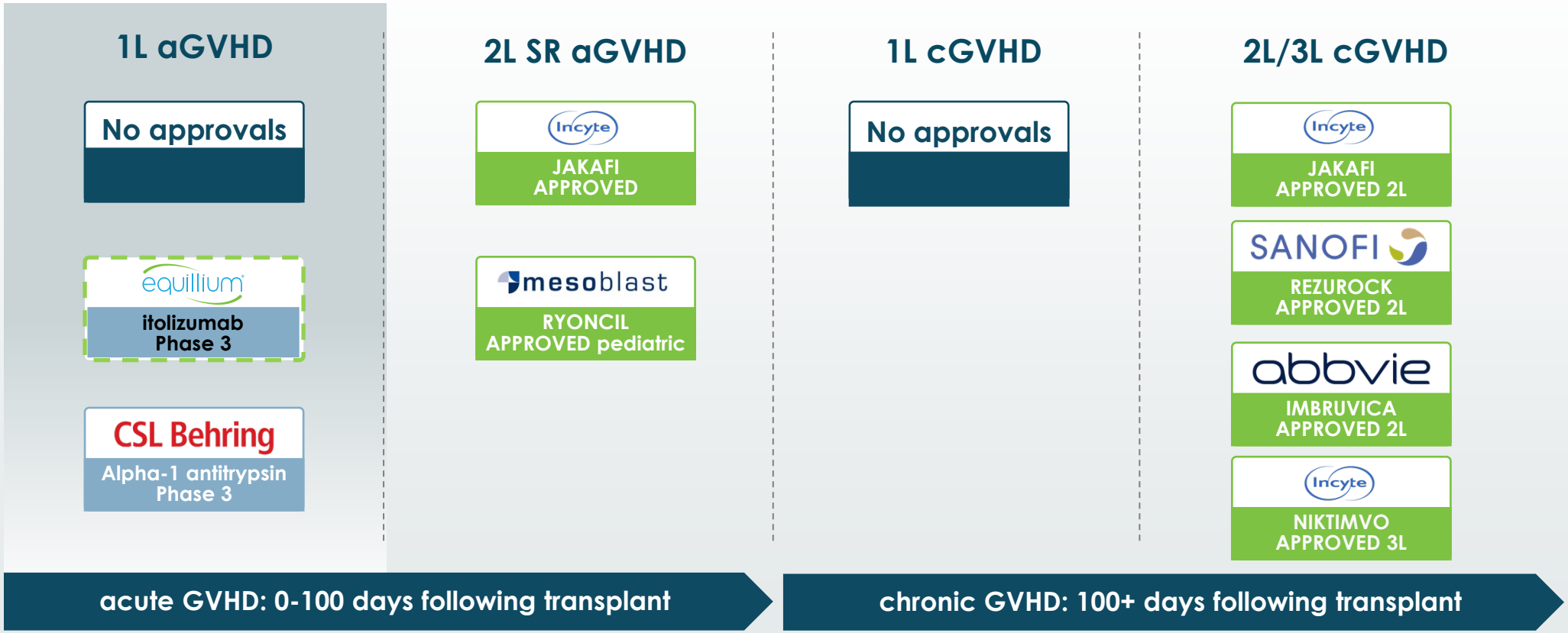
** including but not limited to IFN-γ, TNF-α, IL-4, IL-5, IL-6, IL-13 & IL-17*

aGVHD: No Drugs Approved in First-line Treatment

Growing strategic interest in GVHD with recently demonstrated market potential:

JAKAFI: US sales estimated at $500M

REZUROCK: US sales estimated at $425M (acquired by Sanofi $1.9B in 2021)



2024 revenue estimates, sources Evaluate Pharma & Incyte report, July 2024.

Abbreviations: GVHD, graft-versus-host disease; SR, steroid refractory; aGVHD, acute GVHD; cGVHD, chronic GVHD; 1L, first-line; 2L, second-line; 3L, third-line

Itolizumab

First-in-Class immune-modifying mAb targeting the CD6-ALCAM signaling pathway

Phase 3 EQUATOR Study Efficacy & Safety Data

EQUATOR Study: First-line Treatment of aGVHD

EQUATOR

Phase 3 randomized, double-blind, global pivotal study of itolizumab in 158 patients

John Koreth, MD, Dana-Farber Cancer Institute, Principal Investigator

9 of top 10 U.S. allogeneic HSCT centers

High exposure of itolizumab to key hospital systems and KOLs

Eligible Patients: Grade III-IV & Grade II with lower GI

Dosing: concomitant within 72 hours of high-dose corticosteroid treatment (2 mg/kg)

R

Itolizumab (n=79)
IV 1.6 mg/kg loading dose, followed by 0.8 mg/kg Q2W x 6 doses

Steroid tapering recommendation

Placebo (n=79)
IV Q2W x 7 doses

Day 1 | Day 15 | Day 29 | Day 43 | Day 57 | Day 71 | Day 85

Dosing Schedule: patients followed out to Day 365

Primary & Key Secondary Outcomes

- **CR at Day 29** (primary)
- **ORR at Day 29**
- **Durable CR Day 29 thru Day 99**

Additional Outcomes

- **CR at Day 99**
- **Duration of CR**
- **Failure Free Survival**
- **Overall Survival**

Abbreviations: aGVHD, acute graft-versus-host disease; GI, gastrointestinal; HSCT, hematopoietic stem cell transplant; R, randomization; IV, intravenous; Q2W, every other week; n, number of patients; KOL, key opinion leader; CR, complete response; ORR, overall response rate.

Baseline Demographics & Characteristics (ITT population)

	Itolizumab (n=79)	Placebo (n=79)	TOTAL* (n=158)
Age (years), median (range)	60 (21-73)	58 (18-75)	59 (18-75)
Sex, n (%)			
Male	44 (55.7)	39 (49.4)	83 (52.5)
Female	35 (44.3)	40 (50.6)	75 (47.5)
Region, n (%)			
Europe	41 (51.9)	38 (48.1)	79 (50.0)
North America	30 (38.0)	29 (36.7)	59 (37.3)
Asia	4 (5.1)	9 (11.4)	13 (8.2)
Australia	4 (5.1)	3 (3.8)	7 (4.4)
Organ Involvement at Baseline, n (%)			
Skin	32 (40.5)	32 (40.5)	64 (40.5)
Liver	9 (11.4)	6 (7.6)	15 (9.5)
UGI	34 (43.0)	30 (38.0)	64 (40.5)
LGI	71 (89.9)	75 (94.9)	146 (92.4)
aGVHD Clinical Grade at Baseline, n (%)			
0	0	1 (1.3)	1 (0.6)
I	0	1 (1.3)	1 (0.6)
II	22 (27.8)	16 (20.3)	38 (24.1)
III	48 (60.8)	50 (63.3)	98 (62.0)
IV	9 (11.4)	11 (13.9)	20 (12.7)
Minnesota High Risk	40 (50.6)	48 (60.8)	88 (55.7)

Topline data with a cut-off date of 11-Dec-2024 and subject to change. ITT population includes all randomized subjects who completed through Day 29 or discontinued the study.*
Abbreviations: ITT, intent-to-treat; n, number of patients; UGI, upper gastrointestinal; LGI, lower gastrointestinal; aGVHD, acute graft-versus-host disease

Summary of Safety Results

Itolizumab demonstrated favorable safety and tolerability

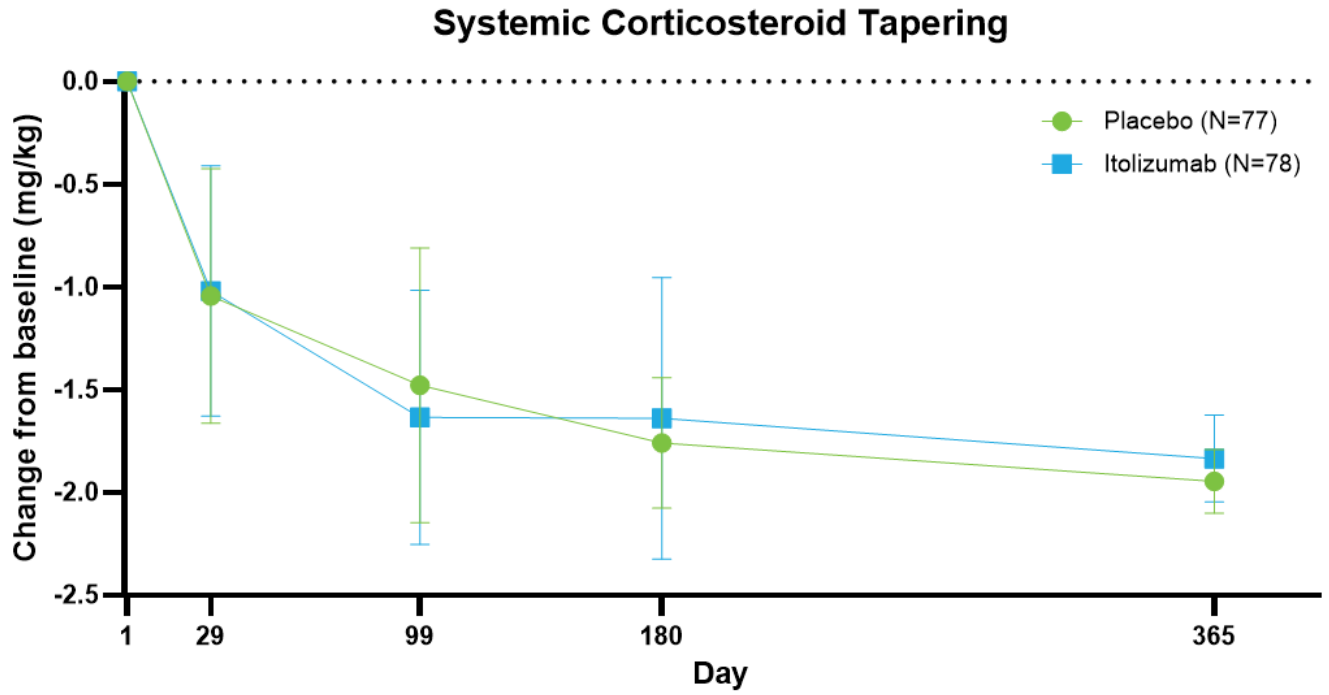
Did not increase the risk of clinical sequelae, including rates of infection and sepsis

Treatment Emergent Adverse Events (Safety Population / mITT) Event, n (%)	Itolizumab N=78	Placebo N=77	Total N=155
Subjects with any TEAE	77 (98.7)	74 (96.1)	151 (97.4)
Subjects with TEAE leading to study drug discontinuation	10 (12.8)	3 (3.9)	13 (8.4)
Subjects with TESAEs	45 (57.7)	47 (61.0)	92 (59.4)
Infections and infestations TESAEs	22 (28.2)	29 (37.7)	51 (32.9)
Treatment-related TESAEs	5 (6.4)	3 (3.9)	8 (5.2)
Subjects with TEAE leading to death	18 (23.1)	25 (32.5)	43 (27.7)
Treatment-related TEAE leading to death	0 (0)	0 (0)	0 (0)
Most Common TESAEs			
Sepsis	4 (5.1)	14 (18.2)	18 (11.6)
Respiratory failure	3 (3.8)	4 (5.2)	7 (4.5)
Pneumonia	3 (3.8)	3 (3.9)	6 (3.9)
Septic shock	2 (2.6)	4 (5.2)	6 (3.9)

Topline data as of 11 December 2024; subject to change.
Abbreviations: mITT, modified intent-to-treat (subjects who received at least one dose; removes three patients from ITT that did not receive any study treatment); TEAE, treatment-emergent adverse event; TESAE treatment-emergent serious adverse event.

Steroid Tapering

Median initial dose on Day 1 was 1.79 and 1.80 mg/kg MPE or equivalent for itolizumab and placebo, respectively (mITT)

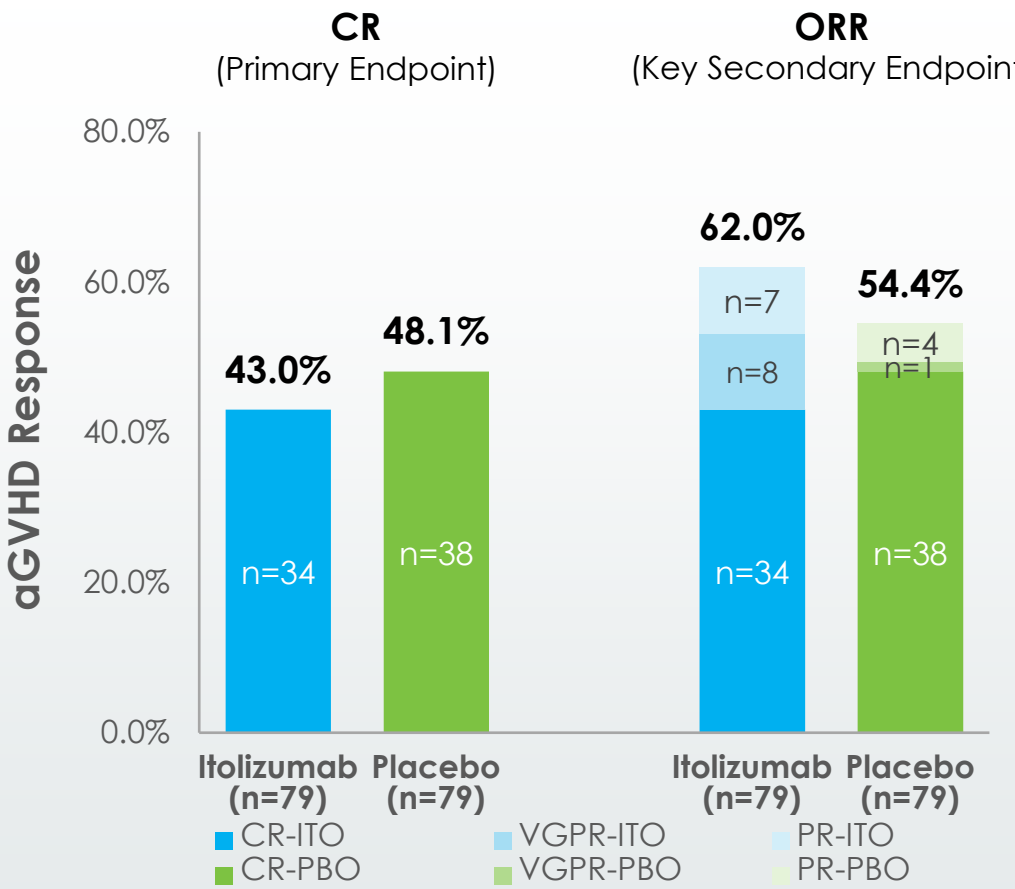


Number of subjects					
Itolizumab	78	67	46	36	20
Placebo	77	61	43	30	13

Topline data with a cut-off date of 11-Dec-2024 and subject to change.
Data presented as mean (SD)
Abbreviations: mITT, modified intent-to-treat; MPE, methylprednisolone

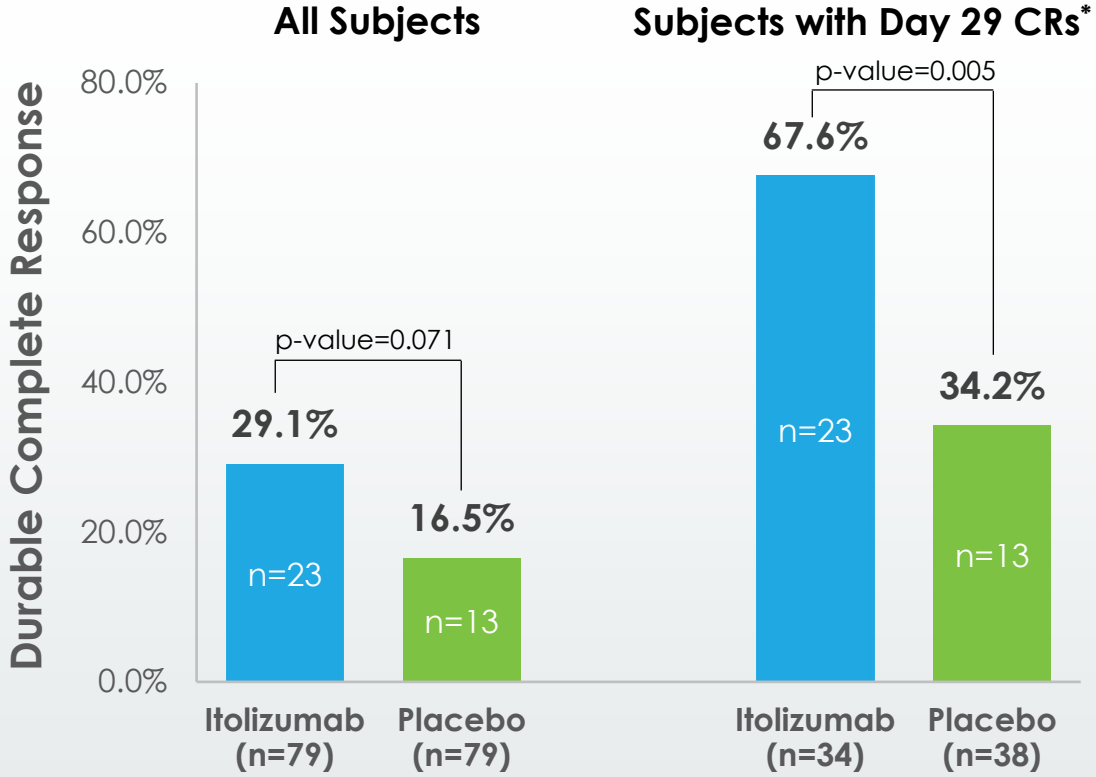
Primary and Key Secondary Outcomes

Day 29 CR and ORR (ITT)



Durable CR* Day 29-99 (ITT)

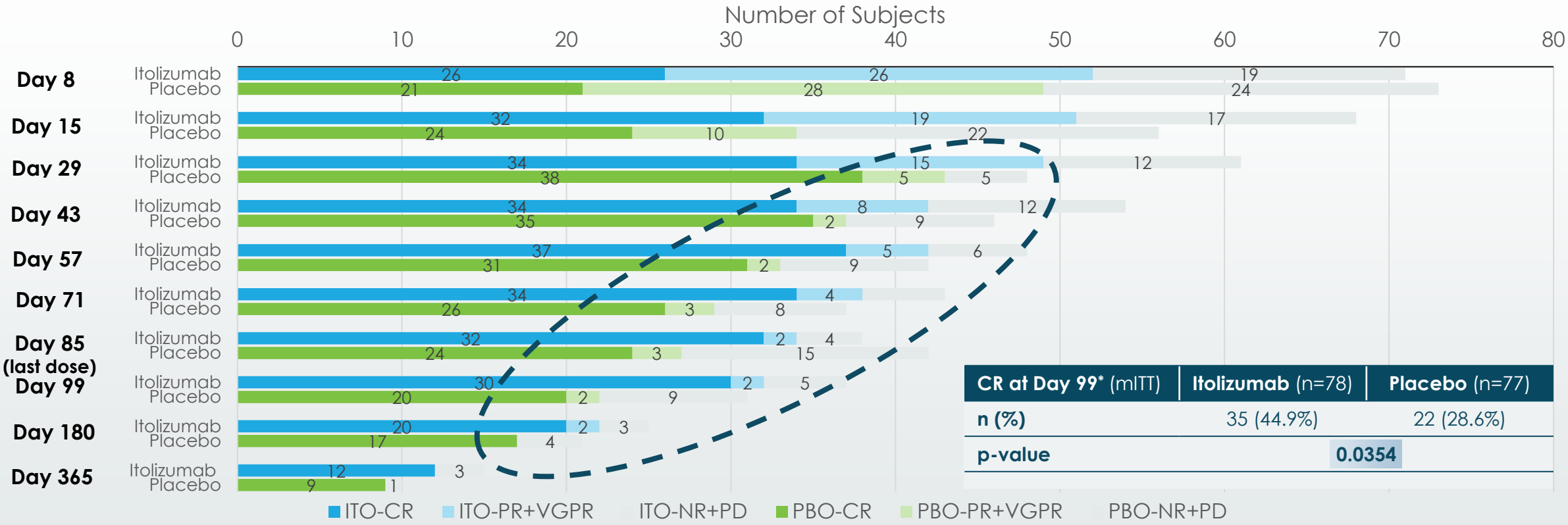
(Key Secondary Endpoint)



*Topline data with a cut-off date of 11-Dec-2024 and subject to change; *D99 estimate as of 12-Feb-2025 with one subject pending final data (post-hoc analysis).*
ITT includes all randomized subjects who completed through Day 29 or discontinued the study. Early Termination or Unscheduled Visits that occurred between Day 23 and 36 were re-mapped to Day 29 if nominal visit was missing (as described in FDA agreed upon Statistical Analysis Plan).
Durable CR endpoint definition: maintained CR at each visit from Day 29 to 99 and did not receive additional aGVHD therapy or steroids ≥1.8 mg/kg MPE or equivalent.
Abbreviations: CR, complete response; PR, partial response; ORR, overall response rate; VGPR, very good partial response; ITT, Intent-to-treat; aGVHD, acute graft-versus-host disease; ITO, itolizumab; PBO, placebo; n, number of patients

CR at Day 99: Achieved Statistical Significance

Itolizumab maintains **durable response through drug exposure window** compared to placebo

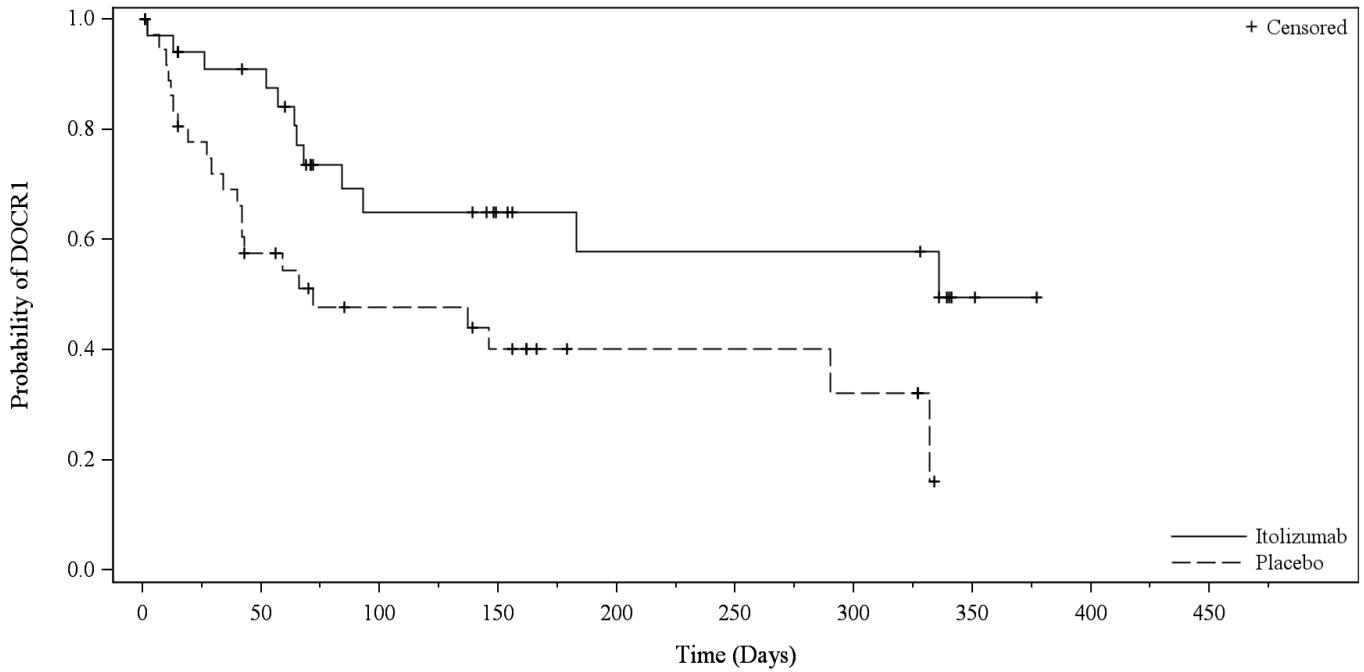


CR at Day 99* (mITT)	**Itolizumab** (n=78)	**Placebo** (n=77)
n (%)	35 (44.9%)	22 (28.6%)
p-value	**0.0354**	

*Graph with topline data with a cut-off date of 11-Dec-2024 and subject to change; *D99 estimate as of 12-Feb-2025 with one patient pending final data (post-hoc analysis).*
Early termination or Unscheduled visits that occurred within a visit's analysis window were assigned to that visit.
Abbreviations: GVHD, graft versus host disease; ITO, itolizumab; CR, complete response; PD, progressive disease; PR, partial response; VGPR, very good partial response; mITT, modified intent-to-treat; PBO, placebo; NR, no response; n, number of patients

Duration of Complete Response: Achieved Statistical Significance

Itolizumab Complete Responders had **statistically significant DOCR1** with a median 336 days vs. 72 days observed on placebo



DOCR1 (ITT)	Itolizumab (n=34)	Placebo (n=38)
Total Subjects with Events, n	12	22
Death	5	4
Received new anti-GVHD Therapy	1	2
Increase in steroids to ≥1.8 mg/kg MPE	1	2
Increase by 1 stage in any organ	5	14
Subjects Censored*, n	22	16
Median (95% CI), days	**336** (84.0, NE)	**72** (40.0, 332)
Hazard Ratio (95% CI)	0.38 (0.18, 0.82)	
p-value	**0.0166**	

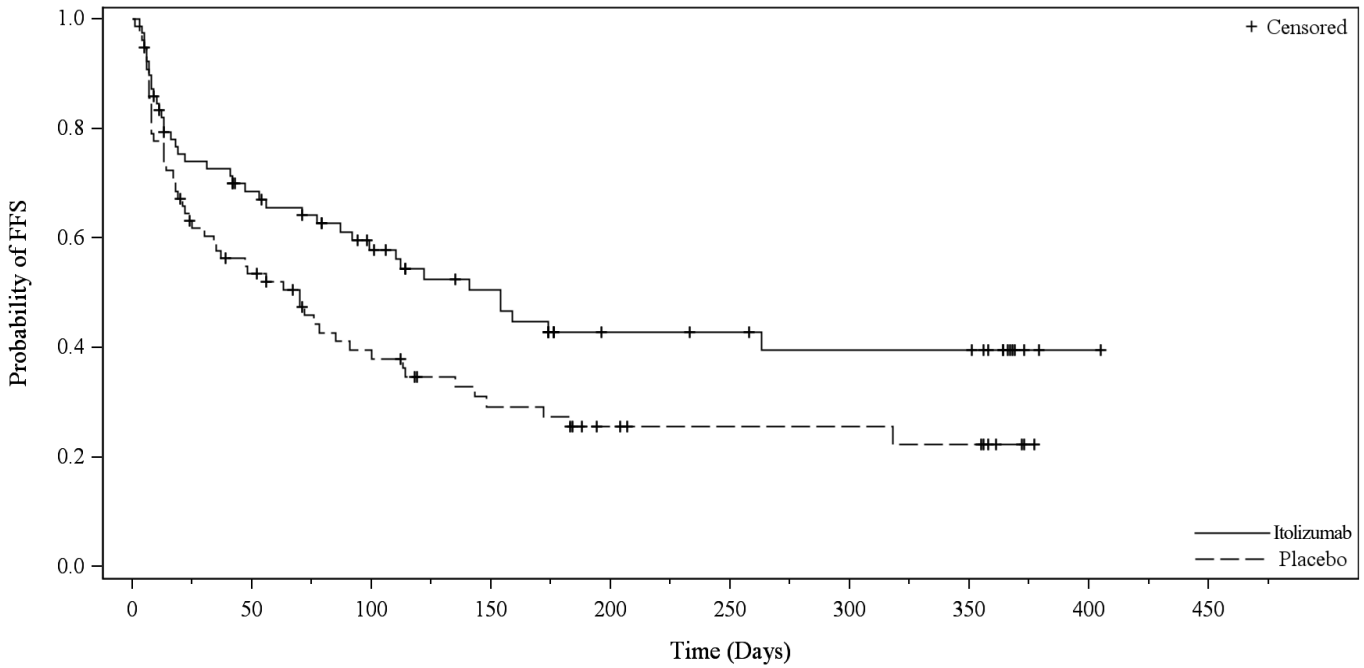
DOCR1: *Time from Day 29 CR to death, new systemic anti-aGVHD therapy, increase in systemic corticosteroids to ≥1.8 mg/kg MPE, or any increase by 1 stage from nadir in any organ. Topline data with a cut-off date of 11-Dec-2024 and subject to change.*

**Censored subjects are those that are currently ongoing in the study or discontinued the study but did not have an event.*

Abbreviations: DOCR, duration of complete response; GVHD, graft versus host disease; CI, confidence interval; MPE, methylprednisolone; n, number of patients

Failure Free Survival: Achieved Statistical Significance

Itolizumab demonstrated **statistically significant Failure Free Survival** with a median 154 days vs. 70 days observed on Placebo

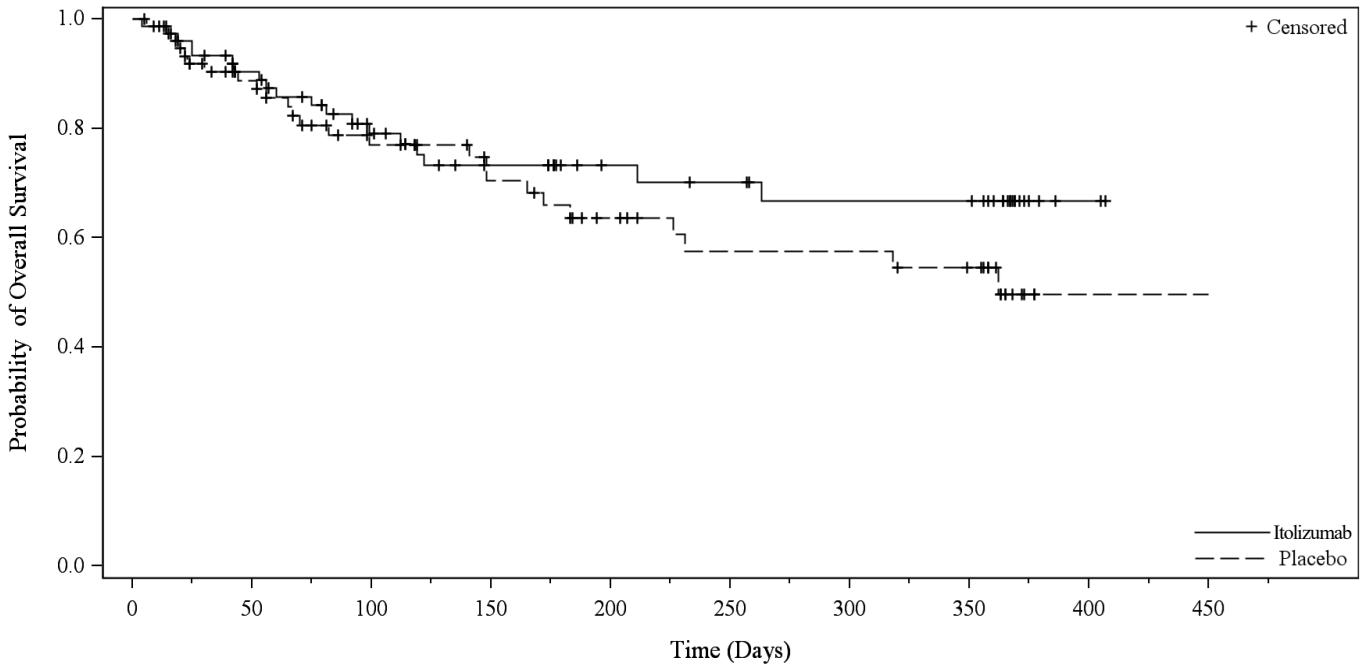


Failure Free Survival (mITT)	Itolizumab (n=78)	Placebo (n=77)
Event, n	40	52
Death	7	7
Primary disease relapse	6	7
Received new anti-GVHD therapy (acute or chronic)	27	38
Subjects Censored*, n	38	25
Median (95% CI), days	**154** (87.0, NE)	**70** (30.0, 113)
Hazard Ratio (95% CI)	**0.66** (0.43, 1.00)	
p-value	**0.0430**	

Failure Free Survival: *Time from Day 1 to earliest occurrence of primary disease relapse, initiation of new systemic anti-GVHD therapy, or death of any cause.*
Topline data with a cut-off date of 11-Dec-2024 and subject to change.
**Censored subjects are those that are currently ongoing in the study or discontinued the study but did not have an event.*
Abbreviations: GVHD, graft versus host disease; CI, confidence interval; mITT, modified intent-to-treat; FFS, failure free survival; NE, not estimable; n, number of patients

Overall Survival: Demonstrated Positive Trend

Itolizumab demonstrated **positive trend in Overall Survival** with mortality at 24.4% vs. 32.5% observed on placebo



Overall Survival (mITT)	Itolizumab (n=78)	Placebo (n=77)
Deaths, n	**19 (24.4%)**	**25 (32.5%)**
Subjects Censored*, n	59	52
KM Rate (95% CI)		
At Day 99	79.1(67.1, 87.1)	76.9(64.5, 85.5)
At Day 180	73.2(60.2, 82.6)	65.9(51.7, 76.8)
At Day 365	66.7(51.4, 78.1)	49.6(32.7, 64.4)
Median (95% CI), days	NE (NE, NE)	362 (183,NE)
Hazard Ratio (95% CI)	0.74 (0.41 1.35)	
p-value	0.3753	

Overall Survival: *Time from treatment start date to date of death due to any cause.*
Topline data with a cut-off date of 11-Dec-2024 and subject to change.
**Censored subjects are those that are currently ongoing in the study or discontinued the study but did not have an event of death.*
Abbreviations: KM, Kaplan-Meier; mITT, modified intent-to-treat; NE, not estimable; n, number of patients; CI, confidence interval

Summary of Efficacy Results

Achieved statistically significant and clinically meaningful longer-term outcomes

Endpoint, n (%)	Itolizumab ITT (N=79) / mITT (N=78)	Placebo ITT (N=79) / mITT (N=77)	p-value
CR at Day 29 (ITT), n (%) **(Primary Endpoint)**	34 (43.0)	38 (48.1)	NSS
ORR at Day 29 (ITT), n (%) **(Key Secondary Endpoint)**	49 (62.0) *VGPR = 8 (10.1)* *PR = 7 (8.9)*	43 (54.4) *VGPR = 1 (1.3)* *PR = 4 (5.1)*	NSS
Durable CR at Day 99 (ITT)[#], n (%) **(Key Secondary Endpoint)**	23 (29.1)	13 (16.5)	NSS
Durable CR at Day 99 (of Day 29 CRs) (ITT)[#*], n (%)	23 (67.6)	13 (34.2)	0.005
CR at Day 99 (mITT)[*], n (%)	35 (44.9)	22 (28.6)	0.035
Duration of CR (mITT), median days	336 days	72 days	0.017
Failure Free Survival (mITT) Kaplan-Meier estimate of rate at Day 365, % Median days	 39.5% 154 days	 22.9% 70 days	 0.043
Overall Survival (mITT) Kaplan-Meier estimate of rate at Day 365, % Deaths, n	 66.7% 19	 49.6% 25	 NSS

Data based on 11 December 2024 database lock, unless otherwise noted, and subject to change. [#]Estimate as of 12 February 2025 with one subject pending final analysis; [*]Post-hoc analysis. Analyses were pre-specified in the Statistical Analysis Plan, unless indicated as a post-hoc analysis.
Abbreviations: ITT, intent-to-treat; mITT, modified intent-to-treat (subjects who received at least one dose; removes three patients that did not receive any study treatment); CR, complete response; NSS, not statistically significant; VGPR, very good partial response; PR, partial response

Itolizumab: Executive Summary

Breakthrough Therapy designation submitted and FDA has granted a meeting to review potential for Accelerated Approval, with outcome expected May 2025 (Orphan Drug & Fast Track designations previously granted)

Itolizumab Phase 3 EQUATOR study in first-line acute graft-versus-host disease topline data demonstrates:

- Favorable safety & tolerability profile
- No meaningful difference in CR and ORR at Day 29
- **Achieved statistical significance and/or clinically meaningful benefit in longer term outcomes:**
  - Durable CR thru Day 99, CR at Day 99, Duration of CR, failure free survival
  - Positive trend in overall survival

Currently no drugs approved for first-line acute GVHD

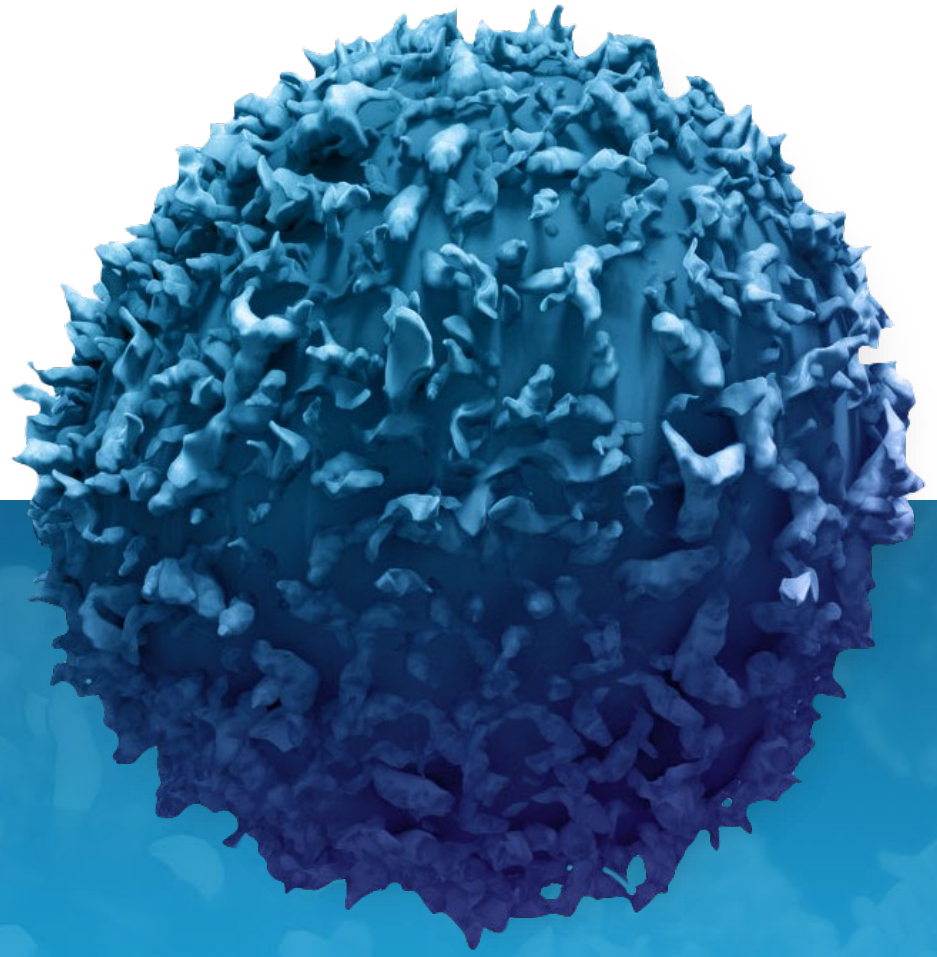
Significant unmet medical need and attractive market opportunity:

- **Critical need for improved longer-term outcomes and survival**
- ~ 5,000 patients develop acute GVHD annually in US
- Mortality in patients with aGVHD remains very high, with overall survival at 1-year as low as 40%*
- Approved therapies in GVHD approaching $1 billion in revenue

Commercial scale manufacturing in place (Biocon) and ability to launch independently with small commercial team

Potential opportunities for rapid indication expansion into other GVHD segments through single Phase 3 studies

** 1-year OS of 70% in patients with grade II aGVHD and 40% in patients with grade III-IV aGVHD; Malard et al., Nat. Rev. Dis. Primers, 2023.*
Abbreviations: CR, complete response; ORR, overall response rate; GVHD, graft-versus-host disease



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Thank you

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