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Reimagining Cancer Treatment

Axatilimab AGAVE-201 Positive Top-Line Data Call / July 2023

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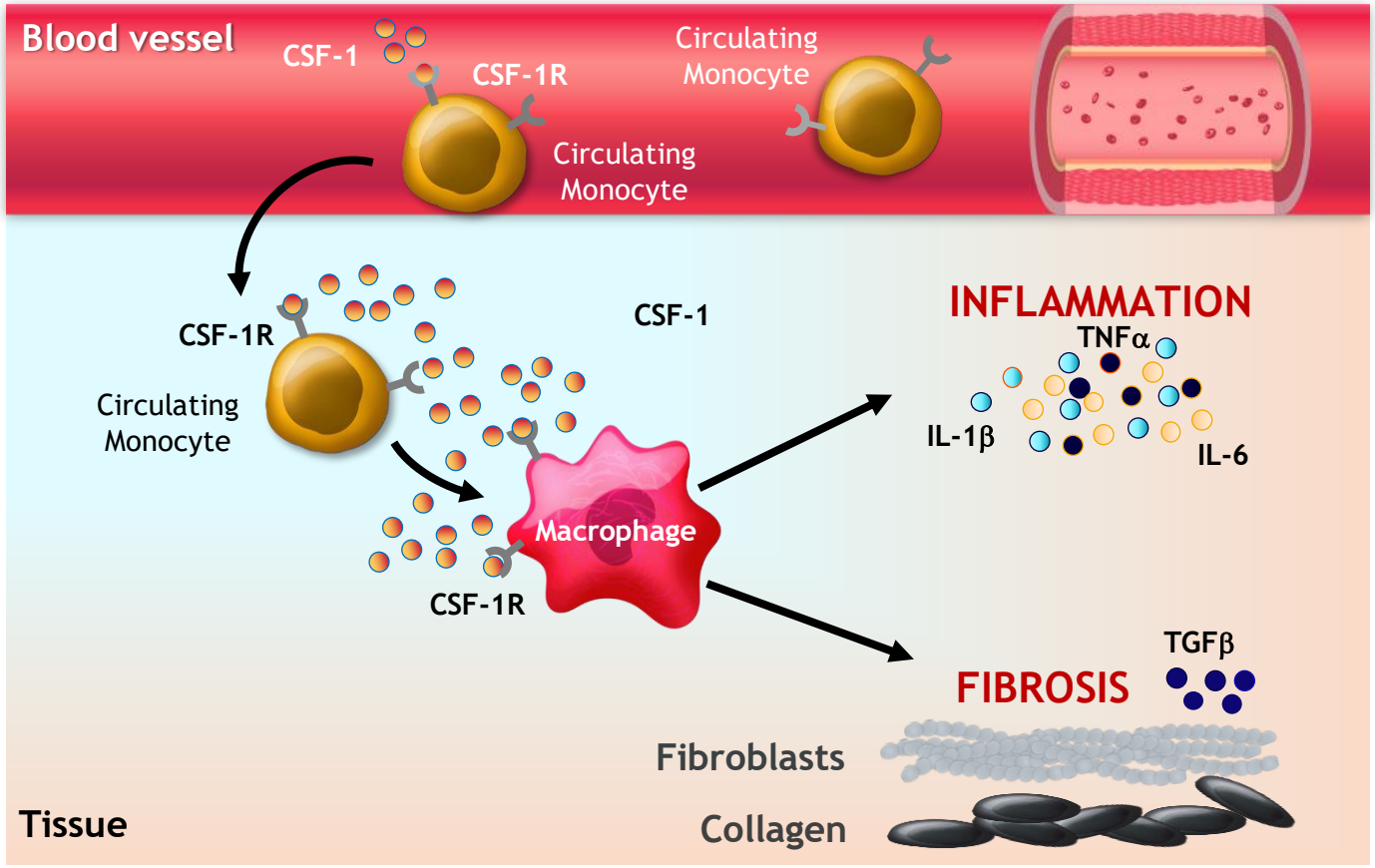
AGAVE-201 provides compelling evidence of the benefit axatilimab could offer patients with refractory cGVHD

- All cohorts in AGAVE-201 met the primary endpoint
- Durable responses accompanied by a reduction in symptom burden
- Axatilimab well tolerated; most common AE events were consistent with on target effects and prior trials of axatilimab
- AGAVE-201 to form the basis for an expected BLA submission by year-end pending agency agreement

AGAVE-201 results provide data to support optimal dose selection

Axatilimab is the first cGVHD treatment to target the disease-modifying macrophage

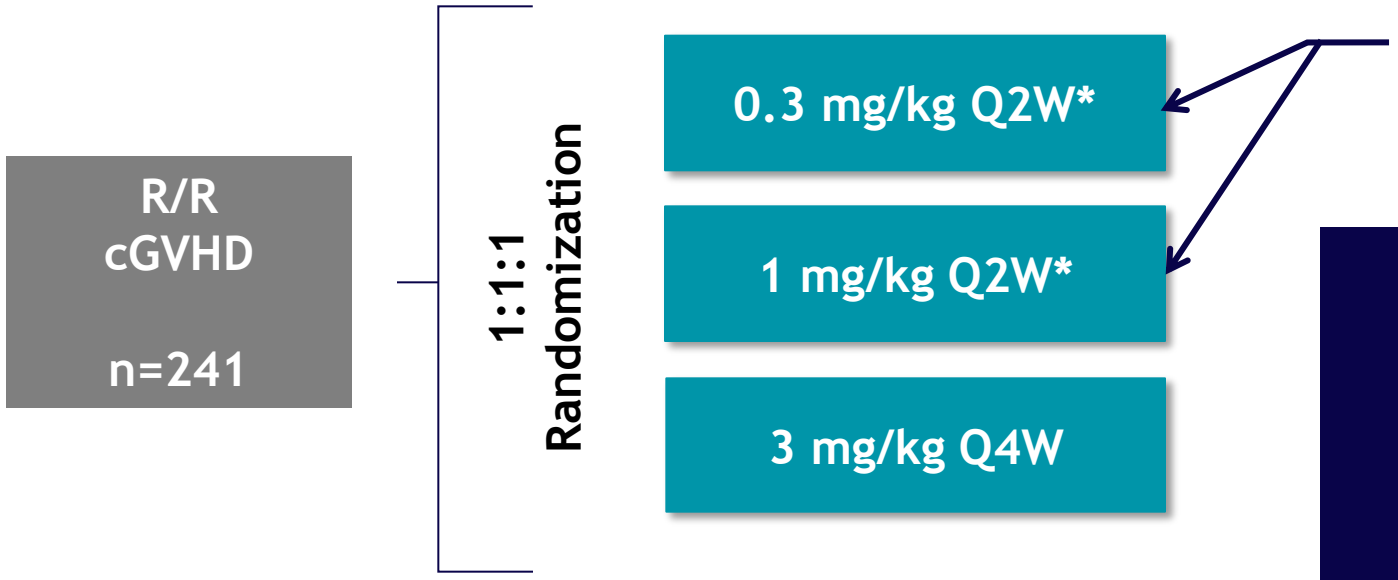
CSF-1R mediates pro-inflammatory and pro-fibrotic monocyte/macrophage differentiation and activation[1]



- Axatilimab may offer a differentiated, practice-changing intervention in cGVHD
- Targeting monocyte-derived macrophages impacts both fibrotic and inflammatory processes and suggests potential to benefit patients alone or in combination with standard of care therapies already available for the management of this disease
- Benefits have been observed across all organ systems including lung, skin, and GI

1. Figure Adapted from MacDonald KP et al. Blood. 2017;129(1):13-21; Chitu et al. Current Opinion in Immunology. 2006;18(1): 39-48

AGAVE-201, a global pivotal trial designed to identify an optimal dose in chronic GHVD patients



** Patients had the option to switch to cohort specific Q4W dose after 6 months on trial*

Primary Endpt: ORR[2] by Cycle 7 Day 1

- Statistical significance achieved if lower bound of the 95% CI of ORR exceeds 30%

Secondary Endpoints:

- Duration of response
- Modified Lee cGVHD Symptom Scale assessment
- Percent reduction in daily steroid dose
- Organ specific response rates

Inclusion criteria:

- 2 years and older[1]
- Recurrent or refractory active cGVHD after ≥ 2 lines of systemic Tx

Stratification factors:

- Prior treatment with ibrutinib, ruxolitinib or belumosudil
- Severity of cGVHD

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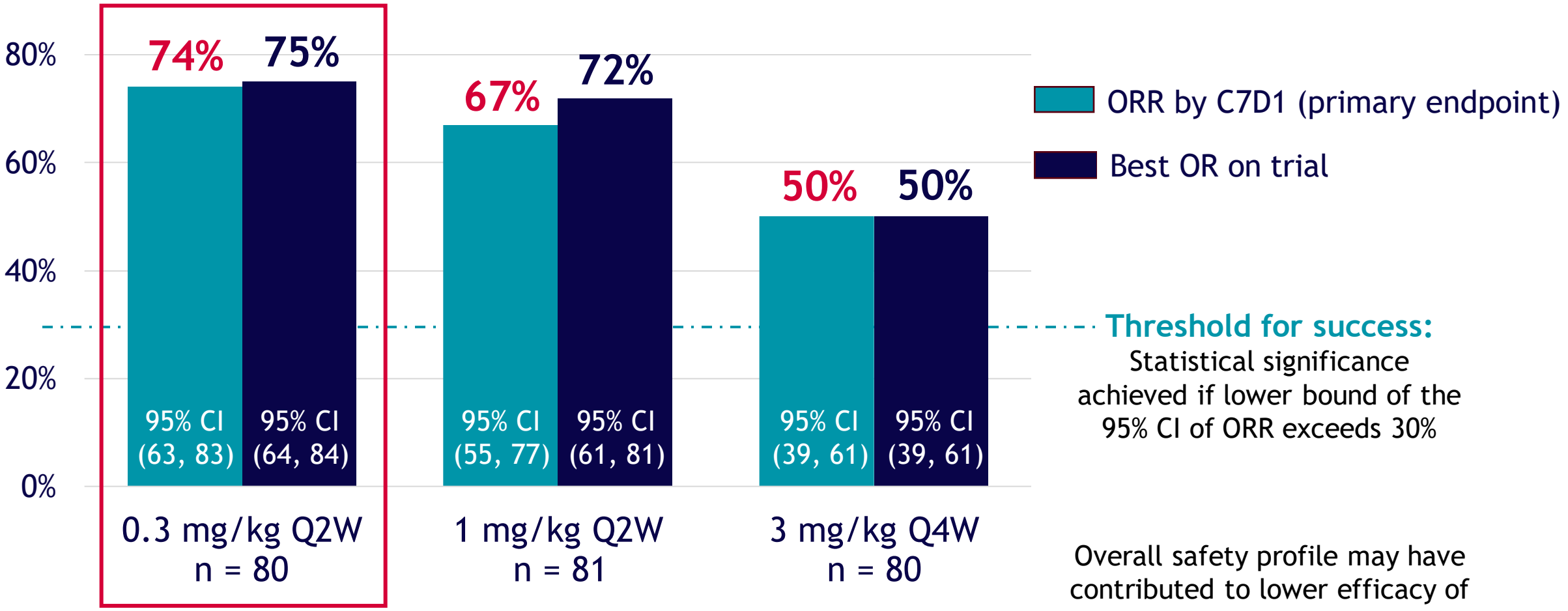
1 Age inclusion criteria differs by country
2. Overall response rate was assessed using the 2014 NIH Consensus Criteria for cGVHD

AGAVE-201 enrolled refractory, late-line cGVHD patients, > 70% had prior treatment with ruxolitinib

Population (ITT)	Total N=241
Age median (min, max), years	53 (7, 81)
Male	63%
Race – white	83%
Median time since cGVHD diagnosis	48 months
≥ 4 organs involved	54%
% Patients with lung manifestations	45%
% patients with NIH severe cGVHD	80%
Median prior therapies	4
≥ 4 prior lines of treatment	65%
Prior ruxolitinib	74%
Prior ibrutinib	31%
Prior belumosudil	23%

Patient characteristics were well balanced across cohorts

All 3 cohorts in AGAVE-201 met the primary endpoint of ORR



ORR = Overall response rate
BOR = Best overall response rate

At 0.3 mg/kg every 2 weeks, responses were durable and accompanied by a reduction in symptom burden

60%

of responders maintained a response at 12 months[1]

55%

of patients showed a >7 pt decrease in mLSS

Responses were observed across patients with prior exposure to approved agents including ibrutinib, ruxolitinib, and/or belumosudil

1) Measured from first response to new systemic therapy or death, based on the Kaplan Meier estimate
2) mLSS = modified Lee chronic GVHD Symptom Scale score

Axatilimab was generally well tolerated

Parameter, n (%)	0.3 mg/kg Q2W
	N=79
≥ Grade 3 treatment-related AE	14 (17.7)
Discontinued treatment for AE	5 (6.3)

Most frequent adverse events of any grade	
Parameter, n (%)	**0.3 mg/kg Q2W**
	N=79
Aspartate aminotransferase increased	11 (13.9)
Blood creatine phosphokinase increased	9 (11.4)
Lipase increased	9 (11.4)
Blood lactate dehydrogenase increased	11 (13.9)
Alanine aminotransferase increased	10 (12.7)
Fatigue	18 (22.8)

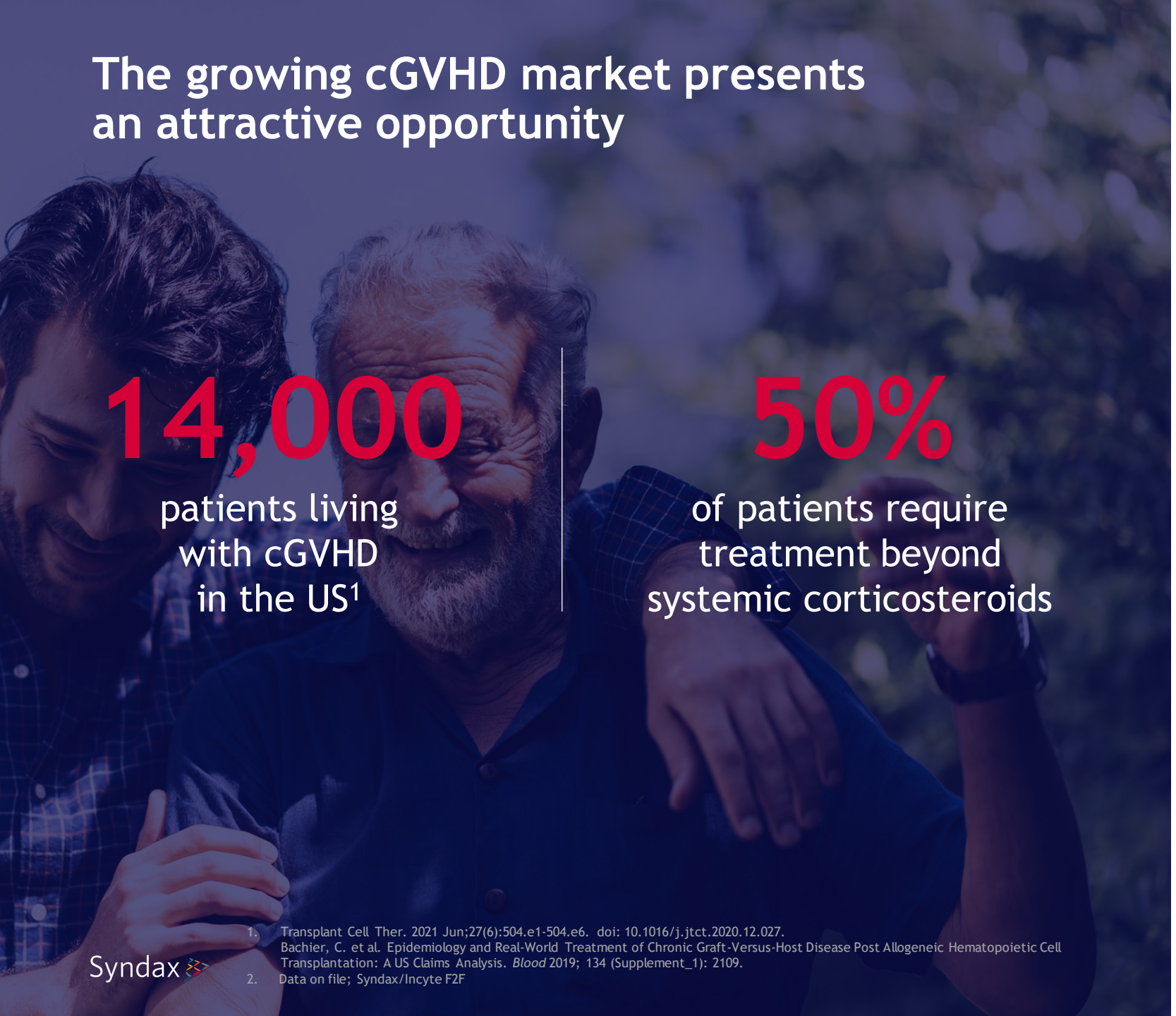
Most common adverse events were consistent with on target effects of CSF-1 inhibition and prior trials of axatilimab

Higher frequency of adverse events were observed at doses above 0.3 mg/kg Q2W

Parameter, n (%)	0.3 mg/kg Q2W	1.0 mg/kg Q2W	3.0 mg/kg Q4W	Total
	N=79	N=81	N=79	N=239
≥ Grade 3 treatment-related AE	14 (17.7)	28 (34.6)	37 (46.8)	79 (33.1)
Discontinued treatment for AE	5 (6.3)	18 (22.2)	14 (17.7)	37 (15.5)

Any grade adverse events in >20% of patients				
Parameter, n (%)	0.3 mg/kg Q2W	1.0 mg/kg Q2W	3.0 mg/kg Q4W	Total
	N=79	N=81	N=79	N=239
Aspartate aminotransferase increased	11 (13.9)	31 (38.3)	43 (54.4)	85 (35.6)
Blood creatine phosphokinase increased	9 (11.4)	26 (32.1)	49 (62.0)	84 (35.1)
Lipase increased	9 (11.4)	21 (25.9)	39 (49.4)	69 (28.9)
Blood lactate dehydrogenase increased	11 (13.9)	22 (27.2)	32 (40.5)	65 (27.2)
Alanine aminotransferase increased	10 (12.7)	18 (22.2)	31 (39.2)	59 (24.7)
Fatigue	18 (22.8)	16 (19.8)	21 (26.6)	55 (23.0)

The growing cGVHD market presents an attractive opportunity



14,000

patients living with cGVHD in the US[1]

50%

of patients require treatment beyond systemic corticosteroids

The estimated global chronic GVHD market in 2022 was $2 - 2.5B and is expected to expand due to[2]:

- Rising prevalence of blood cancers boosted by an increase in the aging population
- Rise in stem cell transplants

1. Transplant Cell Ther. 2021 Jun;27(6):504.e1-504.e6. doi: 10.1016/j.jtct.2020.12.027. Bachier, C. et al. Epidemiology and Real-World Treatment of Chronic Graft-Versus-Host Disease Post Allogeneic Hematopoietic Cell Transplantation: A US Claims Analysis. *Blood* 2019; 134 (Supplement_1): 2109.
2. Data on file; Syndax/Incyte F2F

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Significant unmet need remains across all lines of therapy

If approved, axatilimab will provide a differentiated mechanism from currently approved agents for patients with refractory cGVHD despite at least 2 prior therapies

Current Standard of Care[1]

1st Line	Corticosteroids
2nd Line	JAKAFI® IMBRUVICA®
3rd Line	REZUROCK®

1. U.S. Regulatory approvals in cGVHD: Imbruvica® - August 2017, Rezurock® - July 2021, Jakafi® - September 2021

Axatilimab has the potential to be a differentiated treatment option for cGHVD

Unique MOA for cGVHD

- First agent to target disease causing macrophages to impact fibrosis & inflammation
- Potential synergy with SOC

High and durable ORR

- 74% ORR at 0.3 mg/kg
- 60% of patients treated at 0.3 mg/kg remained in response at 12 months

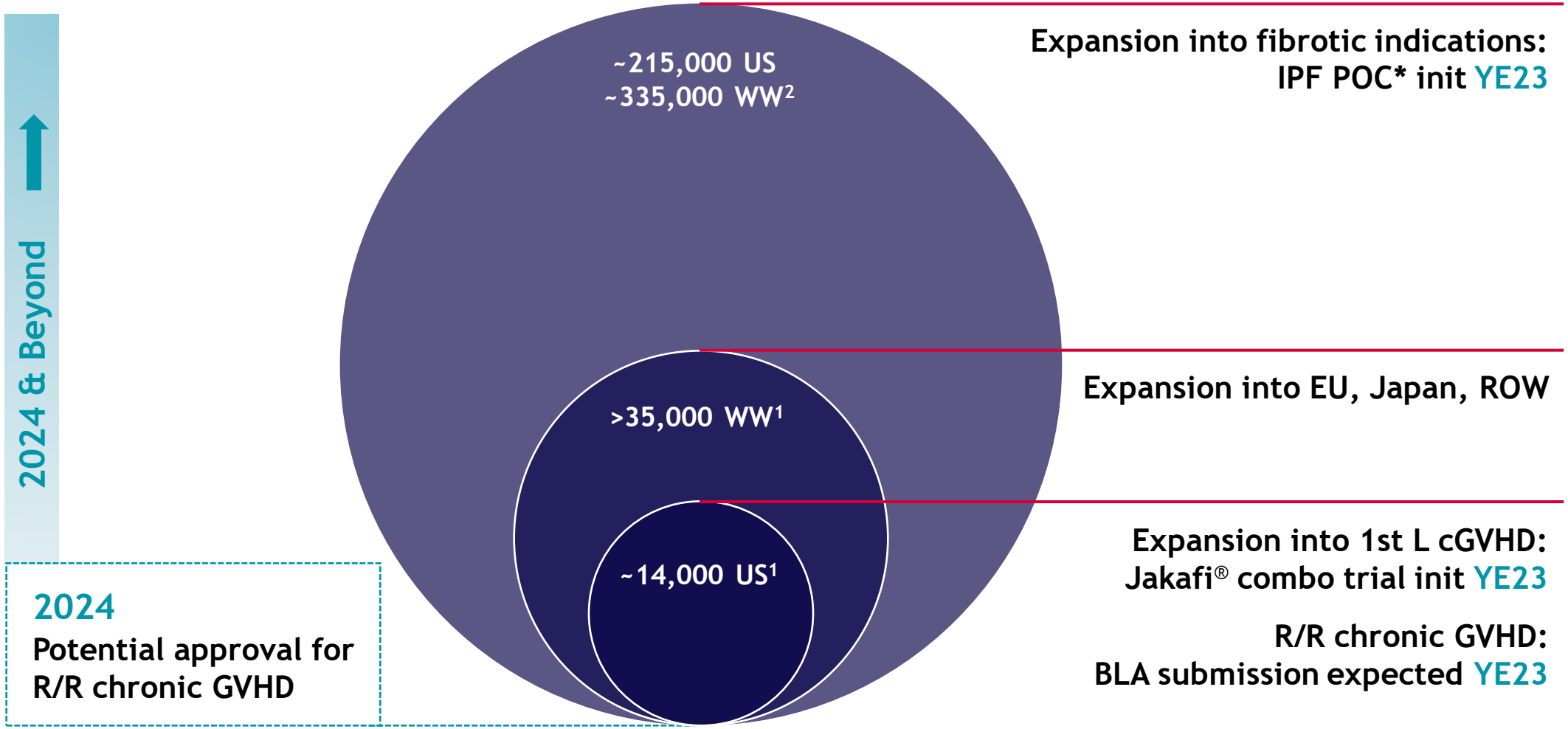
Well tolerated supporting broad use

- Low rate of SAEs and discontinuations at 0.3 mg/kg
- Antibody reduces potential for DDIs vs small molecule competitors

Enrolled population reflects real world

- Efficacy observed in patients following treatment with current SOC
- Option to switch to Q4W dose at 6mo

Axatilimab has the potential to expand into additional high value indications and new geographies



1 SmartImmunology Insights cGVHD report March 2020; 2 SmartImmunology Insights IPF report March 2020. * IPF trial will be conducted and funded by Syndax

Upcoming milestones for axatilimab

- Present full AGAVE-201 results at a medical meeting
- Potential BLA submission by year-end 2023 (led by Incyte)
- Initiate a combination trial with Jakafi® by year-end 2023 (led by Incyte)
- Initiate a Phase 2 trial in IPF by year-end 2023 (led by Syndax)
- Commercial readiness for potential 2024 launch (Syndax and Incyte - the leader in GVHD)


Determined to realize a future in which people with cancer live longer and better than ever before.