

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



1Q23 CORPORATE PRESENTATION | MAY 8, 2023

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# Revumenib and axatilimab on-track to file potential marketing applications in 2023 with several opportunities for expansion

## Revumenib

Menin-KMT2A  
disruption

**Expand within acute leukemia and beyond to solid tumors**

- Expect AUGMENT-101 pivotal data beginning in 3Q23
- Front-line and R/R combo trials ongoing with initial data by YE23
- Initial MSS CRC Phase 1 trial data expected by YE23

## Axatilimab

Anti-CSF-1R

**Expand into earlier lines of cGVHD and fibrotic disease**

- AGAVE-201 pivotal cGHVD data expected mid-23
- Initiate cGVHD combo trial with Jakafi® in 2H23
- Initiate IPF Phase 2 trial in 2H23

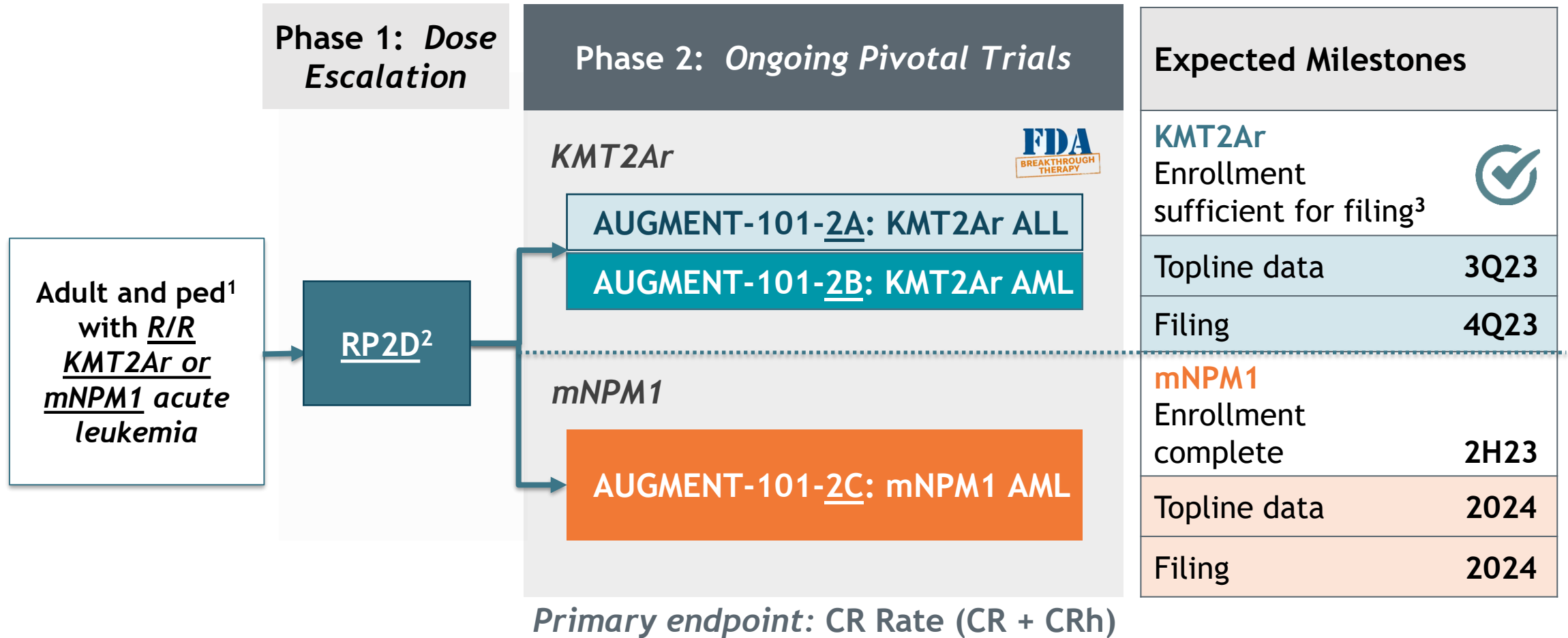
Corporate  
and  
Pipeline

**Expand pipeline through BD**

- Targeting assets in late pre-clin to Phase 1
- Well-capitalized with \$449M in cash and no debt

MSS CRC = Microsatellite Stable Colorectal Carcinoma, IPF = Idiopathic Pulmonary Fibrosis, cGVHD = chronic Graft-Versus-Host Disease, R/R = relapsed/refractory, BD = Breakthrough Therapy designation Cash as of March 31, 2023; includes cash, cash equivalents and short- and long-term investments

# Pivotal AUGMENT-101 trial: Expecting KMT2Ar topline data in 3Q23, enrollment completion for mNPM1 in 2H23



Note: Patients taken to HSCT can restart treatment with revumenib post-transplant; Abbreviations: KMT2Ar = KMT2A rearrangement; mNPM1 = mutated nucleophosmin  
<sup>1</sup>Allows patients ≥30 days of age <sup>2</sup>276mg q12h or 163mg q12h w/ strong CYP3A4 inhibitor <sup>3</sup>Completed enrollment of a sufficient number of KMT2Ar patients to support a registration filing

# Phase 1 data from AUGMENT-101 published in *Nature*

## Article

### The menin inhibitor revumenib in *KMT2A*-rearranged or *NPM1*-mutant leukaemia

<https://doi.org/10.1038/s41586-023-05812-3>

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“ We found an encouraging clinical benefit, with deep molecular remissions and minimal toxicities, in a heavily pretreated population of both children and adults with advanced acute leukemia. ”

	Best Response <sup>1</sup>	Efficacy Pop; n = 60 (%)	
Response	Overall Response Rate <sup>2</sup>	32/60 (53%)	
MRD <sup>neg</sup>	MRD <sup>neg</sup> Rate <sup>3</sup>	18/32 (56%)	
KMT2Ar	Overall Response Rate <sup>2</sup>	27/46 (59%)	Efficacy @ RP2D <sup>4</sup>
	CR/CRh	15/46 (33%)	10/37 (27%)
mNPM1	Overall Response Rate <sup>2</sup>	5/14 (36%)	
	CR/CRh	3/14 (21%)	3/11 (27%)

- 9.1 mo median duration of CR/CRh
- 7.0 mo median OS

Source: Issa, G.C. et al. *Nature* 615, 920-924 (2023). <sup>1</sup> Data Cutoff of March 2022; <sup>2</sup> ORR= CR + CRh + CRp + MLFS; <sup>3</sup> MRD status assessed locally by PCR or MCF; <sup>4</sup> RP2D defined as 113mg or 163 mg q12h for patients receiving concomitant strong CYP3A4 inhibitor therapy or 226mg or 276mg q12h for pts not receiving concomitant strong CYP3A4 inhibitor therapy. Notes: Revumenib was associated with a low frequency of Gr. 3 or higher TRAEs; asymptomatic prolongation of the QT interval identified as only dose-limiting toxicity

# Trials underway to establish revumenib as a backbone of treatment for mNPM1 or KMT2Ar acute leukemia

	Relapsed/Refractory	Front-Line	Maintenance
Revumenib Development			
Trial Description	<p>Validates use of menin inhibition in NPM1 and KMT2Ar acute leukemias, in monotherapy and chemotherapy combinations</p>	<p>Validates the use of menin inhibition with venetoclax/azacytidine, the commonly used regimen in older patients</p>	<p><b><u>AUGMENT-101</u></b>: allows pts to restart Tx post-transplant  <b><u>INTERCEPT</u></b>: examining conversion of MRD+ to MRD-</p>

# Revumenib expansion opportunities in acute leukemia and solid tumors have potential to add meaningful value

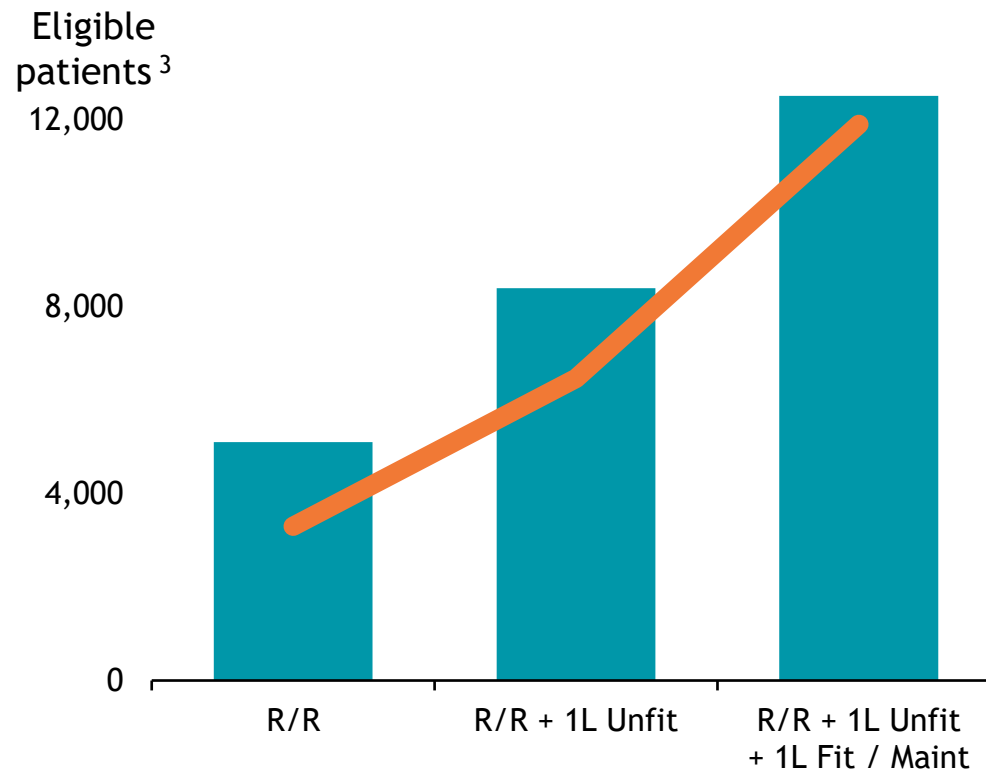
## Potential first/best-in-class agent

- Clear activity in refractory, advanced mNPM1 and KMT2Ar acute leukemia
- High percentage of MRD negative responses

## Profile supports potential use in front-line and maintenance

- Well-tolerated safety profile, no discontinuations due to treatment related AE
- Preclinical data supports combos with venetoclax<sup>1</sup>, chemotherapy<sup>2</sup>

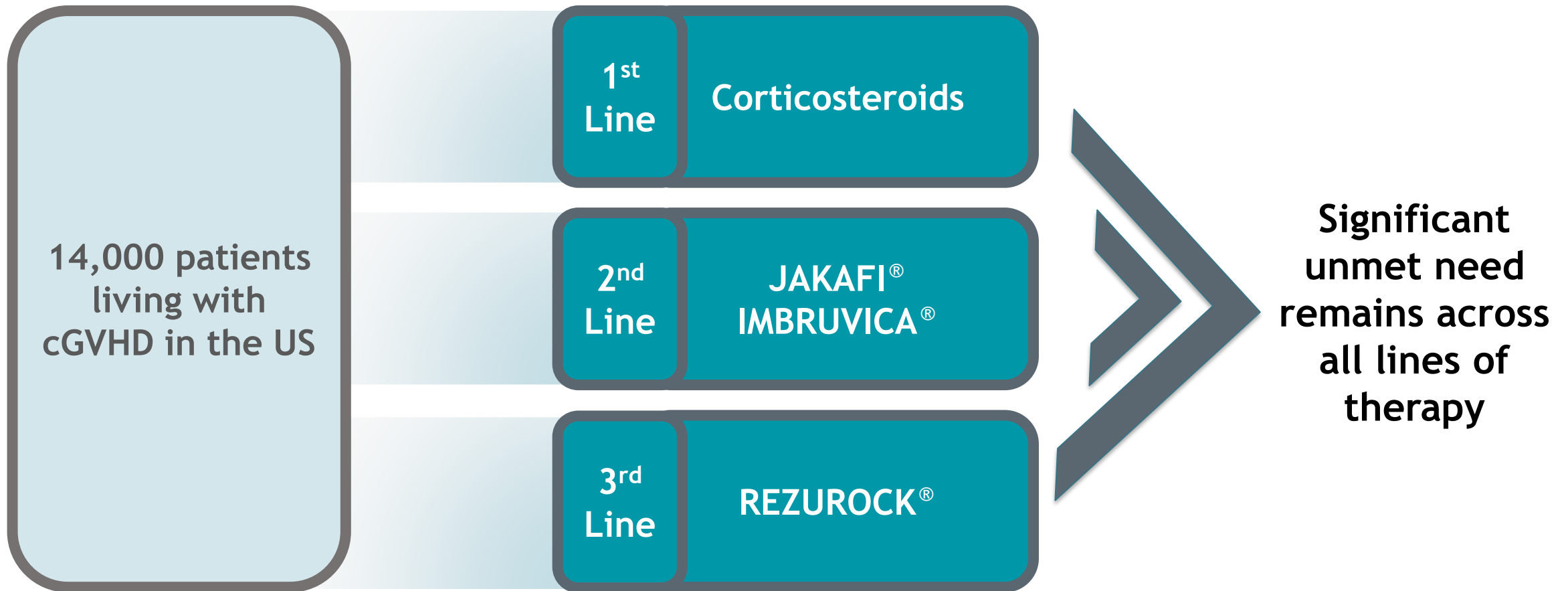
## Est. US market opportunity for mNPM1 and KMT2Ar AML



***Expansion into solid tumors represents another significant opportunity for value***

<sup>1</sup> SMARTAnalyst 2020 <sup>1</sup> Carter, B., et al., Blood 2021; <sup>2</sup> Data on file; <sup>3</sup> SEER + Roche IR presentation Sept 2020 AML incidence estimates.

# Axatilimab could provide a differentiated, effective, and practice-changing intervention in cGVHD



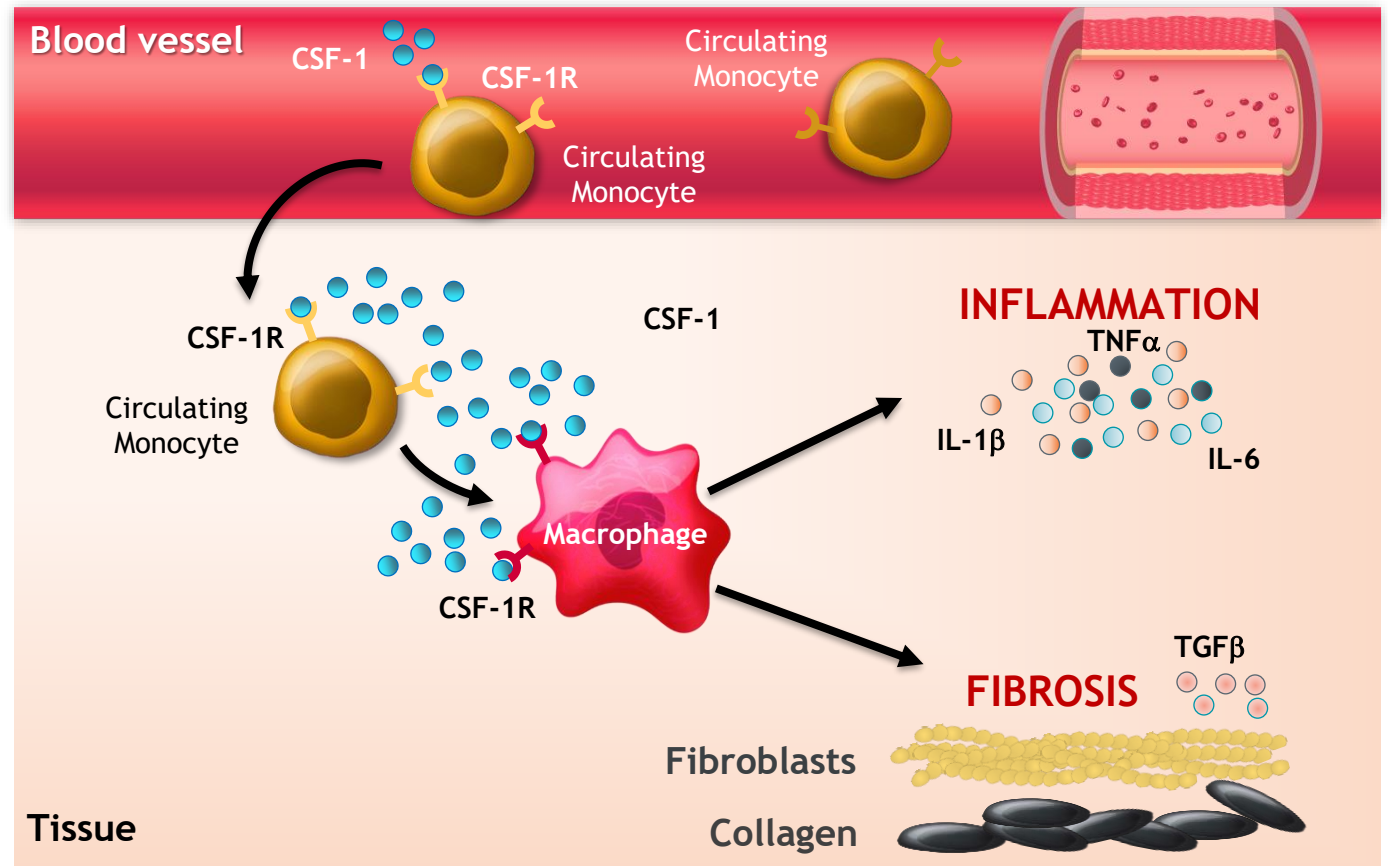
U.S. Regulatory approvals in cGVHD: Imbruvica® - August 2017, Rezurock® - July 2021, Jakafi® - September 2021



# As a CSF-1R inhibitor, axatilimab is well positioned to impact both fibrotic and inflammatory processes

- Non-overlapping MOA offers potential to benefit patients both as monotherapy and in combination with approved agents
- Potential to benefit difficult to manage manifestations such as Lung, Skin, GI
- IV administration can help with compliance and absorption for GI manifestations

## CSF-1R mediates pro-inflammatory and pro-fibrotic monocyte/macrophage differentiation and activation<sup>1</sup>



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

# Axatilimab Phase 1/2 POC trial in cGVHD showed rapid and durable responses

## Phase 2 cohort highlights

82%

ORR by cycle 7 day 1

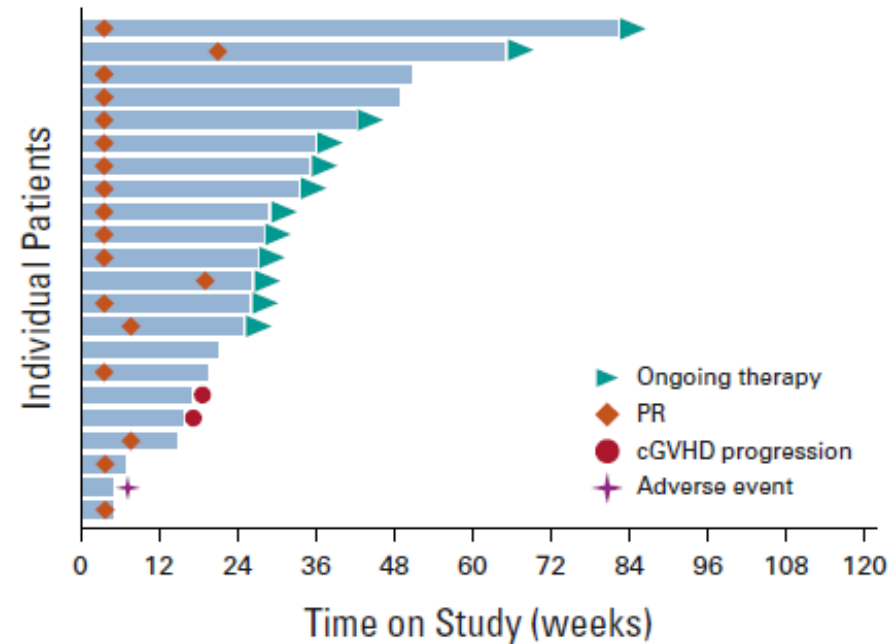
77%

FFS at 12 months

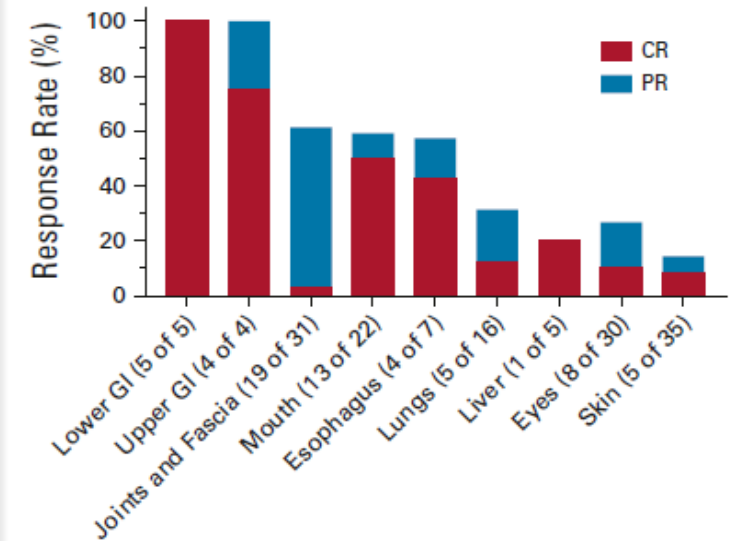
4 wks

Median time to response

## Individual responses and durability of Phase 2 cohort



## Cumulative response rate in cGVHD-involved organs



Responses observed across all organ systems

Data cutoff: 22Oct2021; Source: Kitko, C. L., M. Arora, et. al. J Clin Oncol. 2022, December. DOI: 10.1200/JCO.22.00958; FFS = failure-free survival using a broadened failure definition that incorporate toxicity-related discontinuation and cGVHD progression not included in the standard cGVHD FFS reporting; ORR = overall response rate  
Notes: TRAEs occurred in 75% of patients, with 20% of patients experiencing grade  $\geq 3$  TRAEs; serious adverse events were noted in 40% of patients.



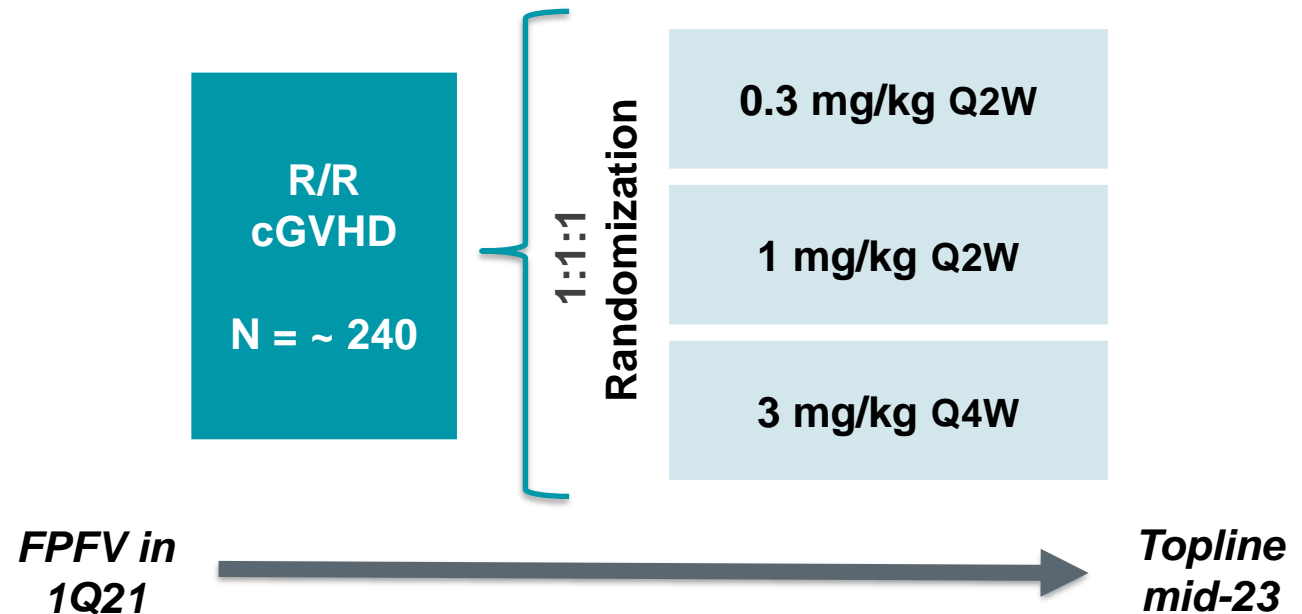
# AGAVE-201: Axatilimab pivotal trial data expected in mid-2023 with a BLA filing by year-end

## Inclusion criteria:

- 2 years and older<sup>1</sup>
- Recurrent or refractory active cGVHD after  $\geq 2$  lines of systemic therapy

## Stratification factors:

- Prior therapy (ibrutinib, ruxolitinib, belumosudil)
- Severity of cGVHD

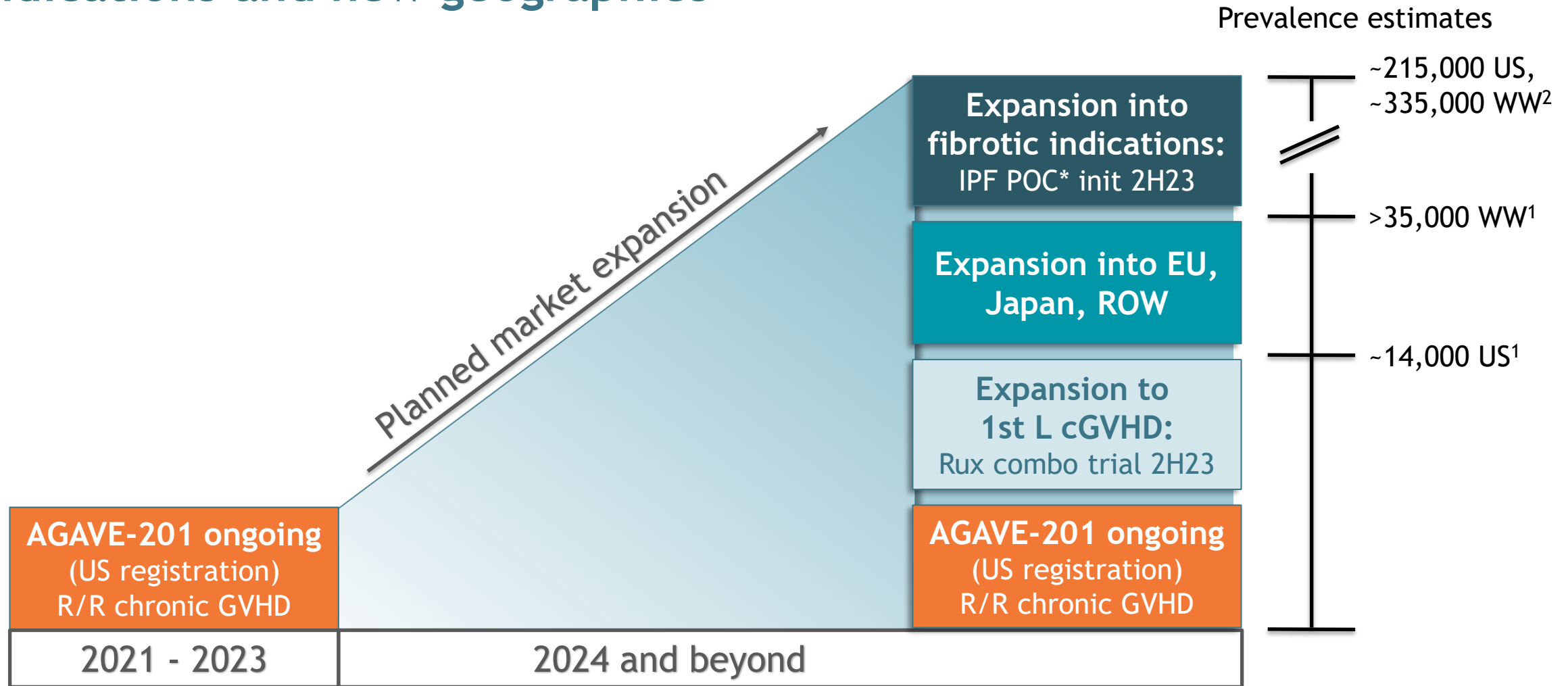


Initiation of combination trial in cGVHD expected in 2H23

<sup>1</sup> Age inclusion criteria differs by country; Front-line combination trial being conducted by Incyte

Primary Endpoint: Objective Response Rate (ORR) by 2014 NIH GVHD Criteria; Key Secondaries: Duration of response, improvement in modified Lee Symptom Scale

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



<sup>1</sup> SmartImmunology Insights cGVHD report March 2020; <sup>2</sup> SmartImmunology Insights IPF report March 2020

\* IPF trial will be conducted and funded by Syndax

# Financial highlights and financial guidance

Ticker		SNDX (NASDAQ)	
Cash and equivalents (at 31 March 2023)		\$449 million	
Shares outstanding* (at 31 March 2023)		69.6 million	
2023 Operating Expense Guidance			
		2Q 2023	FY23 (no change)
Research and development		\$38 - \$43 million	\$160 - \$175 million
Total operating expenses^		\$53 - \$58 million	\$225 - \$240 million

\* Includes pre-funded warrants to purchase 1.1 million common shares (rounded)

^ Includes ~\$30 million non-cash stock compensation expense for the full year

Thank you. Questions?

Syndax 