Syndax

Reimagining Cancer Treatment

Niktimvo™ (axatilimab-csfr) FDA Approval Conference Call

August 14, 2024

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Agenda

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Introduction

Michael Metzger
Chief Executive Officer

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Niktimvo Label & Data

Neil Gallagher, MD, PhD
President, Head of R&D

3

Commercial Launch Plans

Steve Closter
Chief Commercial Officer

4

Financial Considerations

Keith Goldan
Chief Financial Officer

5

Q&A Session

Syndax management team

Niktimvo™ (axatilimab-csfr) is now FDA approved!

- **First and only** treatment for chronic graft-versus-host disease (cGVHD) that binds to CSF-1R to block the processes involved in inflammation and fibrosis
- Approval marks a major breakthrough for patients with refractory cGVHD
- Robust axatilimab clinical development strategy supports potential label expansion into earlier lines of cGVHD and IPF
- Syndax is on track for a historic year with the anticipated approval of its second medicine, revumenib, in 4Q24

Niktimvo™
(axatilimab-csfr)

CSF-1R, Colony-stimulating factor 1 receptor; IPF, Idiopathic pulmonary fibrosis

Syndax and Incyte to co-commercialize Niktimvo in the U.S. and pursue opportunities for label expansion

	Incyte	Syndax
Within U.S.	70% sales effort 50% profit	30% sales effort 50% profit
Outside U.S.	Exclusive rights to commercialization	Double-digit royalties and milestones

CLINICAL DEVELOPMENT PROGRAMS

Trial underway:

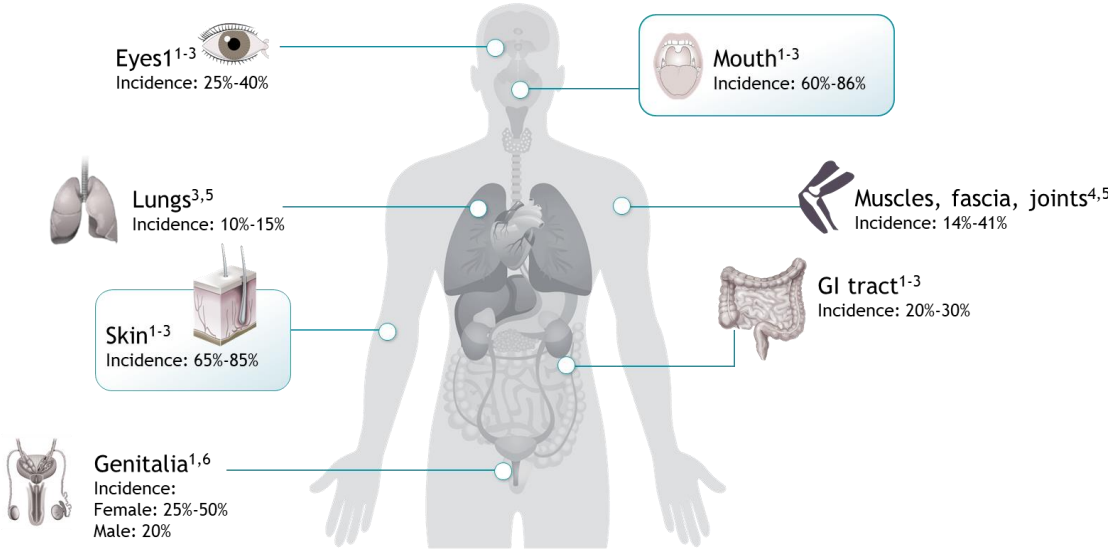
- Ph 2 in idiopathic pulmonary fibrosis (IPF)

Trials expected to initiate in 2H24:

- Ph 2 frontline combination trial with Jakafi® in cGVHD
- Ph 3 frontline combination trial with steroids in cGVHD

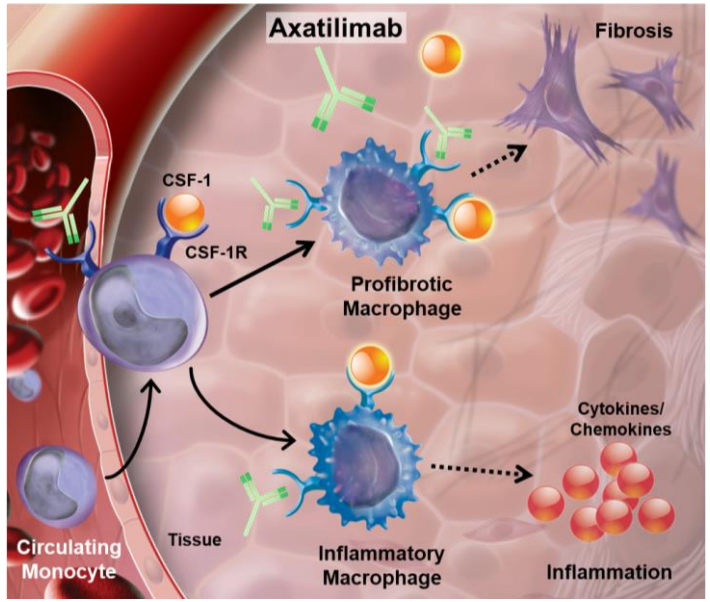
There is a significant need for a new therapeutic approach to cGVHD, a debilitating and difficult to treat disease

cGVHD impacts multiple organ systems, drives significant morbidity and impairs quality of life



Complete responses are rare, and many organs respond poorly to available therapies; nearly 50% of patients progress to third line treatments[1]

Niktimvo is the first approved anti-CSF-1R antibody targeting the drivers of inflammation and fibrosis in cGVHD



Blocking CSF-1R with Niktimvo reduces the levels of proinflammatory and profibrotic monocytes and monocyte-derived macrophages

1. Bachier et al. *Transplant Cell Ther*. 2021; 27(6):504.e1-504.e6.

Overview of Niktimvo (axatilimab-csfr) U.S. prescribing info

INDICATION

- Niktimvo is indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg

DOSAGE & ADMINISTRATION

- The recommended dosage of Niktimvo is 0.3 mg/kg (maximum 35 mg) every 2 weeks in adult and pediatric patients weighing at least 40 kg
- Administered as an intravenous infusion over 30 minutes

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Please see full Prescribing Information for more information.

Niktimvo FDA approval was based on AGAVE-201 trial data

A randomized, open-label, multicenter study (121 study sites, 16 countries)

Key eligibility criteria:

- Adult and pediatric participants with recurrent or refractory active cGVHD whose disease had progressed after ≥2 prior therapies
- Concomitant use of corticosteroids, calcineurin inhibitors, or mTOR inhibitors was allowed; no additional systemic cGVHD therapy was allowed

Primary endpoint:

- Overall response rate (ORR) by Cycle 7 (28-day cycles) Day 1, including complete response or partial response according to the NIH 2014 Consensus Criteria[1]

Secondary and exploratory endpoints:

- Improvement in mLSS (≥7 points)
- Organ-specific response rates, DOR, FFS, OS
- Safety

Of the three doses evaluated[2], 0.3 mg/kg IV every 2 weeks was selected as the recommended therapeutic dose

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DOR, duration of response; FFS, failure-free survival; mLSS, modified Lee Symptom Scale; mTOR, mammalian target of rapamycin; NIH, National Institutes of Health; OS, overall survival. 1. Jagasia et al. Biol Blood Marrow Transplant. 2015;21:389-401. Active cGVD defined per 2014 NIH Consensus Criteria. 2. The AGAVE-201 trial evaluated doses of 0.3 mg/kg Q2W, 1 mg/kg Q2W and 3 mg/kg Q4W.

AGAVE-201 enrolled advanced, heavily pre-treated cGVHD patients

Demographics & Baseline Characteristics of Patients with cGVHD	Niktimvo 0.3 mg/kg every 2 weeks (N=79)
Median age, years (range)	50 (7, 76)
Male, n (%)	46 (58%)
Race – white, n (%)	67 (85%)
Median time (range) from cGVHD diagnosis	47 months (4, 211)
≥ 4 organs involved, n (%)	45 (57%)
Severe cGVHD, n (%)	63 (80%)
Median (range) prior lines of therapy	4 (2, 12)
≥ 4 prior lines of treatment, n (%)	54 (69%)
Prior ruxolitinib, n (%)	57 (72%)
Prior ibrutinib, n (%)	27 (34%)
Prior belumosudil, n (%)	16 (20%)

Compared to the registrational population in the belumosudil trial[1], AGAVE-201 enrolled a population with:

- Significantly longer median time since diagnosis (47 vs. 25 months)
- More severe cGVHD (80% vs 71%)
- More exposure to prior therapies (e.g., 72% vs 31% exposed to ruxolitinib)

1. REZUROCK® (belumosudil) Full Prescribing Information Revised 04/2024

Summary from Niktimvo U.S. prescribing information

Efficacy results	Niktimvo 0.3 mg/kg every 2 weeks (N=79)
Overall response rate through 6 months, n (%) 95% CI	**59 (75%)** 64, 84
Median time to first response (range)	1.5 months (0.9-5.1)
Median duration of treatment (range)	10.3 months (0.5-28.6)

60% of responders maintained a response for at least 12 months[1]

(95% CI: 43, 74)

56% of patients reported symptom improvements[2]

(95% CI: 44, 67)

1. Measured from first response until new systemic therapy for cGHVD or death, based on the Kaplan Meier estimate.
2. Defined as ≥7-point decrease in modified Lee Symptom Scale score in an exploratory analysis through 6 months.

Safety summary from Niktimvo U.S. prescribing information

Boxed warning:

None

Contraindications:

None

Warnings & precautions:

Infusion-related reactions and embryo-fetal toxicity

Most common (≥15%) adverse reactions, including lab abnormalities:

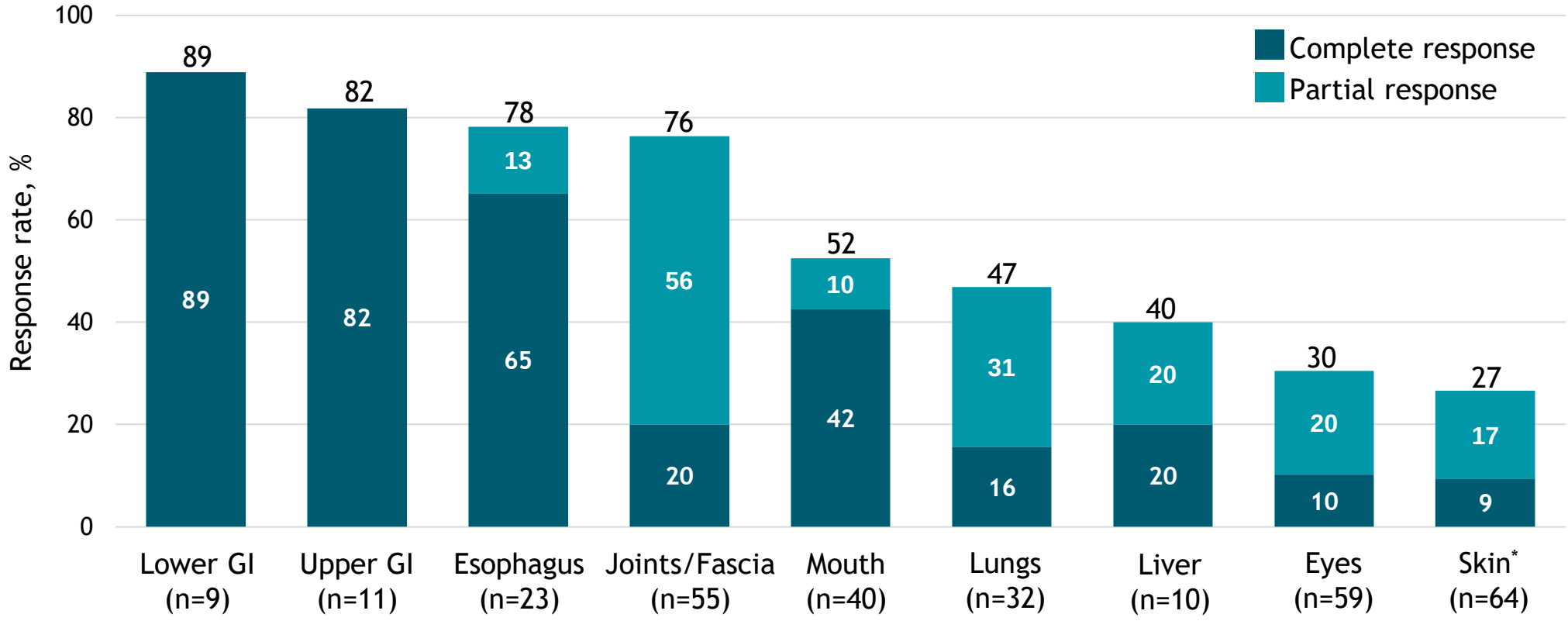
Increased AST, infection (pathogen unspecified), increased ALT, decreased phosphate, decreased hemoglobin, viral infection, increased GGT, musculoskeletal pain, increased lipase, fatigue, increased amylase, increased calcium, increased CPK, increased ALP, nausea, headache, diarrhea, cough, bacterial infection, pyrexia, and dyspnea.

Niktimvo 0.3 mg/kg every 2 weeks (N=79)	
	% of patients
Serious adverse reactions	44%
Dose interruptions due to adverse reactions	44%
Dose reductions due to adverse reactions	8%
Permanent discontinuation due to adverse reactions	10%

AST, aspartate aminotransferase; ALT, alanine aminotransferase; GGT, gamma glutamyl transferase; CPK, creatine phosphokinase; ALP, alkaline phosphatase

Niktimvo showed robust responses across all organs studied in the heavily pre-treated population enrolled in AGAVE-201

Niktimvo 0.3 mg/kg every two weeks

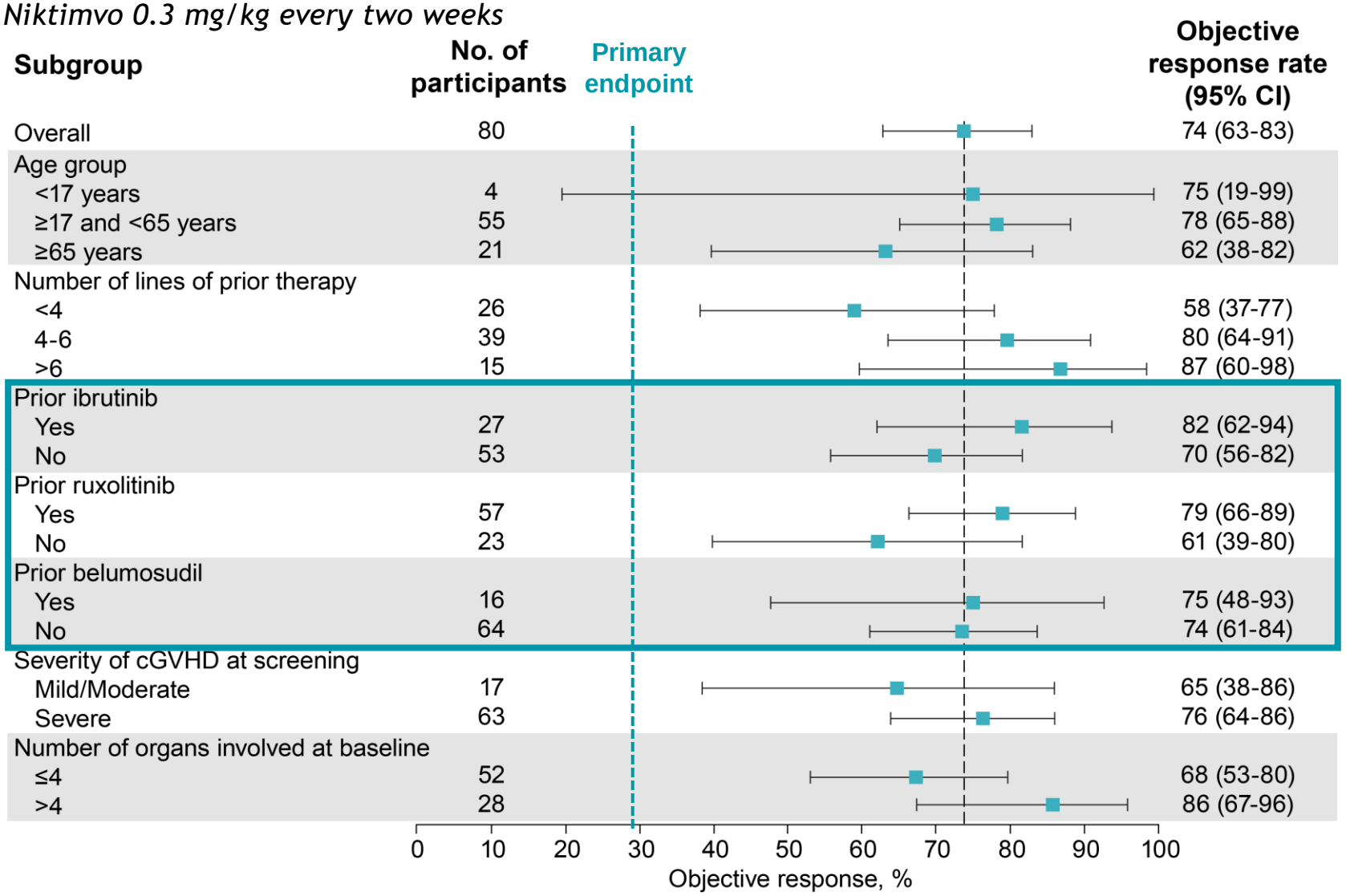


Responses were notable in fibrosis-dominated organs, including esophagus (78%), joints and fascia (76%), lung (47%), and skin (27%)

DeFilipp, Z., et al. (2024, February). "Safety and Efficacy of Axatilimab in Patients With Chronic Graft-Versus-Host Disease (AGAVE-201)." Slides presented at the 2024 Tandem Meeting (American Society for Transplantation and Cellular Therapy [ASTCT]-Center for International Blood and Marrow Transplant Research [CIBMTR]), San Antonio, TX, USA. *Due to rounding, complete response and partial response numbers may not add up to total response rate. GI, gastrointestinal.

Niktimvo showed robust responses across all patient subgroups in the AGAVE-201 trial

Niktimvo 0.3 mg/kg every two weeks



High response rates (≥75%) were seen in patients regardless of whether they had received prior FDA-approved therapies, including belumosudil (REZUROCK), highlighting the distinct mechanism

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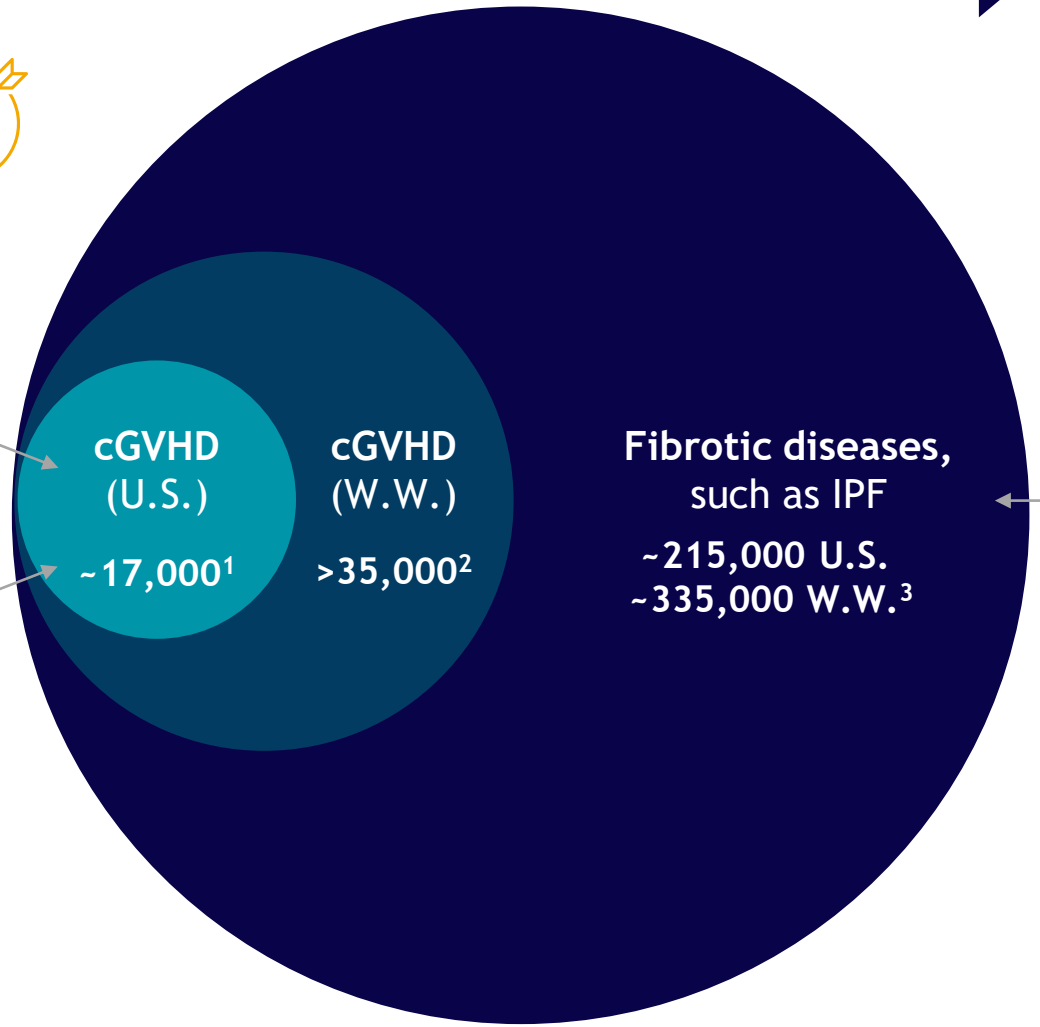
Wolff, D., et al. (2023, December). "Safety and Efficacy of Axatilimab at 3 Different Doses in Patients with Chronic Graft-Versus-Host Disease (AGAVE-201)." Slides presented at the 2023 American Society of Hematology Annual Meeting.

Niktimvo has a significant opportunity in 3L cGVHD in the U.S., with opportunities for geographical and label expansion

2024 → Beyond

Of the 17,000 U.S. chronic GVHD patients on treatment at any one time, we will target the ~6,500 progressing to later lines of treatment after at least two previous lines of treatment, consistent with our label

1L chronic GVHD combination trials planned to initiate in 2H24 could support future potential label expansion



Phase 2 IPF trial underway

Evaluating other potential disease areas

1. Internal data on file; 2. SmartImmunology Insights cGVHD report March 2020; 3. SmartImmunology Insights IPF report March 2020. * IPF trial will be conducted and funded by Syndax

Strategic imperatives for U.S. Niktimvo launch

1. Position Niktimvo as a differentiated 3L cGVHD treatment

2. Secure broad payor coverage for Niktimvo

3. Ensure access and adherence to Niktimvo

Targeted Niktimvo launch strategy will be led by highly experienced team from Incyte and Syndax

- Incyte to lead commercialization and contribute 70% of sales effort, leveraging their leadership in GVHD and extensive pre-existing relationships
- Syndax to contribute 30% of sales effort, deploying its own highly experienced field force
  - Average of 22 years of experience, primarily in hematology/oncology, with an average of 6 product launches
  - Overlapping call point with revumenib targets allows for commercial synergies

At launch, Incyte & Syndax will prioritize top centers with the highest volumes and greatest opportunity for rapid uptake

Robust stakeholder engagement and education is underway to support successful U.S. launch

Syndax and Incyte are committed to driving access to Niktimvo for appropriate patients

PAYOR ENGAGEMENT

- ☑ Prior to approval, Incyte led robust pre-approval information exchanges to raise awareness of the unmet need in refractory cGVHD and role of the CSF-1R pathway
- ☑ Engagement continues with the aim to expedite formulary decisions and drive broad coverage

Payors recognize the morbidity and mortality associated with refractory cGVHD and the need for additional treatment options

PATIENT SUPPORT

Eligible U.S. patients prescribed Niktimvo will have access to IncyteCARES, a comprehensive patient support program, at the time of product launch

IncyteCARES

- *Personalized patient support*
- *Support understanding insurance coverage*
- *Financial assistance for eligible patients*
- *Ongoing education and additional resources*

Accounting for net profits/losses on sales of Niktimvo: Illustrative example

Syndax will report collaboration profits on a net basis; Incyte will record product sales

Net Profits:

Niktimvo Assumption	
Net product sales of Niktimvo	$ 1,000
Cost of Goods Sold	$ 250
Shared Commercialization and other Expense	$ 100
Net profit	$ 650
Syndax's 50% share of net profit	$ 325

Syndax Illustrative P&L	
Collaborative Arrangement Revenue	$ 325
Total Revenues	$ 325
Research & Development, net	$ 200
SG&A	$ 130
Share of Collaboration Loss	$ -
Total Operating Expenses	$ 330

Net Losses:

Niktimvo Assumption	
Net product sales of Niktimvo	$ 1,000
Cost of Goods Sold	$ 250
Shared Commercialization and other Expense	$ 800
Net (loss)	$ (50)
Syndax's 50% share of net (loss)	$ (25)

Syndax Illustrative P&L	
Collaborative Arrangement Revenue	$ -
Total Revenues	$ -
Research & Development, net	$ 200
SG&A	$ 130
Share of Collaboration Loss	$ 25
Total Operating Expenses	$ 355

Expected upcoming milestones

Niktimvo (axatilimab-csfr)

Anti-CSF-1R

- Launch in refractory chronic GVHD no later than early first quarter 2025
- Initiation of chronic GVHD frontline combination trial with Jakafi in 2H24
- Initiation of chronic GVHD frontline combination trial with steroids in 2H24

REVUMENIB

Menin-KMT2A disruption

- PDUFA action date of December 26, 2024, in R/R KMT2Ar acute leukemia; immediate launch
- Pivotal data from AUGMENT-101 R/R mNPM1 cohort in 4Q24; potential sNDA filing in 1H25
- Present additional revumenib data in acute leukemias in 2H24
- Initiation of pivotal combination trial with ven/aza in frontline mNPM1 or KMT2Ar acute leukemias by YE24


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