

SynAct Pharma AB

Q2 Report

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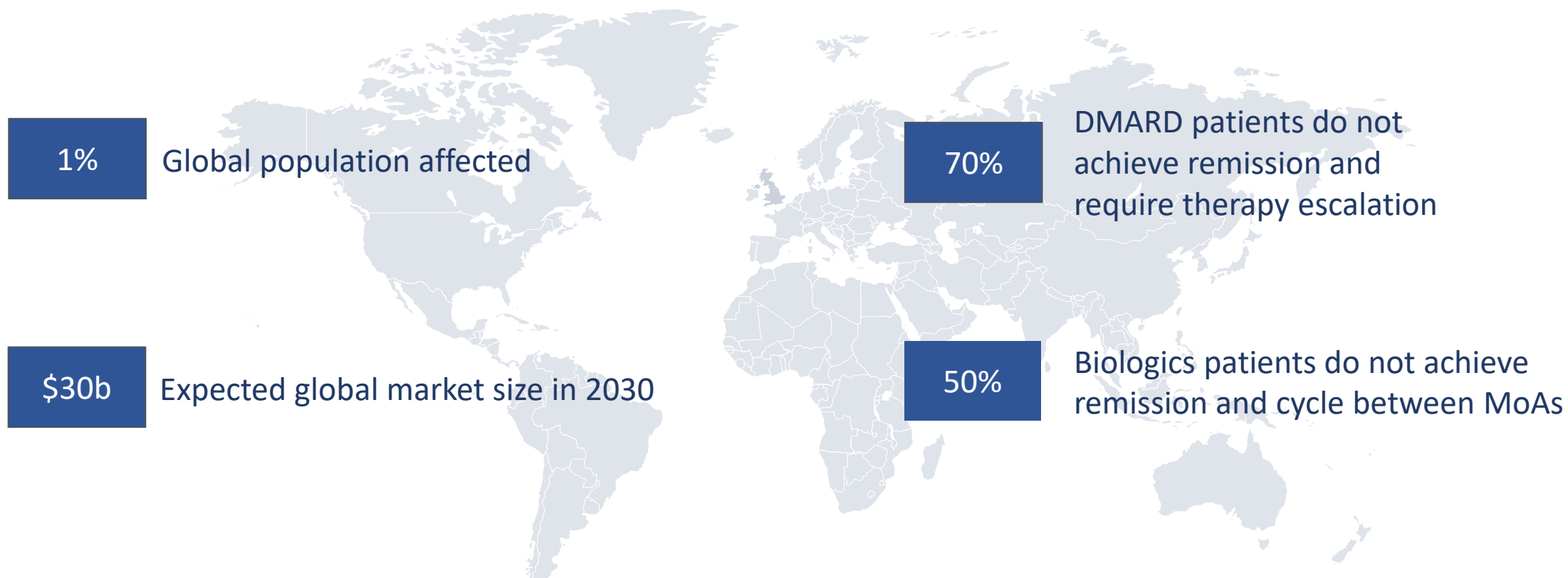
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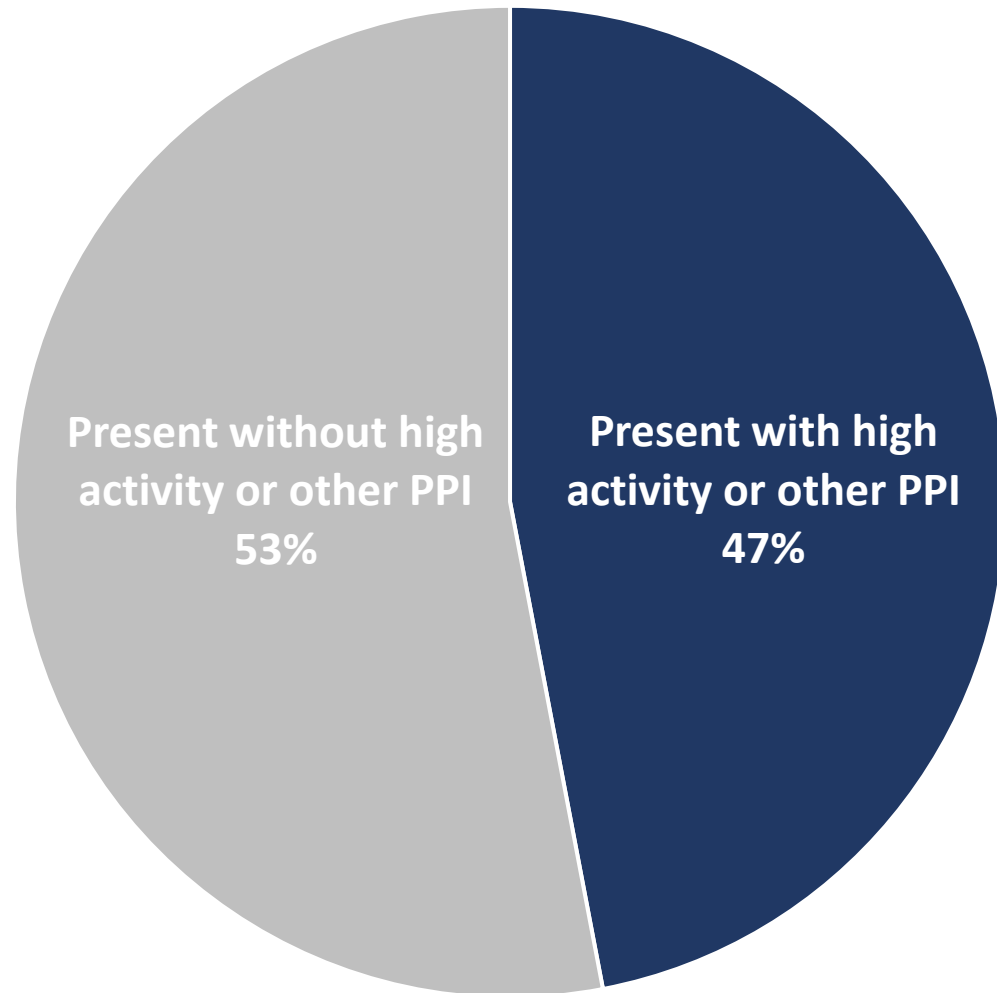
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RA affects about 1% of the global population, and while there are several classes of approved therapies remission remain elusive



AP1189 could be well suited to address the unmet needs in RA

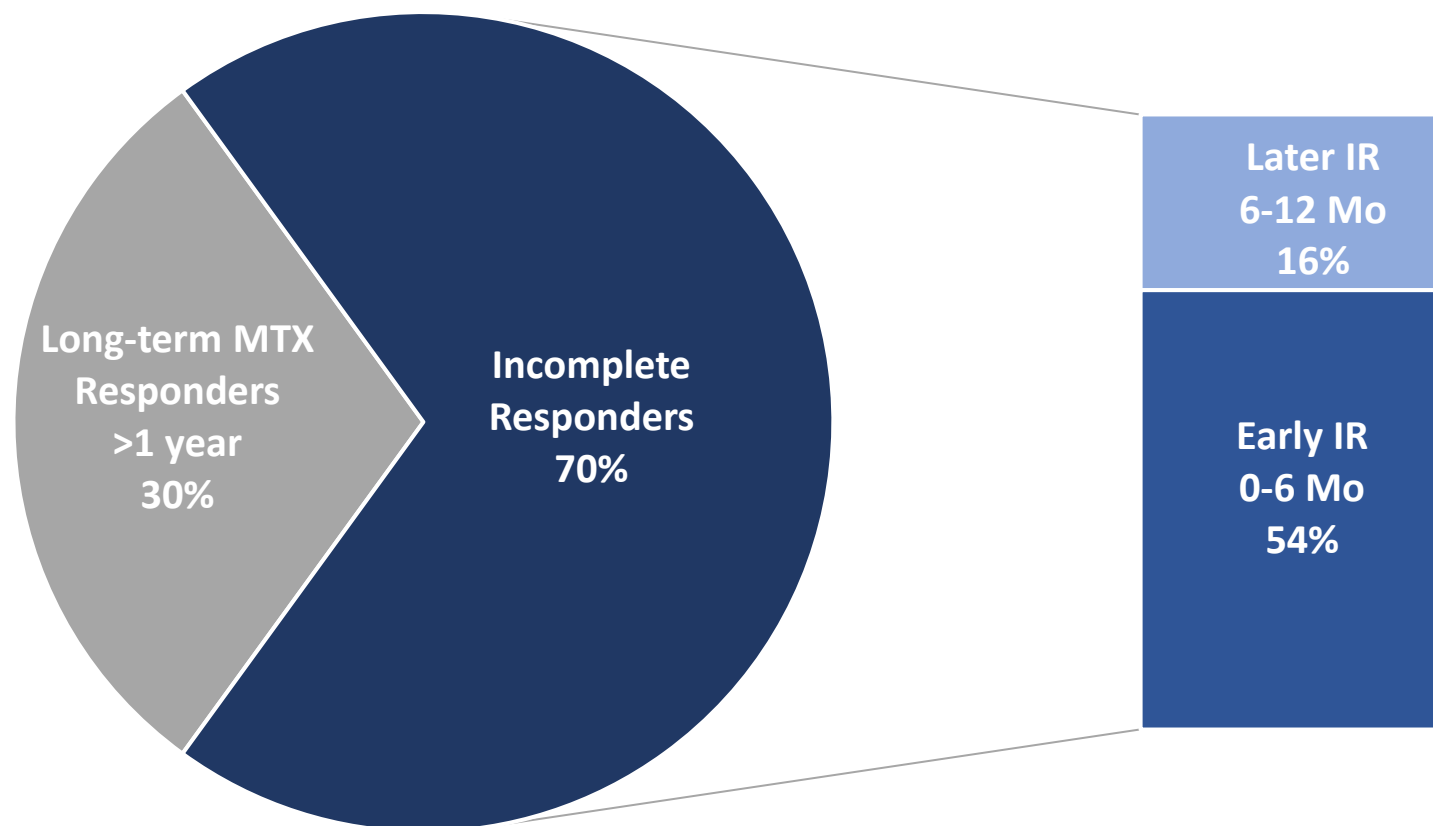
Treatment naïve RA patients present with high activity and other poor prognostic indicators almost 50% of the time



Highly-Active Naïve:

- Studied in BEGIN and EXPAND studies
- Highly active disease is the dominating poor prognostic indicator (PPI) in ACR and EULAR recommendations¹
- Up to 47% of treatment-naïve RA patients can present with highly active disease and these patients tend to have a lower response to DMARDs including MTX^{2,3}

DMARDs are time-tested 1st-line RA therapies but the majority of treated patients will not achieve a durable response on DMARD monotherapy

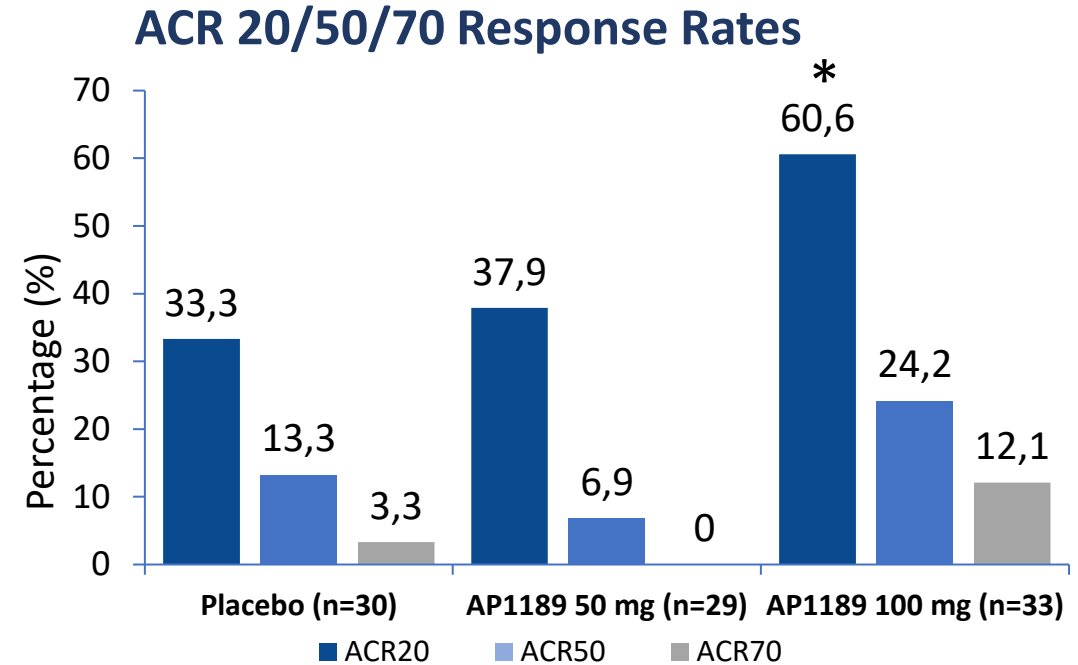
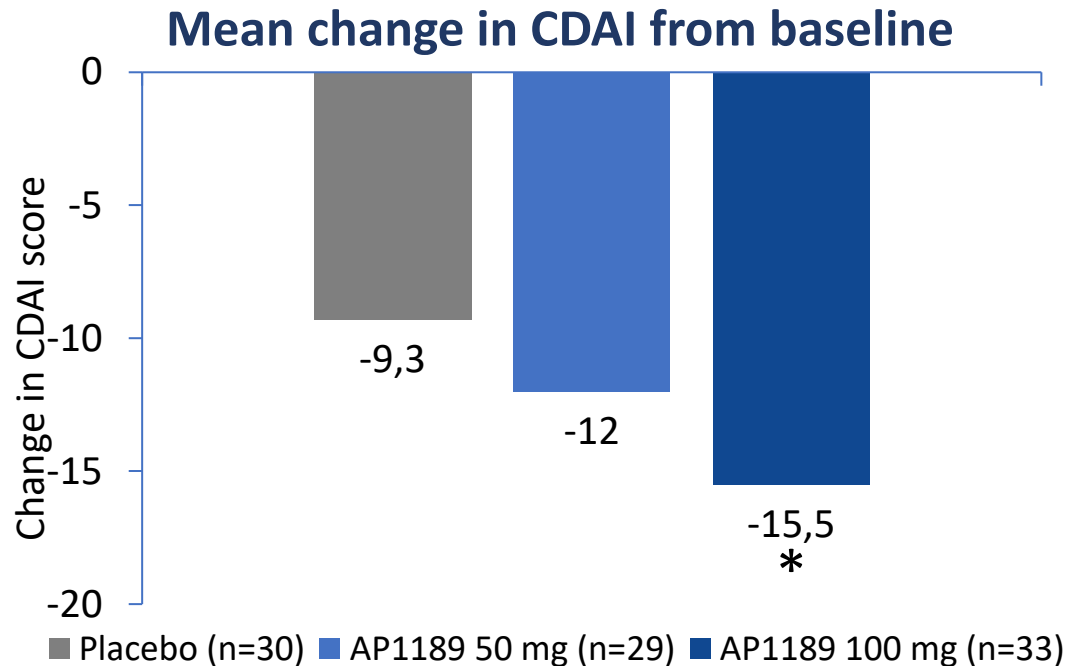


DMARD-IR:

- This is the patient population being studied in RESOLVE
- Up to 50% of 1st DMARD Tx will not achieve low disease activity and 70% will fail a 2nd DMARD Tx¹
- Up to 54% of MTX-Tx patients will be DMARD-IR at 3mo²
- ~20% of patients who initially respond to MTX will lose responsiveness²
- Up to 22% of patients experience intolerance even with long-term MTX usage³

Resomelagon (AP1189) demonstrated significant treatment effects in patients with severe treatment-naïve RA in the 4-week BEGIN P2a clinical trial

Phase 2a study in treatment naïve RA patients with high disease activity (CDAI >22 at randomization) in combination with MTX with 4 weeks treatment



**Mean improvement in CDAI above the minimally important clinical difference (MCID)⁺
Robust 1-Month ACR20/50/70 response rates for 100mg AP1189**

The emerging resomelagon clinical profile supports continued RA development for potential broad utility

Resomelagon Emerging Clinical Profile	Severe Tx- Naïve	DMARD-IR
<p><u>Once-Daily Oral Dosing</u> Simple one-daily oral tablet</p>	<ul style="list-style-type: none"> Oral convenience key for early patients especially as most on multiple medications 	<ul style="list-style-type: none"> Oral convenience key for early patients especially as most on multiple medications
<p><u>Quick Onset of Action</u> Efficacy at 2-weeks in BEGIN and in 1st day in COVID</p>	<ul style="list-style-type: none"> Patients are presenting with severe disease activity so quick onset is key 	<ul style="list-style-type: none"> Patients have likely been suffering with moderate to severe disease for months
<p><u>High-Degree of Efficacy</u> BEGIN responses like JAKs</p>	<ul style="list-style-type: none"> MTX tends to work less well in these patients 	<ul style="list-style-type: none"> These patients need better disease control and have been dealing with DMARD inadequacies
<p><u>Safe and Well Tolerated</u> No emerging safety issues seen over MTX background</p>	<ul style="list-style-type: none"> Less likelihood of unexpected safety issues derailing initial therapy 	<ul style="list-style-type: none"> Alternatives to resomelagon have black boxed warnings of potential life-threatening SAEs
<p><u>Non-Immunosuppressive</u> MC MoA without cortisol release (no MC2R)</p>	<ul style="list-style-type: none"> Lack of additional immunosuppression is key in this patient population with co-morbidities 	<ul style="list-style-type: none"> Lack of additional immunosuppression is key in this patient population with co-morbidities
<p><u>Compatible</u> No known compatibility concerns with RA Tx</p>	<ul style="list-style-type: none"> Compatibility with MTX facilitates combo usage No additional concerns to treat these patients more aggressively at initiation 	<ul style="list-style-type: none"> Compatibility with MTX facilitates combo usage No known compatibility issues and lack of immunosuppression allow for potential use with biologics

DMARD insufficient positioning targets a higher volume commercially attractive space not well served by current therapies

These lines of therapy are established by clinical practice, step-therapy indications and access restrictions

Key Approved Therapies	MTX, sulfasalazine, hydroxychloroquine, azathioprine, leflunomide	Humira, Enbrel, Cimzia, Remicade, Actemra, Rinvoq, Olumiant, Xeljanz, biosimilars	Actemra, Orencia, Rituxan, Rinvoq, Olumiant, Xeljanz, biosimilars	Actemra, Orencia, Rituxan, Rinvoq, Olumiant, Xeljanz, Acthar (US), biosimilars
Line of Tx	1 st -Line	2 nd -Line	3 rd -Line	4 th -Line
Key Pipeline Therapies	AP1189, Zunsemetinib (MK2), Rabeximod (NFkB)		Olokizumab (IL6) Otilimab (GMCSF) Arteglia (IL6)	Olokizumab (IL6) Otilimab (GMCSF) Arteglia (IL6)

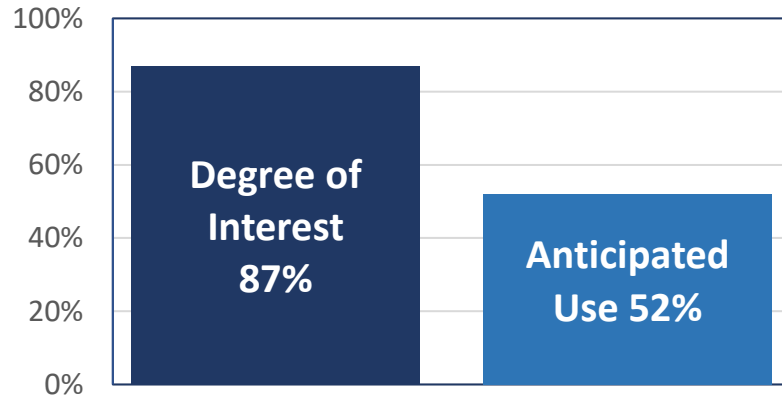


DMARD-Insufficient Positioning :

- Encompasses both severe-Tx naïve and DMARD-IR opportunities
- Provides the basis for a volume-driven market opportunity with pricing flexibility to shape access
- Less direct competition with biologics and JAKs creates more opportunity to establish proper practice patterns and access guidelines
- Establishes a position in RA that is 'transferrable' to other inflammatory diseases

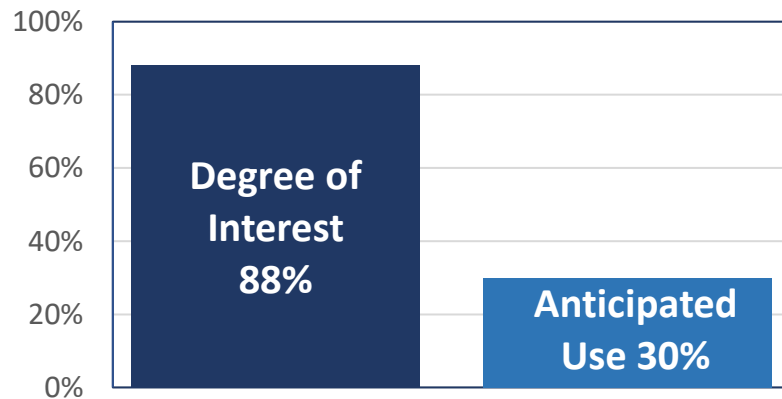
US high-volume rheumatologists stated a strong interest and high intent to use in both DMARD-IR and anti-TNF-IR RA patients

Rheum Interest in AP1189 for DMARD-IR



“Oh man. I'd love to use this up front. I'd love to use it right after methotrexate. I'd love to use it before. I'd love to see this upfront. I mean the non immunosuppressive working kind of endogenously and not doing all the steroid evils, but almost kind of kicking butt like a steroid, uh, yeah, count me in for that one. . .”

Rheum Interest in AP1189 for ant-TNF-IR



“There will be patients that present in such bad shape that I take them to a TNF with MTX right off the bat simply because of my comfort level with TNFs. If those patients don't respond to the TNF, then this would certainly be an option. . .”

Update on pipeline



SynAct Pharma – Pipeline overview

Asset	Indication	Pre-clinical	Phase I	Phase IIa	Phase IIb	Phase III
Resomelagon (AP1189)	Rheumatoid Arthritis Severe treatment-naïve with MTX	Completed			Ongoing	Resolve Part B (Approved in IND)
	Rheumatoid Arthritis DMARD-IR	Completed		Ongoing	Resolve Part B (Approved in IND)	
	Nephrotic syndrome (iMN)	Completed		Ongoing		
	Virus- Induced Respiratory Insufficiency	Completed				
TXP-11	Prevention of organ failures in complicated surgery	Ongoing				
Small Molecules and Peptides	Autoimmune and inflammatory conditions	Ongoing				



Completed



Ongoing



Resolve Part B
(Approved in IND)

EXPAND STUDY P2b study in treatment naive RA patients.

Dosing completed in July 2023 -

Patient Population:

- Previous treatment naïve, eligible for initiation of DMARD treatment (MTX)
- CDAI >22 at baseline – min of 6 swollen and tender joints
- Glucocorticoids only allowed as rescue medicine

Resomelagon (AP1189) 100* mg, combination with MTX

Placebo, combination with MTX

12 Weeks dosing

Key Study Parameters

Dosing and Duration

- 12 weeks of once-daily dosing of solid tablet AP1189 or placebo- conducted at site in Eastern Europe- Successful completion of recruitment ahead of schedule

Study Size and Sites

- Designed to recruit 60 patients per group – actual number randomized is 127

Primary Endpoints

- ACR20 response rate at 12 weeks as compared to placebo

Secondary Endpoints

- CDAI score; DAS28 score; FACIT-Fatigue; HAQ/RAQoI

MRI- SubStudy

- Evaluation of Synovial inflammation using Dynamic Contrast Enhanced MRI Quantification (DEMRIQ and RAMRIS)

RESOLVE Study - Adaptive P2 trial design in DMARD-IR patients

Dosing in part A will be completed in August – Conducted under an US-IND in US and Europe

Part A – 4 weeks dosing

Part B – 12 weeks dosing

3 dose levels of Resomelagon (AP1189) cont. MTX

Up to 3 dose levels of Resomelagon (AP1189), cont. MTX

Placebo, cont. MTX

Placebo, cont. MTX

Patient Population:

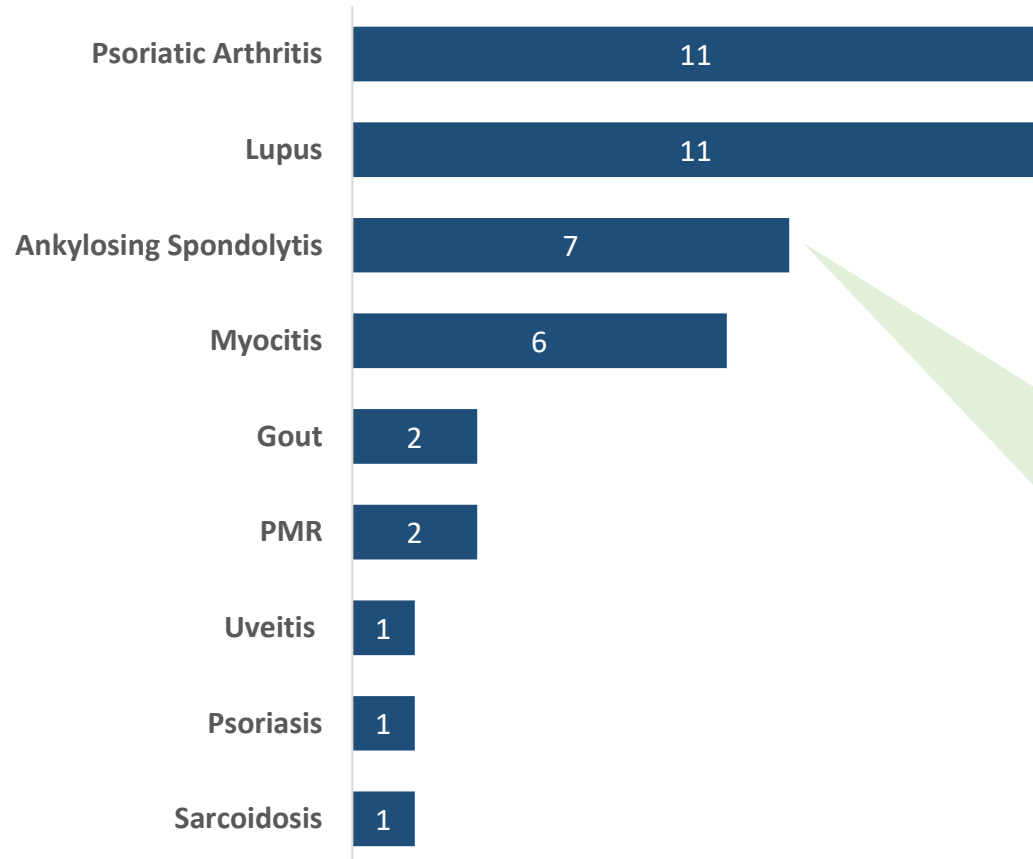
- >3 mo MTX treatment
- Documented incomplete response or loss of response
- Min of 6 swollen and 6 tender joints and/or increased CRP

Key Study Parameters

Dosing	<ul style="list-style-type: none"> ▪ Once-daily dosing of solid tablet AP1189 or placebo
Study Size and Sites	<ul style="list-style-type: none"> ▪ Part A: 30 pts per group ▪ Part B: 75 patients per group
Primary Efficacy Endpoints	<ul style="list-style-type: none"> ▪ ACR20 response rate at 4 Weeks (part A) and 12 weeks as compared to placebo
Secondary Endpoints	<ul style="list-style-type: none"> ▪ CDAI score; DAS28 score; FACIT-Fatigue; HAQ/RAQoI
MRI- substudy (part B only)	<ul style="list-style-type: none"> ▪ Evaluation of Synovial inflammation and potential effects on joint destruction using Dynamic Contrast Enhanced MRI Quantification (DEMRIQ and RAMRIS)

Resomelagon (AP1189) - Beyond RA – Rheumatologists express significant Interest for development in additional rheumatology diseases

Additional rheumatology diseases-of-interest for Resomelagon (AP1189)



Psoriatic arthritis

Use may depend on if Product X improves both dermal symptoms and joint symptoms

Interest in AP1189: **7.9/10** [5-10]

Potential patient eligibility for AP1189: **58%** [15-85%]

Treatment paradigm: Similar to RA

"I would definitely expect [Product X] to work because ACTH, that is Acthar, and corticotropin, are both approved for PSA, PSO, lupus, and gout...[but it doesn't address dermal presentation] very well" –US11

Lupus

Interest in AP1189: **7.9/10** [7-9]

Potential patient eligibility for AP1189: **44%** [20-75%]

Treatment paradigm: Similar to RA

"We're always looking for stuff for lupus, which is, by nature, very refractory and we have few options" –US04

Ankylosing spondylitis

Interest in AP1189: **7.5/10** [5-10]

Potential patient eligibility for AP1189: **50%** [25-75%]

Treatment paradigm: Similar to RA

"Theoretically whatever can be used in any inflammatory disease can be used across the board. They're not all the same but they share some common pathways." –US16

Financial summary



Financial summary

Operating activities

(SEK m)	23-Q2	22Q2	23-H1	22-H1
R&D costs	-29.0	-14.3	-72.6	-27.8
G&A costs	-14.5	-12.1	-29.1	-20.9
EBIT	-43.5	-26.4	-101.7	-48.7

Financial position

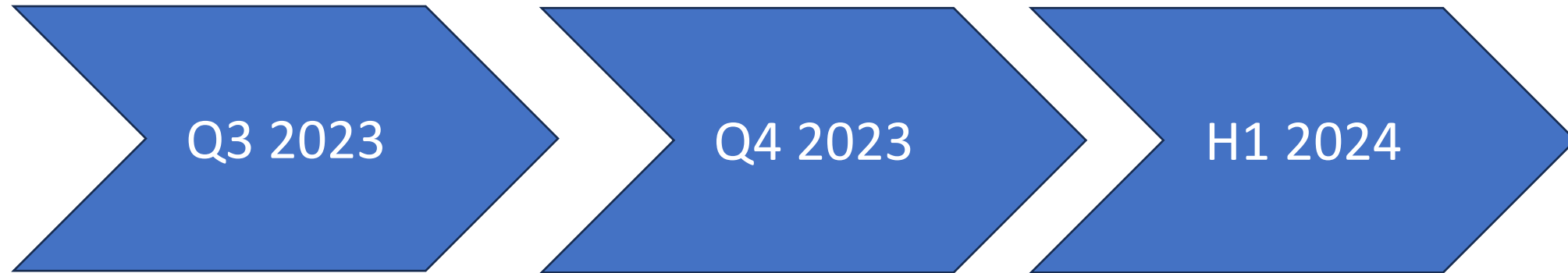
(SEK m)	30/06/23	30/06/22	31/12/22
Intangible assets	229.5	-	-
Cash	44.4	96.5	108.2
Other assets	23.6	37.5	34.4
Total assets	298.5	134.0	142.6
Equity	241.5	102.7	126.5
L-T debt	29.6	1.3	1.1
S-T debt	27.4	30.0	15.0

- Higher R&D costs due to more study activities vs LY
- G&A 2023 is affected by one-offs
- Intangible assets increase, due to TXP acquisition beg 2023
- H1 Operating CF was SEK -65.2m (-53.9). Less costs H2 as recruitment in EXPAND and RESOLVE was completed in July
- LT debt, mainly tax credit and TXP suppl. purchase price
No bank loans or similar

Upcoming news flow and closing remarks



Upcoming news flow



September: Topline results from Expand

October: Topline results from Part A Resolve

Initiation of Resolve Part B

More results from Expand

Initiation of Phase I TXP-11

More results from Part A Resolve

More pipeline updates

Thank you

