SYNACT PHARMA

INFLAMMATION RESOLUTION

SynAct Pharma AB

Treating Inflammation through Resolution Therapy

BIO Boston June 2023

CEO Torbjörn Bjerke, MD

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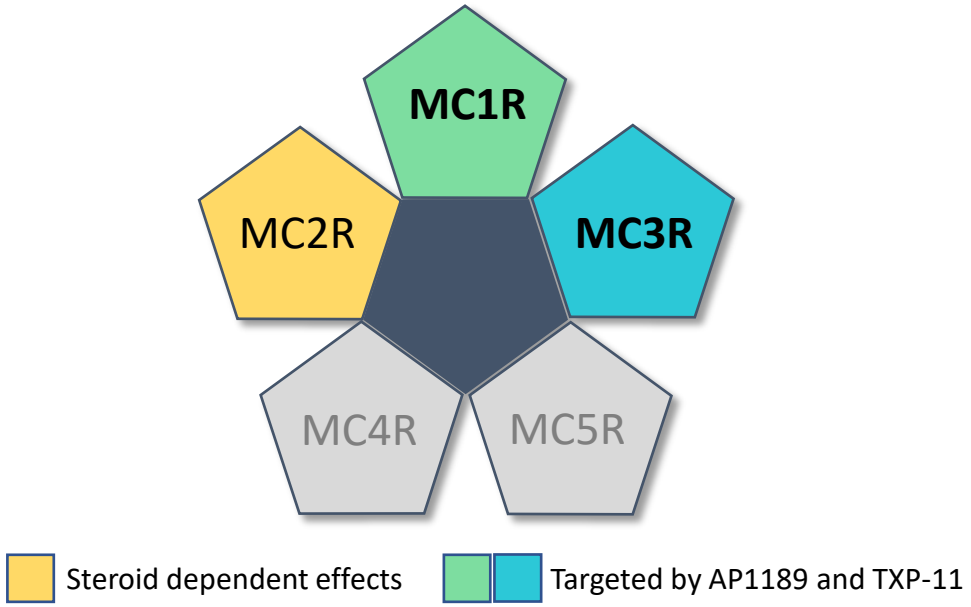
SynAct Pharma – In Brief

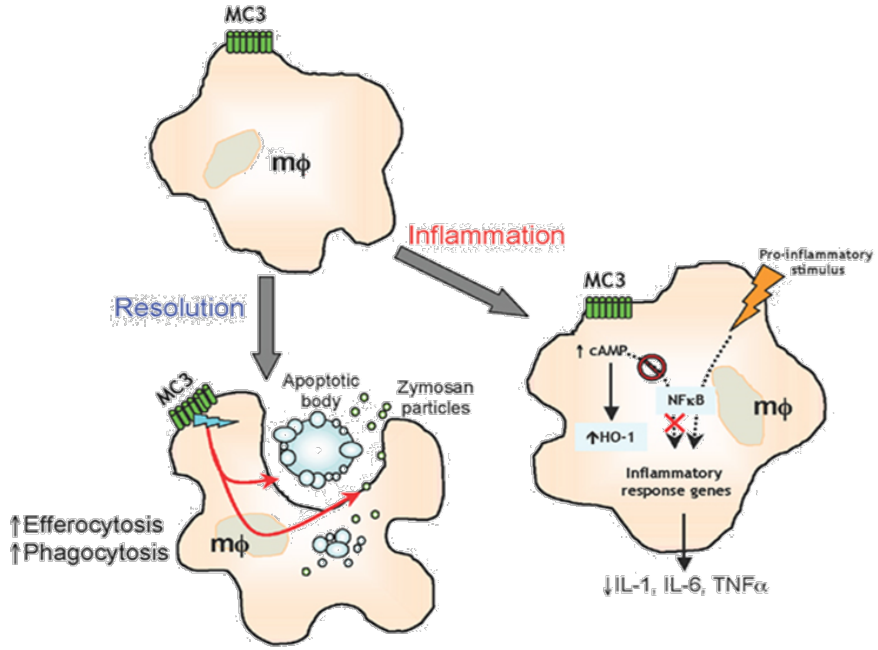
- **SynAct Pharma is a clinical stage biotechnology company focused on resolving inflammation through melanocortin biology to treat inflammatory and autoimmune diseases**
- **Oral small molecule, AP1189, is currently in active Phase 2 development for rheumatoid arthritis (RA) and nephrotic syndrome (iMN)**
- **Achieving communicated milestones:**
  - ✓ 1H22 – Listed on Nasdaq Stockholm Main Market
  - ✓ 2H22 – Resumed amended iMN P2a trial
  - ✓ 2H22 – Filed and opened US IND
  - ✓ 2H22 – Initiated Phase 2b (P2b) in early severe RA
  - ✓ 2H22 – Initiated Phase 2a/b in DMARD-IR RA under FDA IND
  - ✓ 1H23 – Completed acquisition of TXP Pharma
- **Three Phase 2 studies reading out in 2023:**
  - P2b in severe treatment naïve RA patients in combination with methotrexate (MTX)
  - Phase 2a (P2a) in RA patients experiencing an incomplete response to MTX (P2b protocol filed)
  - P2a in patients with nephrotic syndrome (iMN) experiencing severe proteinuria

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					
	Rheumatoid Arthritis DMARD-IR					
	Nephrotic syndrome (iMN)					
	Virus- Induced Respiratory Insufficiency					
TXP-11	**Prevention of organ failures in complicated surgery**					
Small Molecules and Peptides	**Autoimmune and inflammatory conditions**					

SynAct is developing selective melanocortin agonists with both anti-inflammatory and pro-inflammation resolution activity



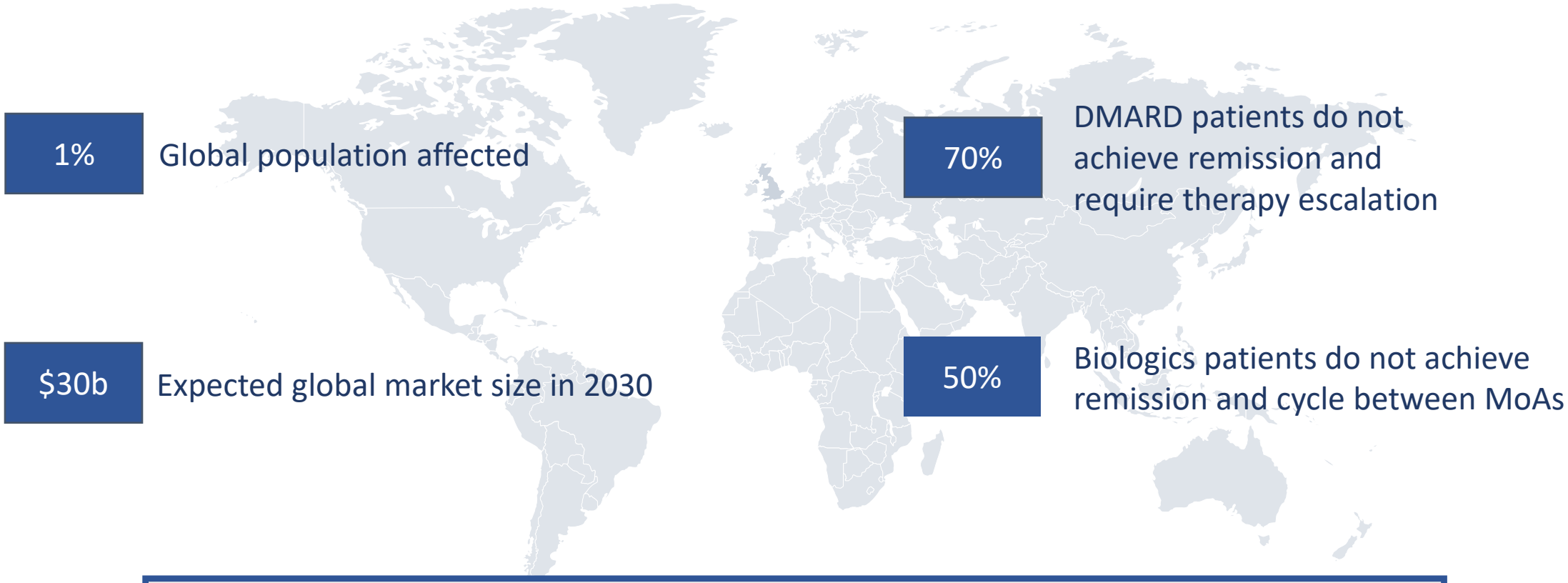


- Resomelagon induces selective stimulation of **melanocortin receptors 1 and 3 (MC1R and MC3R)** present on immune active cells promotes direct immunomodulatory effects
- **SynActs MCR agonists have no activity against MC2R**, present in the adrenal glands, which causes the release of cortisol when stimulated and results in steroid side effects and tolerability issues

- **Exbibits anti-inflammatory activity** via MC1R and MC3R stimulation on targets cells – such as lowering the release of pro-inflammatory cytokines
- **Promotes pro-resolution pathways** following stimulation of MC1R and MC3R on targets cells – such as increasing efferocytosis in macrophages

ACTH: adrenocorticotropic hormone; MCR: melanocortin receptor

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



1% Global population affected

$30b Expected global market size in 2030

70% DMARD patients do not achieve remission and require therapy escalation

50% Biologics patients do not achieve remission and cycle between MoAs

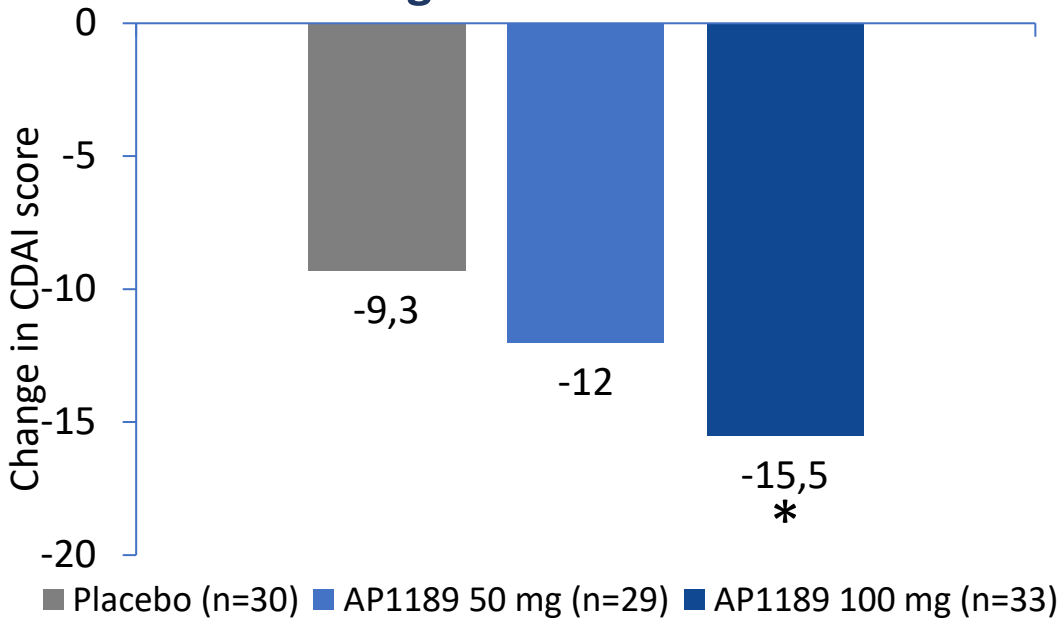
AP1189 could be well suited to address the unmet needs in RA

Rheumatoid Arthritis: Global Drug Forecast and Market Analysis to 2029, Reference Code: GDHC209PID

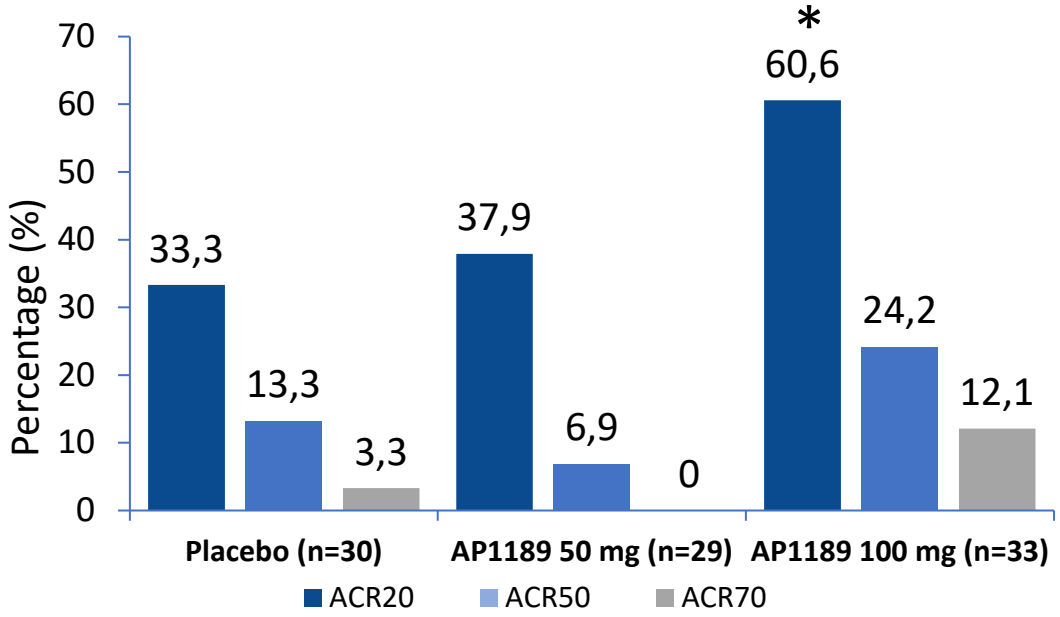
Resomelagon (AP1189) demonstrated significant treatment effects in patients with severe treatment-naïve RA in the 4-week BEGIN P2a clinical trial

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

Mean change in CDAI from baseline



ACR 20/50/70 Response Rates

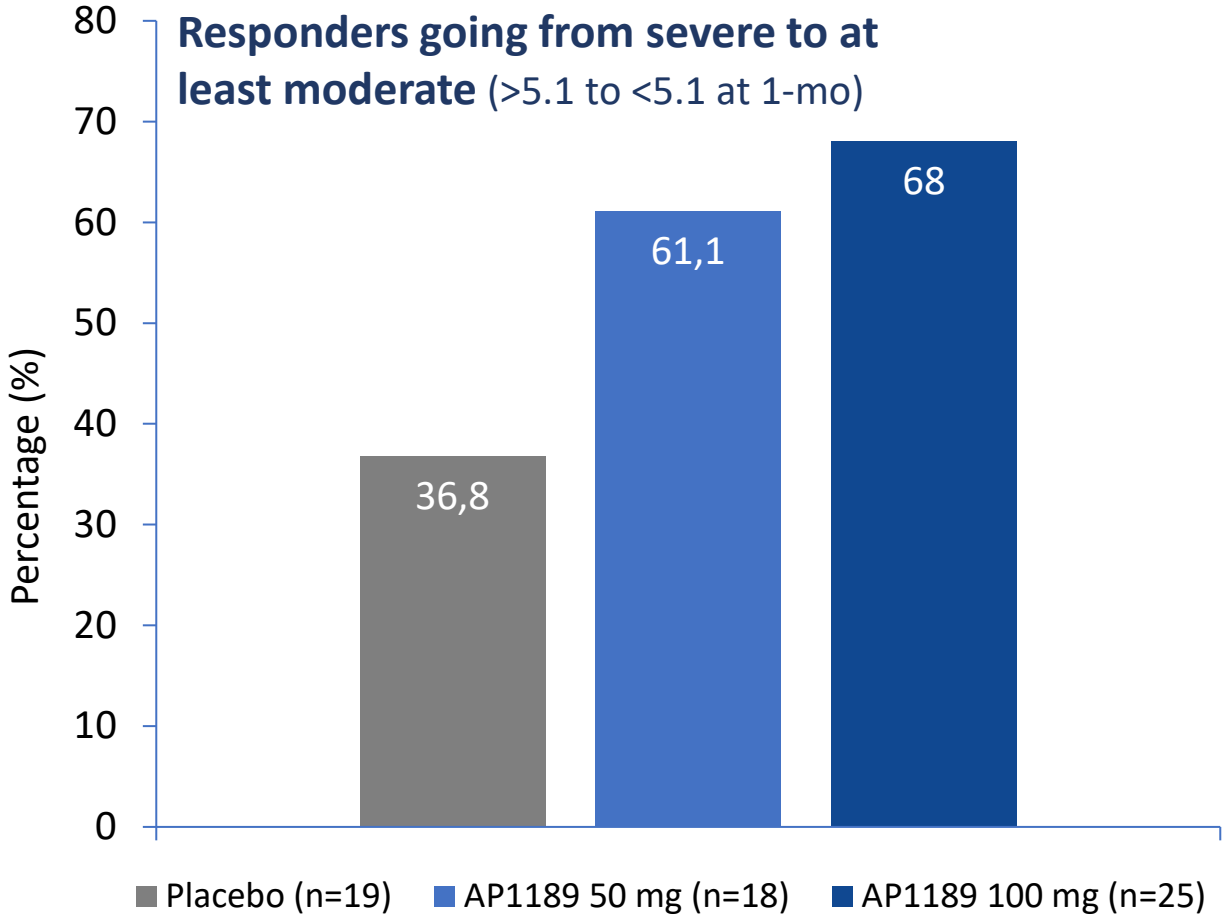


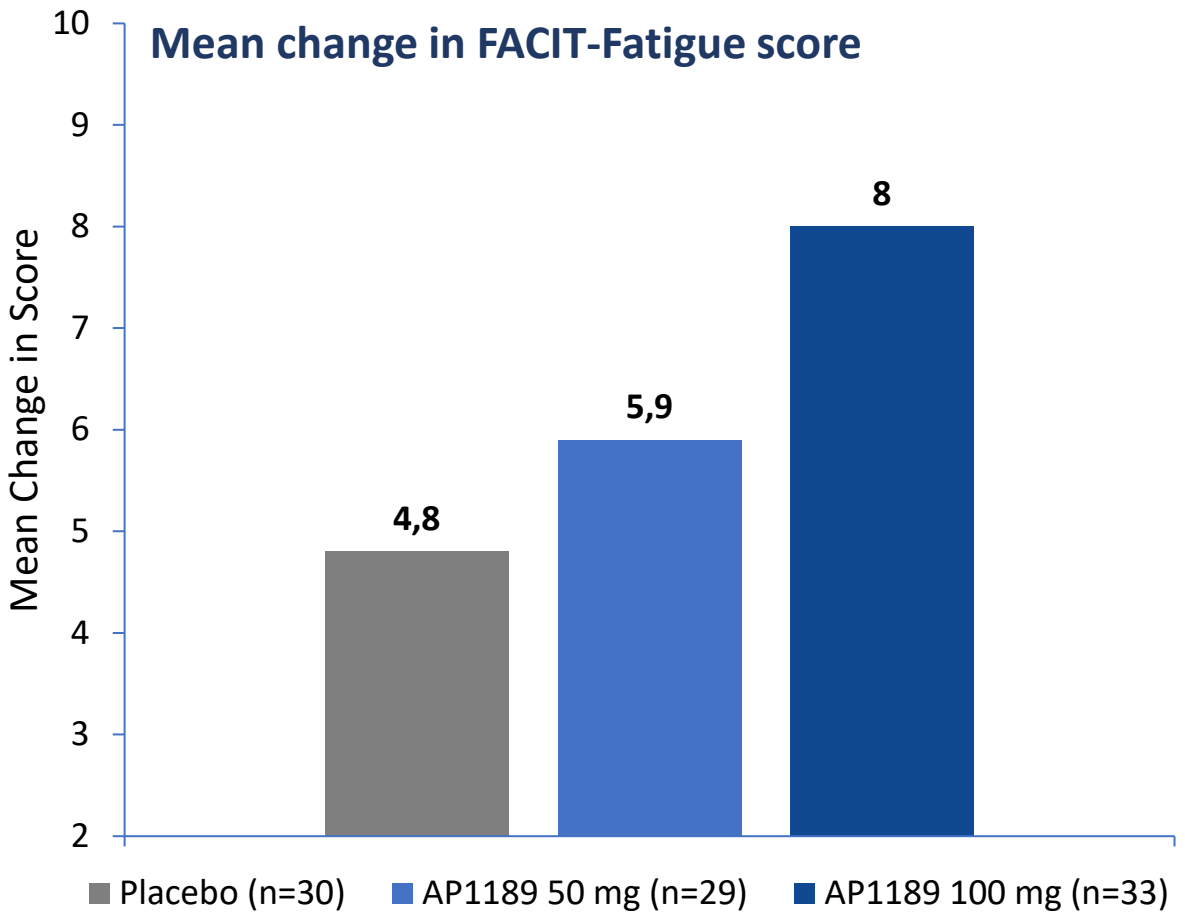
Mean improvement in CDAI above the minimally important clinical difference (MCID)⁺
Robust 1-Month ACR20/50/70 response rates for 100mg AP1189

* = p<0.05 vs placebo

(+) Curtis et. Al *Arthritis Care Res (Hoboken)*. 2015 October; 67(10)

Meaningful improvements were also seen in DAS28 (CRP) and FACIT-Fatigue Scores





Good effects seen with 100mg in patients with very active DAS28 (>5.1) at baseline

Mean change in 100mg group is 2x the minimal clinically important difference (MCID)⁺

(+) Cella et. Al *The Journal of Rheumatology 2005; 32:5*

4-Week daily AP1189 dosing was safe and well tolerated in the BEGIN study

Adverse Events[1]

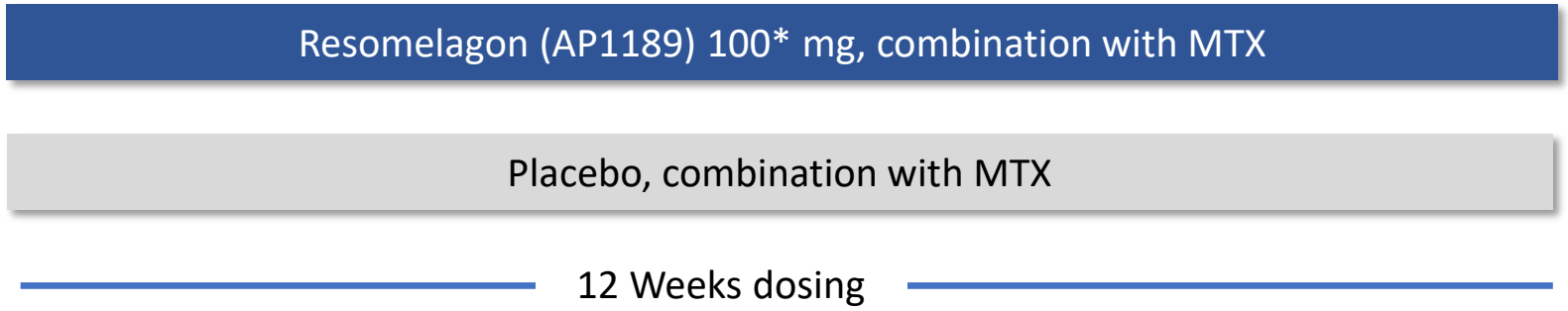
Group (n)	Placebo + MTX (34)	AP1189 + MTX		Total (105)
		50 mg (35)	100 mg (36)	
SAEs n	0	0	0	0
AEs n	34	65	53	152
Mild/Mod/Severe	28/4/2	45/20/0	43/10/0	116/34/2
% Mild	82%	69%	81%	76%
Pts with ≥ 1 AE n (%)	17 (50)	20 (57)	20 (56)	57 (54)
Discontinuation n (%)	1[2] (3)	0 (0)	1[3] (3)	2 (2)
AEs >10% of Pts, n				
Nausea[4]	7	5	7	19
ALT increase[5]	3	6	0	9
Headache[4]	0	2	5	7

(1) All study AEs; As per protocol safety assessments were conducted at level of all AEs not only treatment-emergent AEs
(2) Baseline ALT>3x upper normal level; patient discontinued from study when levels were read
(3) Onset of herpes zoster; Investigator decided to DC MTX which necessitated study discontinuation
(4) Headache and nausea were transient and occurred more frequently early in dosing period
(5) Laboratory value AEs determined by investigator; 8/10 ALT increases were mild and 3 occurred outside of dosing period

EXPAND STUDY P2b study in previous treatment naive RA patients. Recruitment completed in April 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



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/RAQol
MRI- SubStudy	▪ Evaluation of Synovial inflammation using Dynamic Contrast Enhanced MRI Quantification (DEMRIQ)

*:Free base – correspond to 125 mg acetate salt used in the BEGIN study

AP1189- Adaptive P2 trial design in DMARD-IR patients
Currently recruiting in US and Europe under an US- IND- Data on part A in H2 2023

Part A – 4 weeks dosing

3 dose levels of Resomelagon (AP1189) cont. MTX

Placebo, cont. MTX

Part B – 12 weeks dosing

Up to 3 dose levels of Resomelagon (AP1189), 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	▪ Once-daily dosing of solid tablet AP1189 or placebo
Study Size and Sites	▪ Part A: 30 pts per group ▪ Part B: 75 patients per group
Primary Efficacy Endpoints	▪ ACR20 response rate at 4 Weeks (part A) and 12 weeks as compared to placebo
Secondary Endpoints	▪ CDAI score; DAS28 score; FACIT-Fatigue; HAQ/RAQol
MRI- substudy (part B only)	▪ Evaluation of Synovial inflammation and potential effects on joint destruction using Dynamic Contrast Enhanced MRI Quantification (DEMRIQ)

The emerging Resomelagon (AP1189) clinical profile supports continued RA development for potential broad utility

Emerging Resomelagon Clinical profile	
• **Once-Daily Oral Dosing**	• New oral tablet being used in both EXPOAND and RESOLVE • Oral convenience for early lines of therapy
• **Quick Onset of Action**	• Efficacy seen at 2-week time point in BEGIN • Efficacy seen in 1st day in hospitalized COVID study
• **High-degree of efficacy**	• BEGIN 1-mo responses were in-line with JAK inhibitors
• **Safe and Well Tolerated**	• No emerging safety issues seen thus far in clinical assessment • No signs of increased infection rates or other serious safety concerns
• **Steroid-Free MoA**	• Melanocortin efficacy with no steroid-associated side-effects (no MC2R)
• **Compatible with MTX**	• Shown to be compatible with MTX • No known compatibility concerns with TNF or other biologics

- Initial development has been focused on first-line use with MTX in patients presenting with high disease activity (HAN) and in patients with incomplete responses to MTX (MTX-IR)

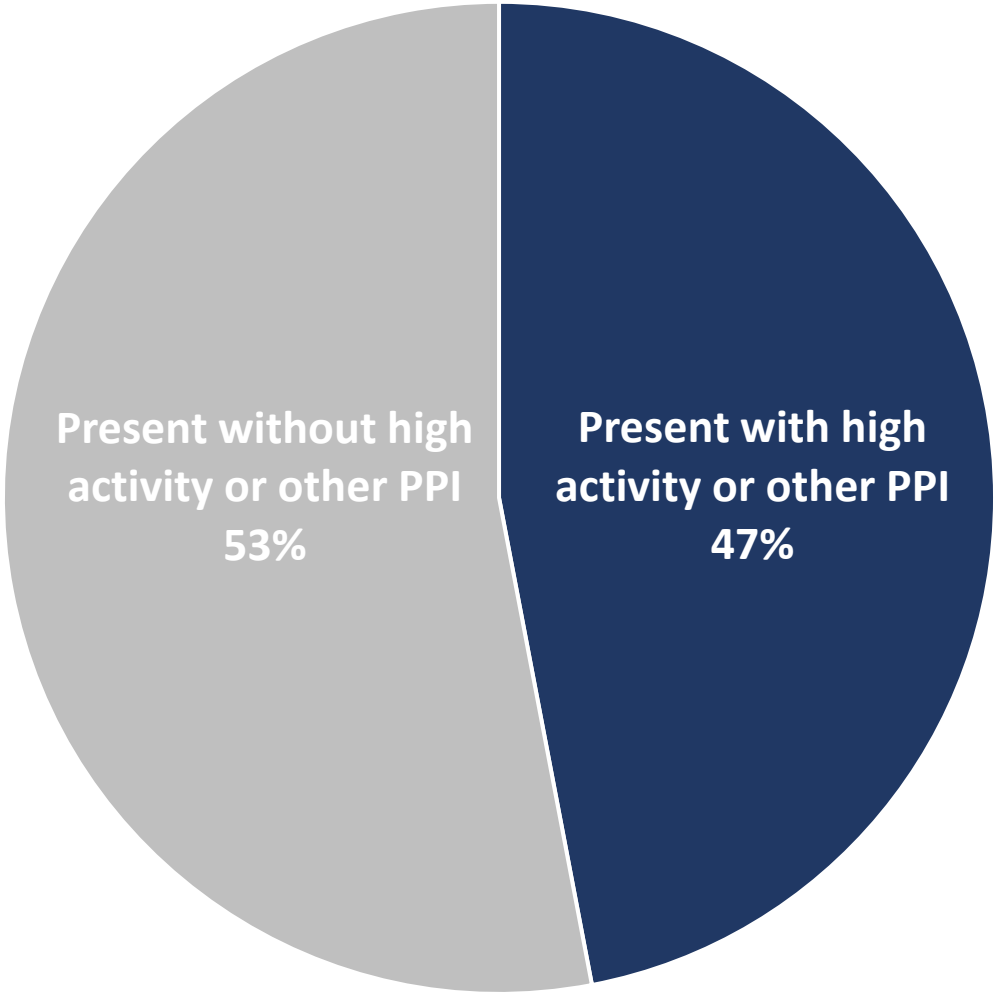
Resomelagon (AP1189) can resolve Inflammation without causing immunosuppression which may make it potentially suitable for broad use in RA

- **Most approved RA therapies are immunosuppressive and have black boxed warnings of potentially serious and possibly fatal serious adverse event reactions**
- **Resomelagon (AP1189) in contrast resolves inflammation without immunosuppression in a convenient oral form making it potentially suitable for broad foundational use in RA**

	1st-Line - DMARDS	2nd-Line -	3rd-Line	4th-Line
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

AP1189 Potential Positions	**HAN**			
		DMARD-IR		
	Disease Activity Flares (3mo course)			

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

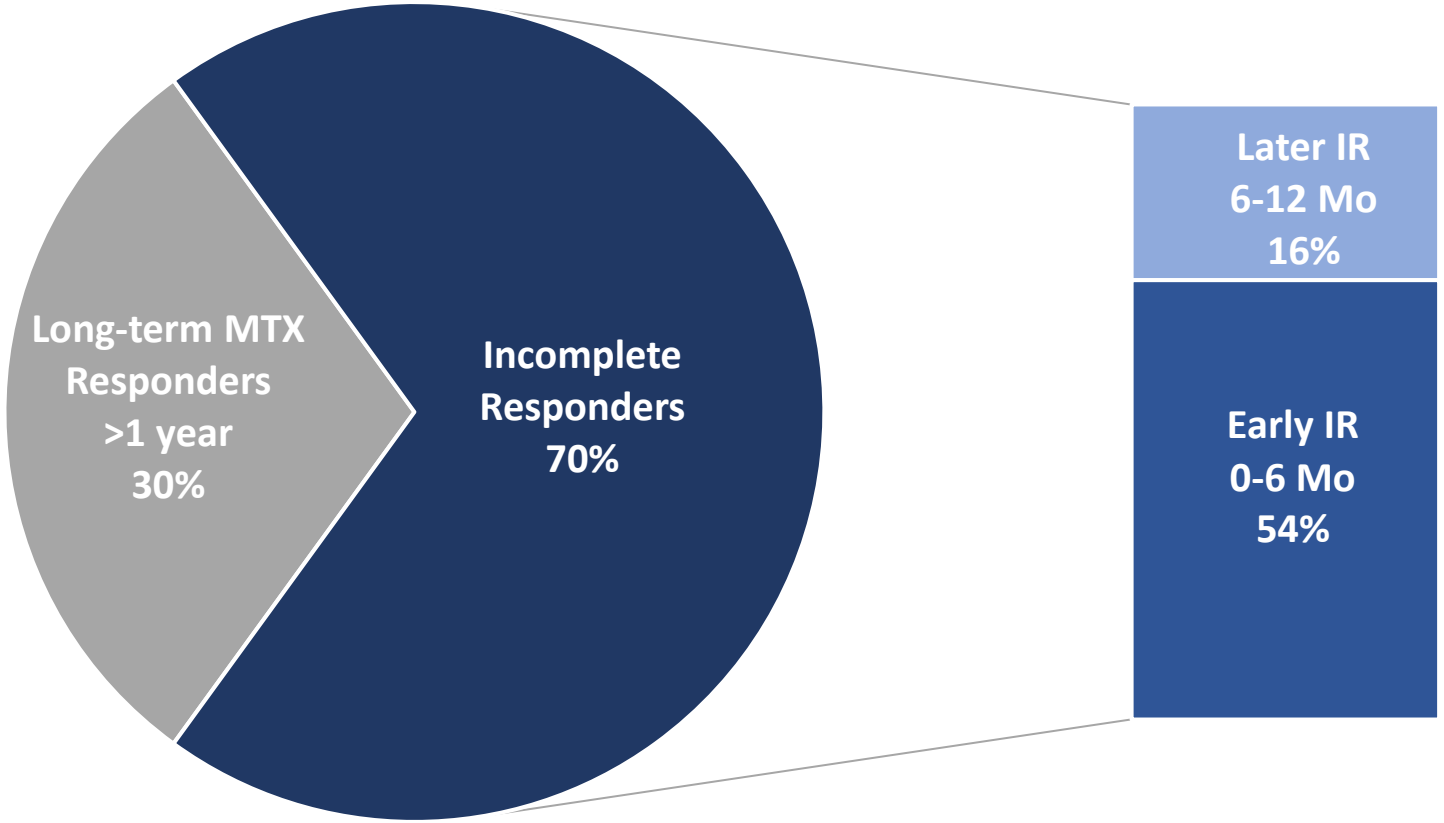


Highly-Active Naïve:

- Studied in BEGIN and EXPAND studies
- Highly active disease is the dominating poor prognostic indicator (PPI) in ACR and EULAR recommendations[1]
- 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]

1. Albrecht and Zink Arthritis Research & Therapy (2017) 19:68 2. Shpatz et al. IMAJ (2021) vol 23
3. Baganz et al. Seminars in Arthritis and Rheumatism 48 (2019) 976!982

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



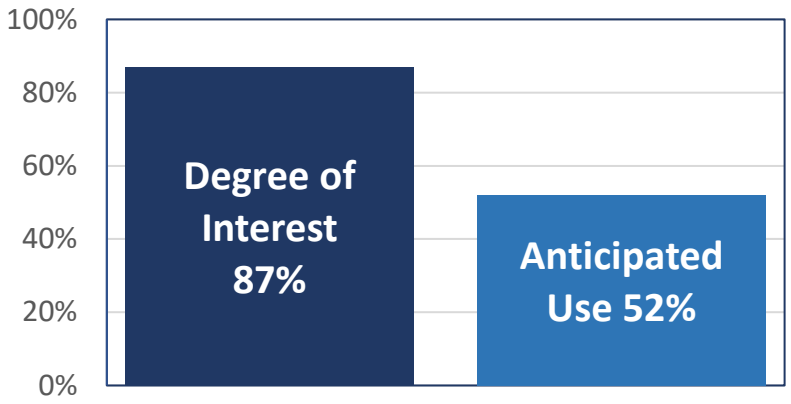
DMARD-IR:

- 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 Tx[1]
- Up to 54% of MTX-Tx patients will be DMARD-IR at 3mo[2]
- ~20% of patients who initially respond to MTX will loose responsiveness[2]
- Up to 22% of patients experience intolerance even with long-term MTX usage[3]

1. Baganz et al. Seminars in Arthritis and Rheumatism 48 (2019) 976!982; 2. GlobalData RA custom primary market research studies 2021-2023, on file; 3. Amaral et al. Advances in Rheumatology (2020) 60:4

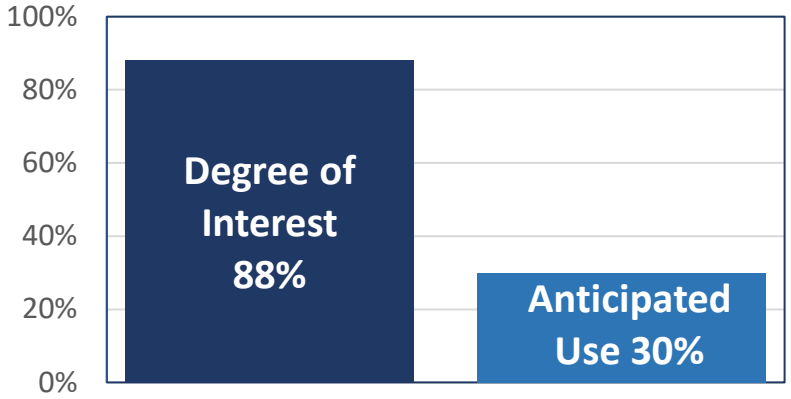
US high-volume rheumatologists stated a strong interest and high intent to use in both DMARD-IR and anti-TNF-IR RA patients

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

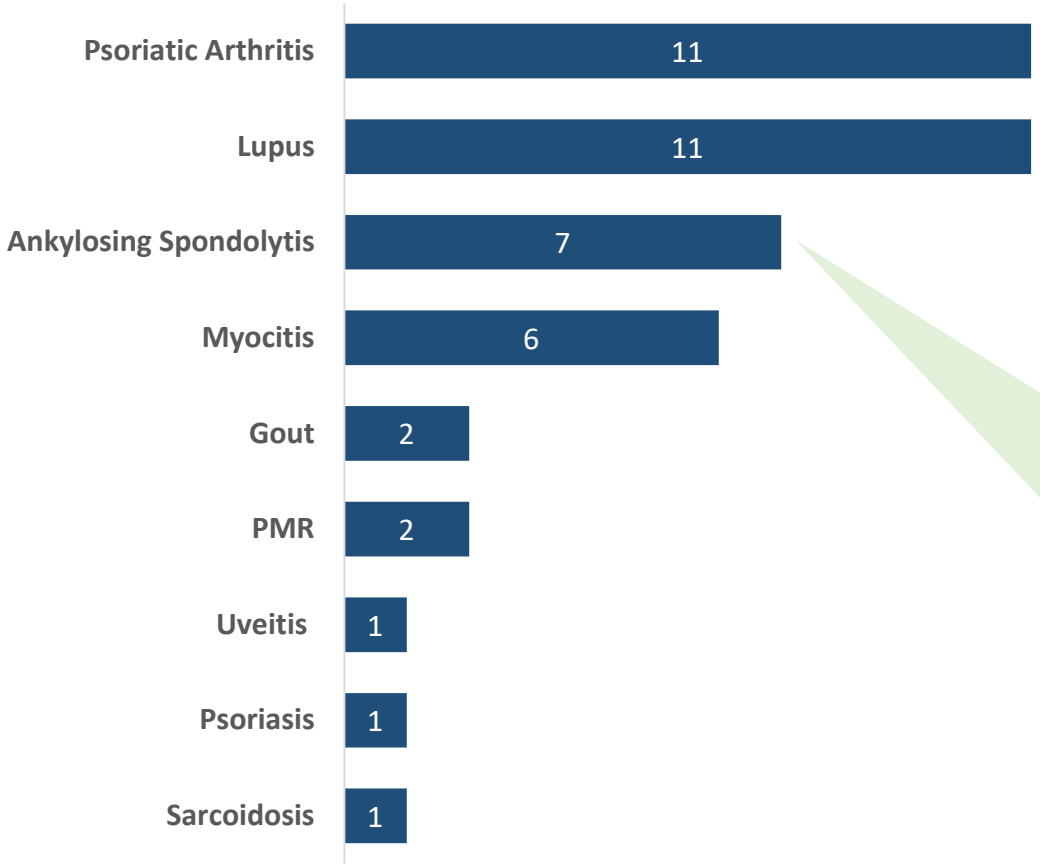


"There will be patients that present in such bad shape that I take them to a TNF with MTX right off the bat simply because of my comfort level with TNFs. If those patients don't respond to the TNF, then this would certainly be an option. .."

GlobalData RA custom primary market research studies 2021-2023, on file

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

GlobalData RA custom primary market research studies 2021-2023, on file

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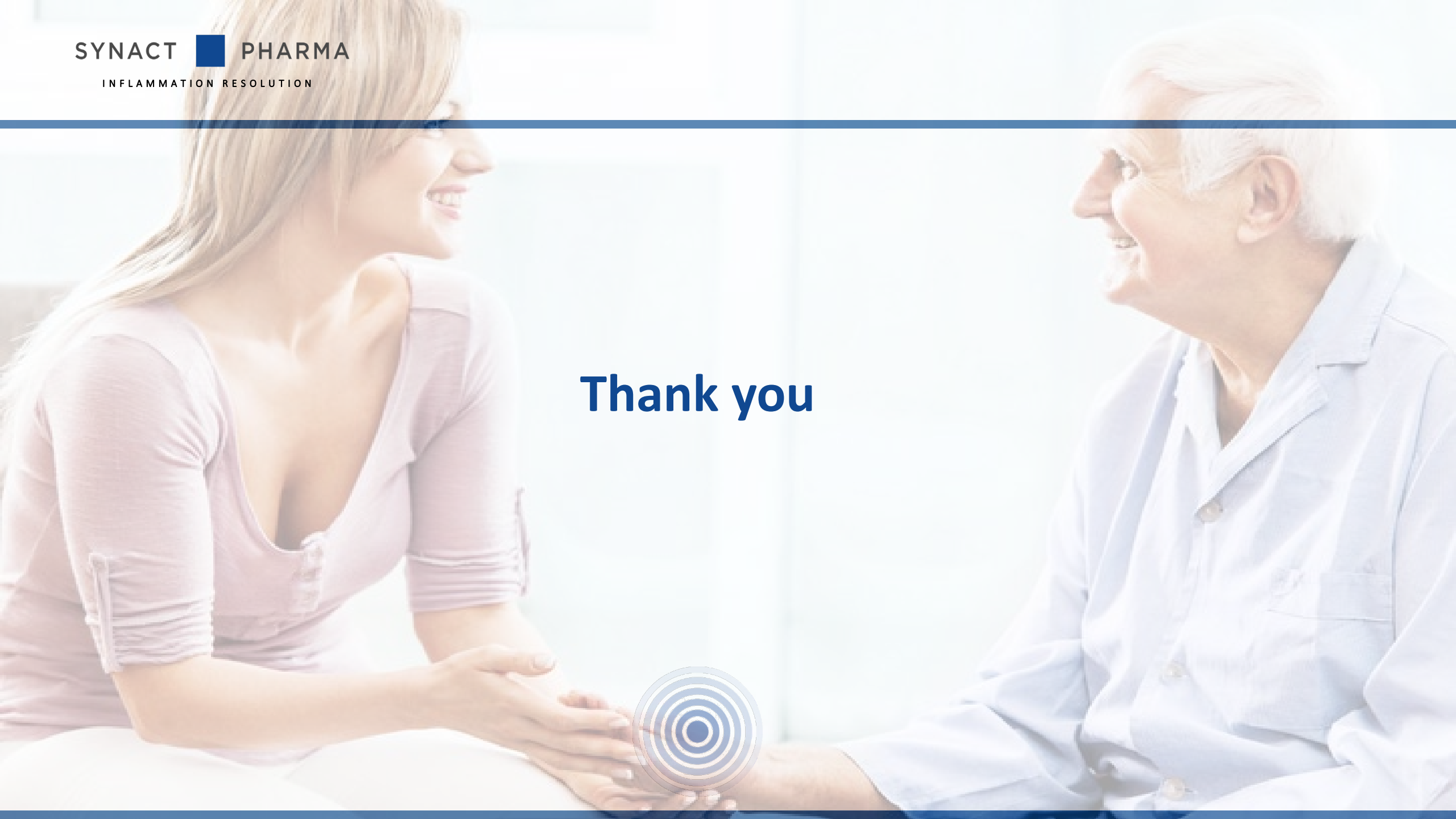

Thank you