

SynAct Pharma AB

Treating Inflammation through Resolution Therapy

ØU Life Science – 30 October 2024

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Synact Pharma- Treating Inflammation through Resolution Therapy

SynAct Pharma AB is a clinical stage biotechnology company focused on the resolution of inflammation through the selective activation of the melanocortin system. The company has a broad portfolio of oral and injectable selective melanocortin agonists aimed at inducing anti-inflammatory and inflammation resolution activity in autoimmune and inflammatory diseases to help patients achieve immune balance and overcome their inflammation.

VISION

To lead the development of inflammation resolution therapeutics, a new approach to treating inflammatory diseases that does not suppress the immune system and that enables patients to achieve immune balance and live beyond their inflammation.

MISSION

SynAct seeks to develop resomelagon (AP1189) and its peptide melanocortin agonists through proof-of-concept Phase 2 clinical studies. SynAct will seek to establish partnerships and collaborations with like-minded parties for Phase 3 studies and beyond

Synact Pharma – Overview

2013	Company Founded
2016	Listed at Spotlight Stock Market in Sweden
2019	Completes Phase I – AP 1189
2020	Completes Phase II – AP 1189 – in RA
2021	Completes Phase IIa – AP 1189 – COVID Completes Phase IIa – AP 1189 – RA (Begin study)
2022	Uplisted to Nasdaq, Stockholm
2023	Acquisition of TXP Pharma Completes Resolve and Expand studies – Phase II studies
2024	Replacement of Board and CEO - new focused strategy implemented

SynAct Pharma – highly experienced Management Team

Jeppé Øvli Øvlesen, MBA – CEO



- Over 20 years of experience as CEO of various companies
- Founding Board Member of more than 10 biotech and MedTech companies
- Co-founder of TXP Pharma
- Former CFO and VP of Business Development at Action Pharma



Björn Westberg, MSc – CFO



- Over 25 years of experience within various financial roles in the pharmaceutical industry
- Former CFO of Recipharm, Bonesupport, Enea
- Various finance management roles in AstraZeneca
- Experience in investor relations, financing, acquisitions and other business deals



Thomas Jonassen, MD – CSO, Co-founder



- Associate Professor at Cardiovascular Pharmacology, University of Copenhagen
- Visiting Professor at WHRI, Barts and London School of Medicine
- Co-founder of TXP Pharma and ResoTher Pharma
- Co-founder and former CSO of Action Pharma



Thomas Boesen, PhD – COO



- Over 20 years of experience in the biotech and pharmaceutical industry
- Inventor on 35 granted patents
- Co-founder of MedChem and TXP Pharma
- Former VP of Discovery at Action Pharma



James Knight, MBA – CBO



- Over 25 years of experience in the biotech industry, ranging from R&D to Commercial Strategy and Business Development
- Former VP of Portfolio Strategy at Questcor Pharmaceuticals



Kirsten Harting, MD & Executive MBA - CMO



- Over 30 years of experience from the global pharmaceutical industry and biotech
- Senior Vice president & Chief Medical Officer
- Responsible for development and approval of several new innovative drugs
- Global launch of new medicine
- Integrating medical and commercial understanding



SynAct Pharma – very experienced Board of Directors

	Shareholder	Company independent	Independent to major shareholders
<p>Anders Kronborg, M.Econ</p>  <ul style="list-style-type: none"> CEO or CFO, during 1996-2007 in Danish media companies Kinnevik, 2007-2015, various positions including COO between 2012-2015 LEO Pharma, 2015-2022 as CFO and interim CEO supporting growth by several M&A activities Resother Pharma, CEO since 2022 	Yes	Yes	Yes
<p>Sten Scheibye, PhD and B.Com</p>  <ul style="list-style-type: none"> Started as medical sales rep, registration officer before moving into more commercial roles and senior leadership Coloplast as CEO. During his tenure, Coloplast 6-doubled turnover and 8-doubled share performance Chairman of Novo Nordisk A/S, where he had a board seat for 10 years, then became Chairman of the Novo Nordisk Foundation Various board positions 	Yes	Yes	Yes
<p>Sten R Sørensen, BSc</p>  <ul style="list-style-type: none"> Over 30 years in the pharmaceutical and biotech industries Head of marketing positions in Monsanto and AstraZeneca Initiated two groundbreaking preventive survival studies in heart failure Cereno Scientific, CEO since 2015 	Yes	No	Yes
<p>Jeppé Øvli Øvlesen, MBA</p> <ul style="list-style-type: none"> See previous page 	Yes	No	Yes



Business development strategy

Based on a solid interest from big pharma and big biotech companies in discussing previous studies during 2022-2024 a close interaction will be conducted during 2025.

Regular updates will be ongoing during the next 12 month with the scope to enter into specific partnering discussions from mid 2025.

A wide range of potential deal structures are explored ranging from full acquisitions to licensing deals.

Option to acquire and collaboration agreements are being explored for TXP compounds.

Strong Patent Situation

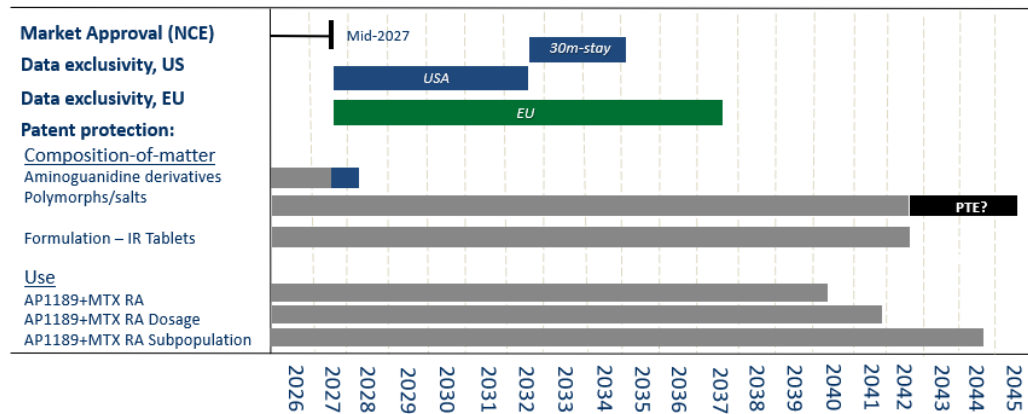
Resomelagon (AP1189)

- Multi layer strategy to protect core technology
- Composition-of-matter protection potentially until 2042
- Use patents in key indications until 2044
- Protection in major markets

Peptides

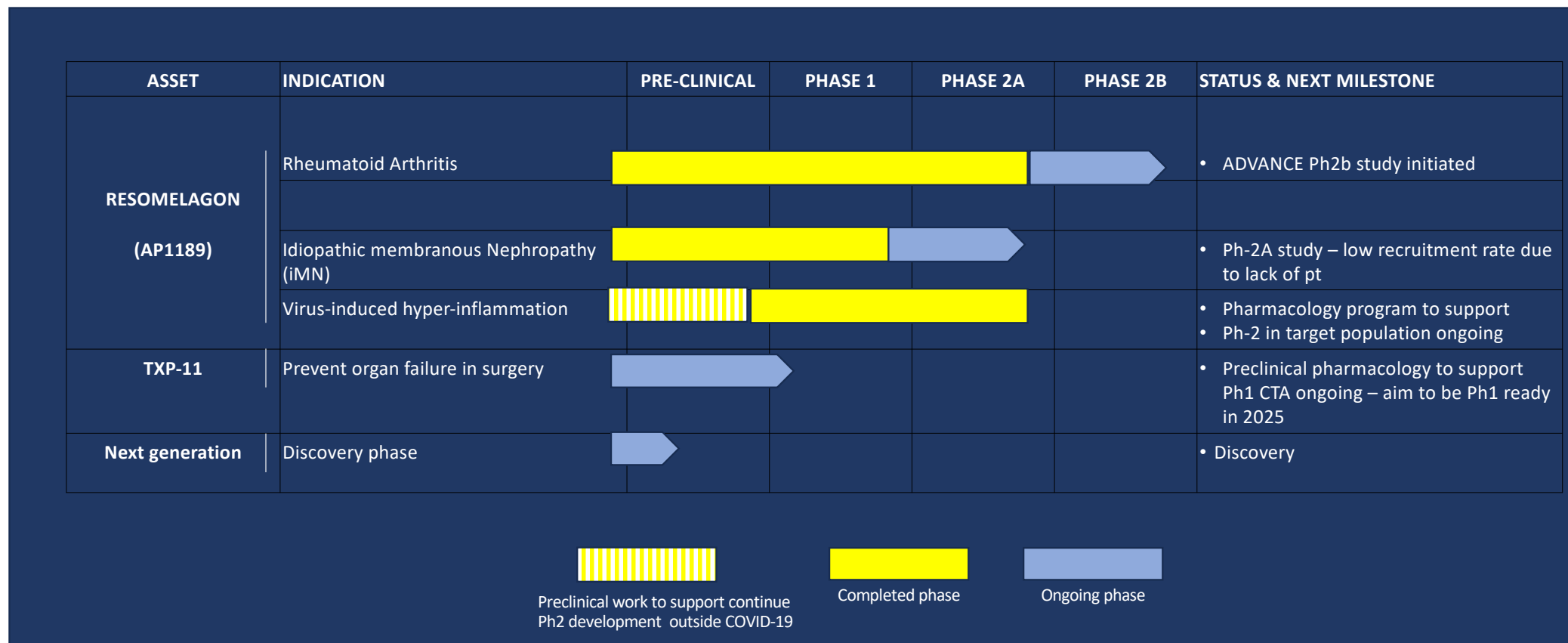
- BAP technology and melanocortin agonists until 2033
- BAP technology for therapeutic peptides until 2035
- Exedin-4 analogues (GLP-1) until 2041

Exclusivity Scenario (US/EU)- Current portfolio AP1189 for treatment of Rheumatoid Arthritis (First approval)

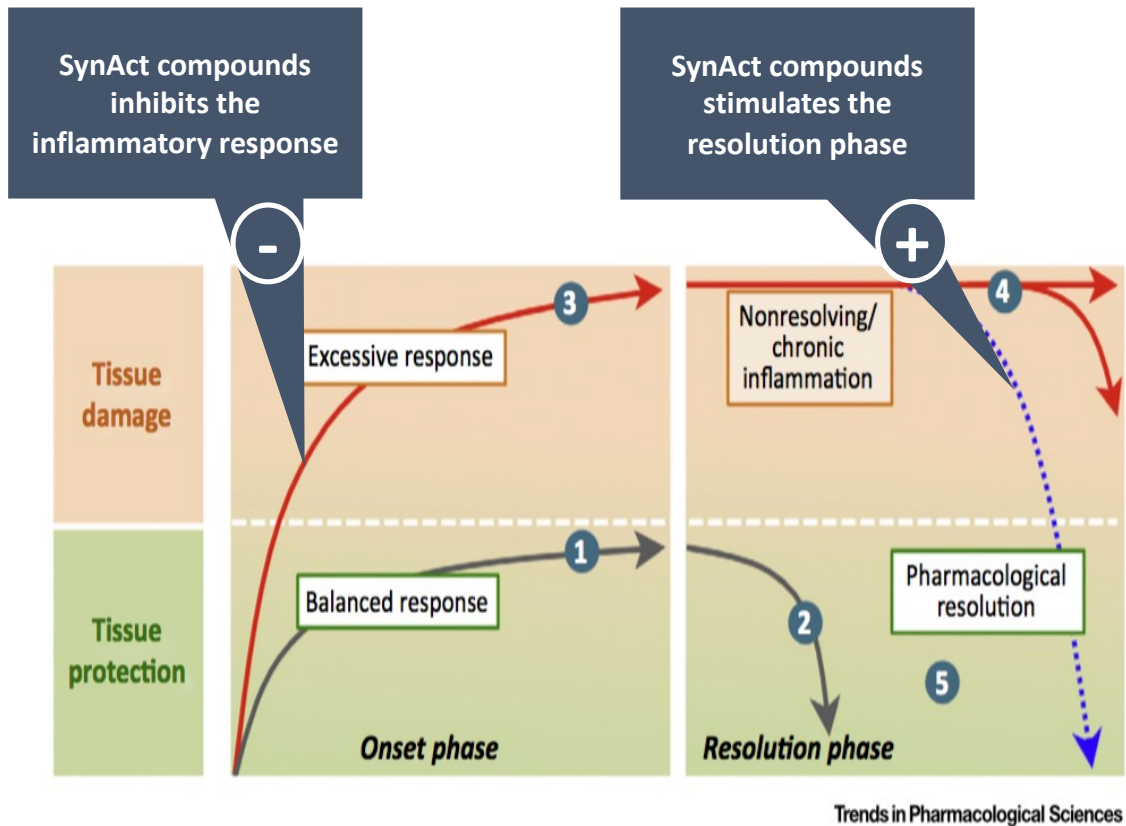


- US: 30m litigation stay to delay generic ANDA with FDA under some conditions
- US: 6m pediatric exclusivity can be available to all exclusivities covering AP1189 existing at the time of a pediatric exclusivity approval
- EU: 6m pediatric exclusivity can be added to the SPC (EU PTE)

Pipeline - overview



SynAct compounds promotes resolution of inflammation

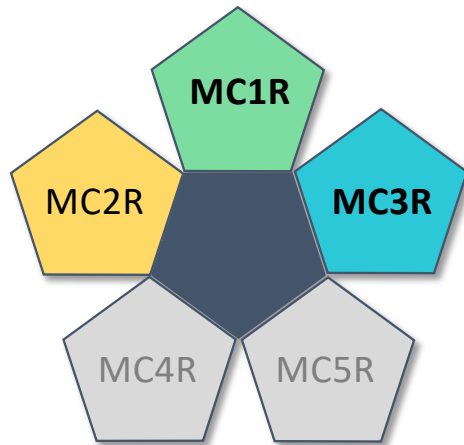


The inflammatory response

- 1 Inflammatory response effectively controlled in extent and time – protects tissues and limits damage
- 2 Pathways activated to safely terminate the inflammatory response and promote healing
- 3 Exaggerated response to inflammatory stimuli can have detrimental consequences and harm tissues
- 4 Failure to achieve resolution of inflammation can result in chronic inflammation
- 5 Activation of endogenous resolution pathways has the potential to restore tissues and function

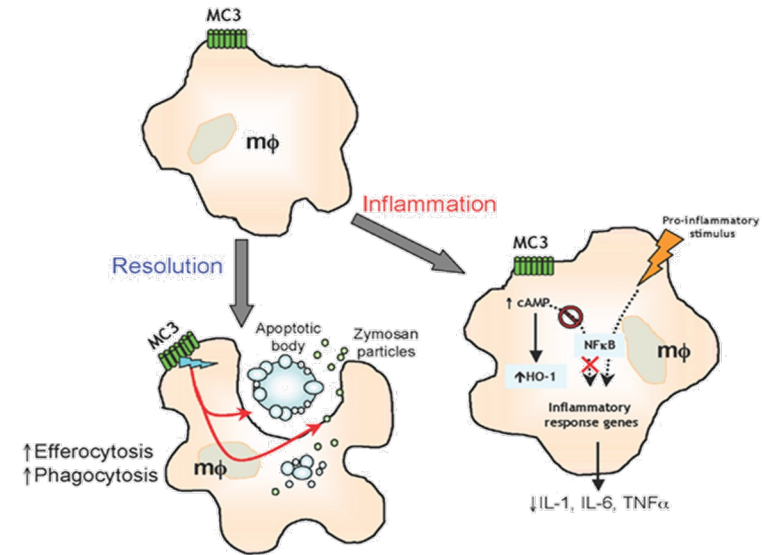
Cartoon adapted from Perretti et al. *Trends Pharmacol Sci* 2015;36:737–55

SynAct compounds promote resolution of inflammation through stimulation of melanocortin receptors on key cells in the inflammatory system



Steroid dependent effects

 Targeted by AP1189 and TXP-11

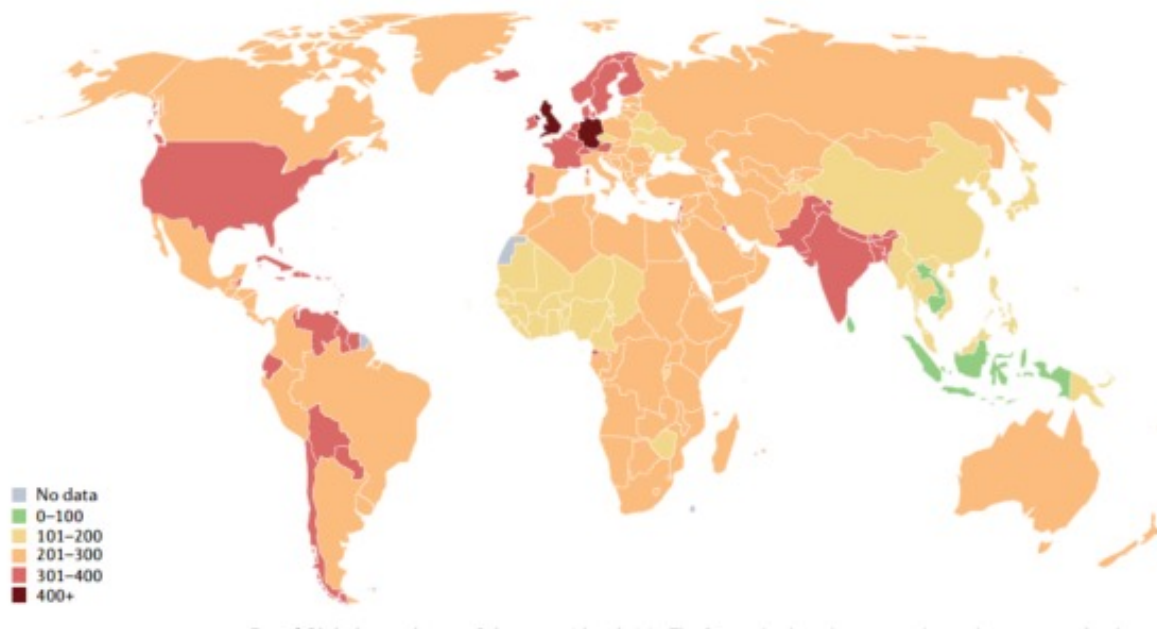


- Resomelagon induces selective stimulation of **melanocortin receptors 1 and 3 (MC1R and MC3R)** present on immune active cells promotes direct immunomodulatory effects
- **SynActs MCR agonists have no activity against MC2R**, present in the adrenal glands, which causes the release of cortisol when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

- **Exhibits 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

Rheumatoid Arthritis (RA) - Chronic inflammatory (autoimmune) disease

Rheumatoid arthritis (RA) is a chronic inflammatory disorder affecting joints. In some pts RA damage a wide variety of body systems, including the skin, eyes, lungs, heart and blood vessels. Uncontrolled disease as associated with severe complications. **No curative treatments**



RA is a global disease

Currently approximately 18 million people worldwide with RA

Is Prevalent in Developed Countries

Prevalence is between 0.2-1.0%, larger in industrialized countries

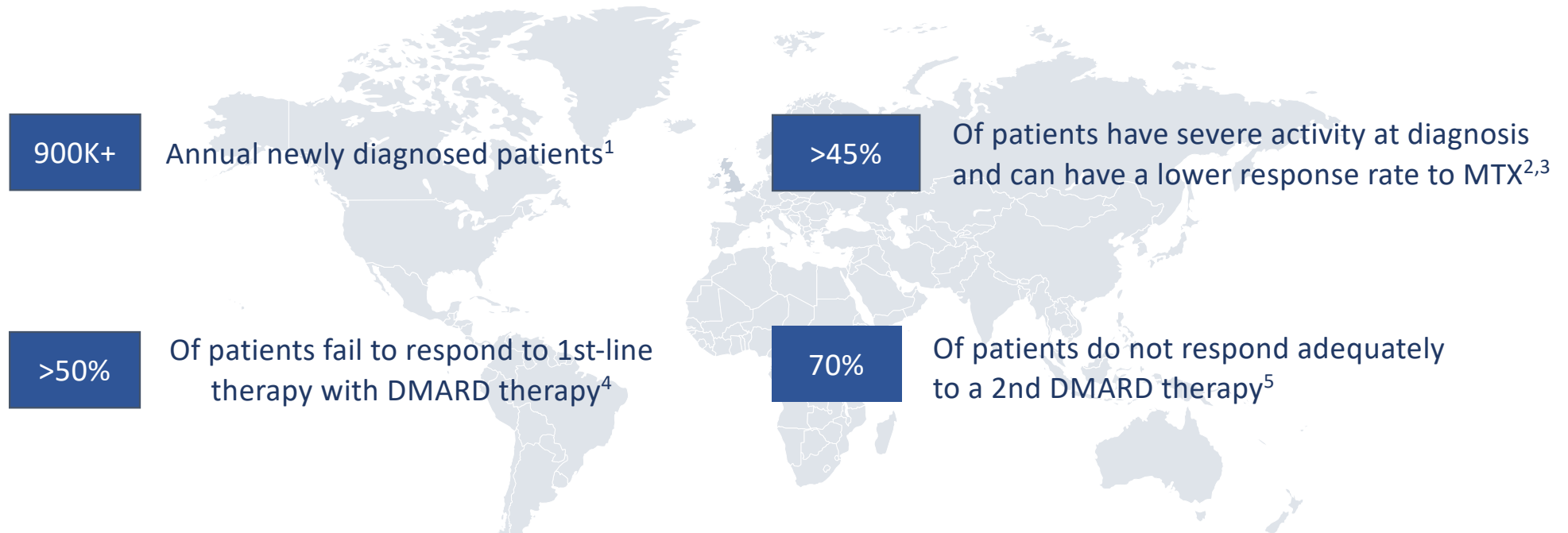
Major Markets: US, GER, UK, SPA, IT, FRA, JP, CN, IN, AUS, BRA, CAN; MEX, ZAF, KOR.

Number of newly diagnosed is growing:

	2024:	2030:	2040:
MM16 Estimates:	920.000	1.000.000	1.200.000
US + Europe 5:	325.000	345.000	385.000

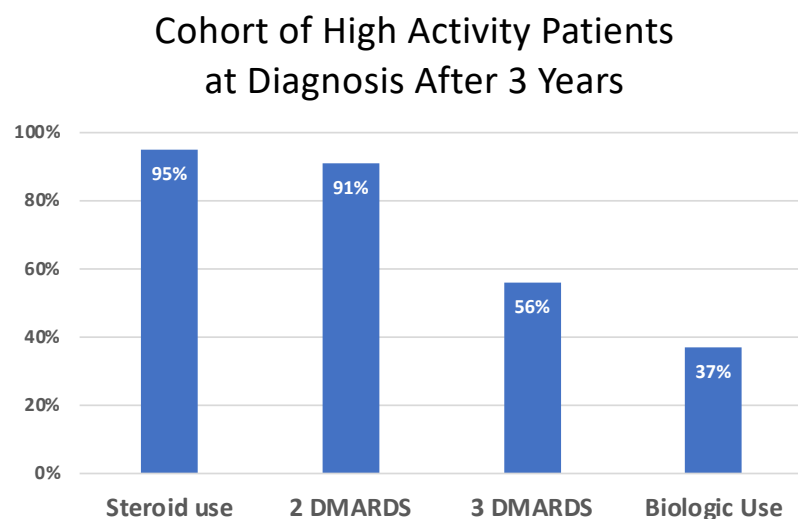
Drivers are population growth, age expectancy, lifestyle, and improved health care.

1st-line therapies fail most RA patients especially those with severe disease



Resomelagon could be well suited to help early-stage patients presenting with severe disease activity

Patients presenting with high disease activity have a poorer disease prognosis and can be less responsive to MTX



- **Highly active disease is the key poor prognostic indicator in ACR and EULAR recommendations¹**

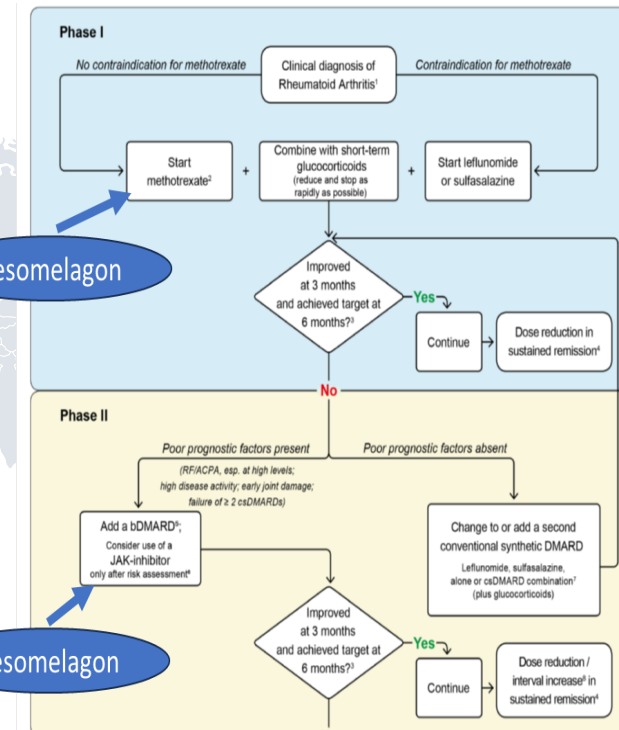
“Damage to joints occurs in the first 2–3 years. There is a narrow window to preserve the joints and the patient's quality of life.”²
- **Highly active patients tend to have lower responses to MTX with 6mo response rates ranging from 33% to 52%³**
- **In newly diagnosed RA patients followed for 3 years:²**
 - 95% of patients required steroids (avg 15mg/day)
 - 56% had added/cycled with 3 DMARD agents
 - 37% had initiated use of at least 1 biologic

Resomelagon could be well suited to address the needs of patients with high disease activity not fully addressed by MTX therapy alone

Resomelagon (AP1189) in the current treatment roadmap

- Therapy with cDMARDs, ie MTX should be started as soon as the diagnosis of RA is made
- Treatment should aim at reaching a target of sustained remission or low disease activity in every patient
- GCs should be considered when initiating MTX treatment but should be tapered and discontinued within 3 months (EULAR 2022).
- TNF-blockers are not recommended for first line treatment because of the additional risks of toxicity (ACR 2021)

EULAR treatment roadmap for moderate and severe RA



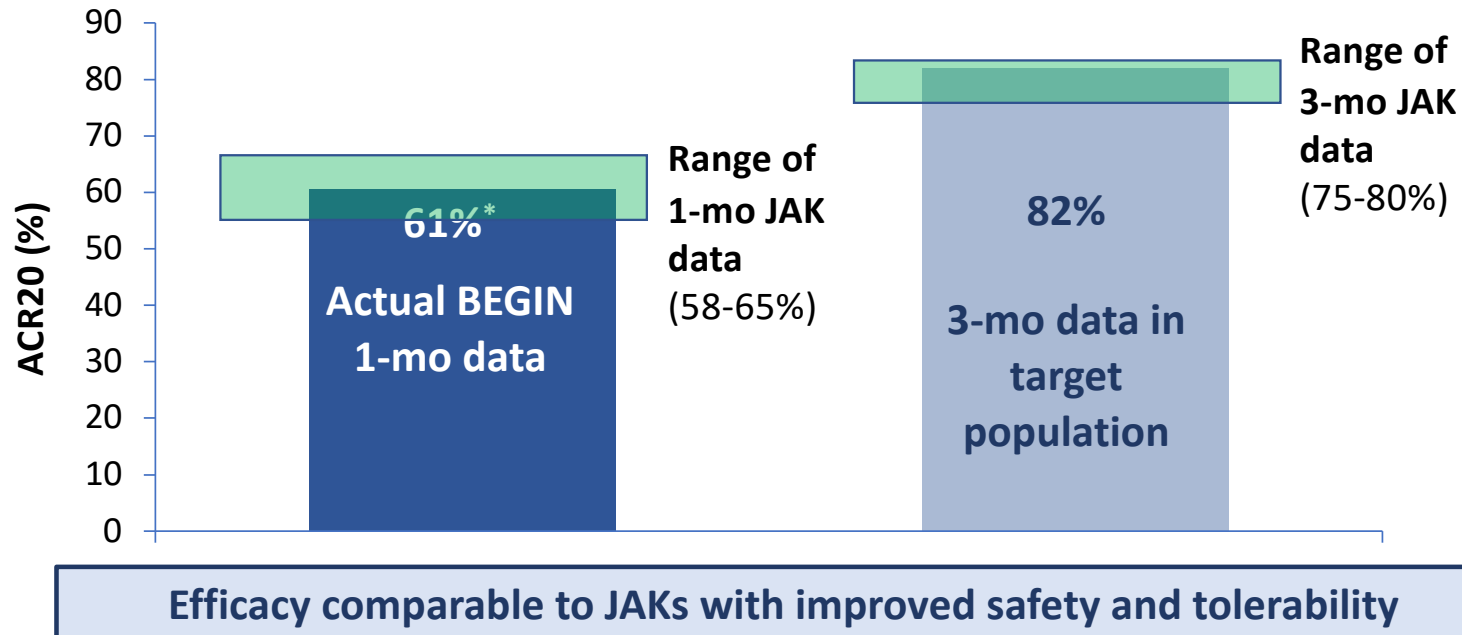
Resomelagon

Resomelagon

Early intervention with resomelagon (AP1189) could be a novel treatment approach to increase the likelihood of disease control

Resomelagon (AP1189) – Proven treatment potential in target population of newly diagnosed RA pt with signs of systemic inflammation

Key readouts from clinical studies in target population – The Begin Study – and subgroup of patients in the EXPAND study



Resomelagon Complements the Current Treatment Regimen - Favorable Safety Profile, Early Onset and Ease of Use

Target Product Profile

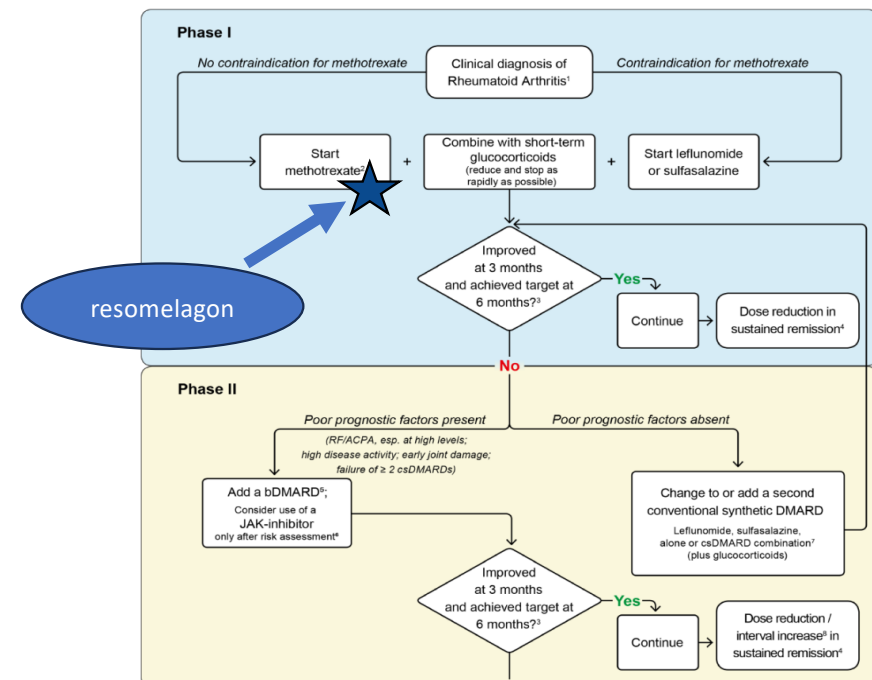
Once daily oral tablet: - limits need of training – patient convenient - optimal to enhance patient compliance.

Safety Profile: Favorable safety profile, resolution therapy limits risk of immunosuppression – reduced need for safety monitoring and in person consultations, ie positive impact on health care system and patients' well-being.

Efficacy: Clinical data support relevant treatment effect in target population newly diagnosed RA patients with high disease activity including signs of systemic inflammation

Fits Current Guideline: Increase likelihood to disease control as add on to existing treatment options with potential to reduce use of glucocorticoids or delay or even reduce second line treatments as the bDMARDs.

EULAR treatment roadmap for moderate and severe RA



Source: Ann Rheum Dis 2023;82:3–18

ADVANCE STUDY P2b dose-range study in newly diagnoses treatment naive RA patients with high disease activity - Ongoing.

Patient Population:

- Newly diagnosed treatment naïve RA pts, eligible for initiation of MTX treatment
- CRP at baseline >3 mg/L
- CDAI >22 at baseline DAS28-CRP >5.1 – min of 6 swollen and tender joints
- Glucocorticoids only allowed as rescue medicine

Resomelagon (AP1189) 3 dose levels in combination with MTX

Placebo, combination with MTX

12 Weeks dosing

Key Study Parameters

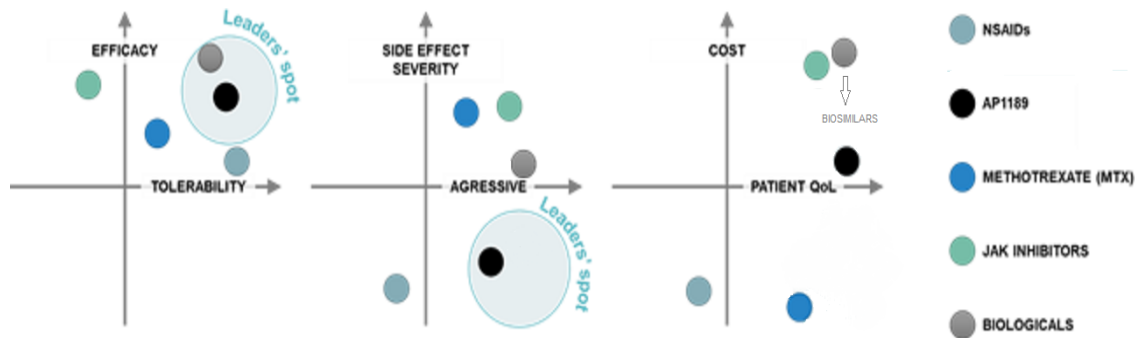
Dosing and Duration	<ul style="list-style-type: none"> ▪ 12 weeks of once-daily dosing of resomelagon (AP1189) tablet or placebo- conducted at sites in US and Europe
Study Size and Sites	<ul style="list-style-type: none"> ▪ Designed to recruit 60 patients per group – dose levels: 40, 70 and 100 mg once daily - ▪ Study initiated at sites in US- Expected to initiate the study in Europe in Q4, 2024. – plan for 12 months recruitment period -
Primary Endpoints	<ul style="list-style-type: none"> ▪ Safety and Tolerability ▪ Change in DAS28 –CRP during the 12 weeks treatment period
Secondary Endpoints	<ul style="list-style-type: none"> ▪ ACR20/ACR50/ACR70; CDAI score; HAQ/RAQoI

Resomelagon - Adding efficacy to MTX without adding steroids

Emerging AP1189 Clinical profile	
• Once-Daily Oral Dosing	<ul style="list-style-type: none">• Once daily oral tablet• Oral convenience for early lines of therapy
• High-degree of efficacy	<ul style="list-style-type: none">• BEGIN 1-mo responses and EXPAND 3-mo data in newly diagnosed with severe disease activity (with eCRP) were in-line with JAK inhibitors
• Safe and Well Tolerated	<ul style="list-style-type: none">• No emerging safety issues seen thus far in clinical assessment• No signs of increased infection rates or other serious safety concerns
• Steroid-Free MoA	<ul style="list-style-type: none">• Efficacy in early RA with severe disease without need for steroids
• Compatible with MTX	<ul style="list-style-type: none">• Shown to be compatible with MTX• No known compatibility concerns with TNF or other biologics

- The combination of efficacy, safety and oral once-daily convenience is very well suited for this opportunity
- Preliminary estimates for resomelagon in newly diagnosed patients with severe disease > \$2B annually

Resomelagon (AP1189) is well positioned to meet the needs in the RA Market



Improved Quality of Life and Reduced Cost

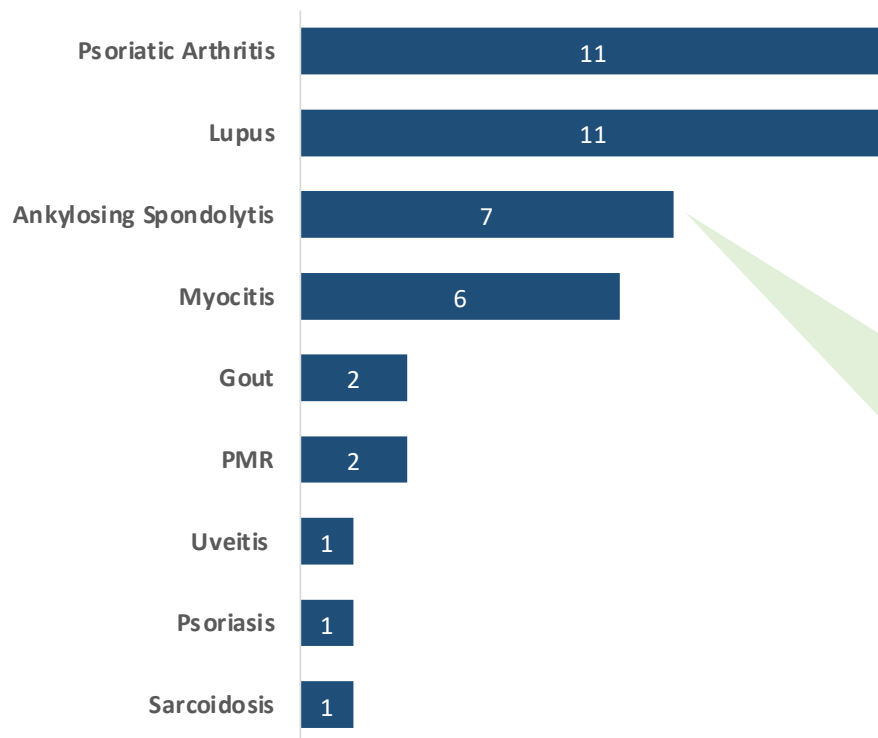
- Fast onset of action and good safety
- Reduced risk of going into more severe stages of RA
- improve ability to keep working and maintain daily life with longer life-time expectancy.
- Society benefits from reduced health care cost, improved productivity.

Benefits Justifies Pricing

- It is anticipated that AP1189 will be competitively priced with a premium to cDMARDs
- Priced below bDMARDs and JAK inhibitors would increase market access and reduce overall health care cost

Resomelagon beyond RA – Rheumatologists express significant Interest for development in additional rheumatology diseases beyond RA

Additional rheumatology diseases-of-interest for 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

Key milestones 2025

Key milestones 2025 – Full focus

- Drive Phase IIB clinical development of AP 1189 in RA
- Make TXP Compounds Phase I ready
- Business development with the scope to complete commercial deal upon good Phase II data

