

Treating Inflammation through
Resolution Therapy

SynAct Pharma AB



Forward Looking Statements

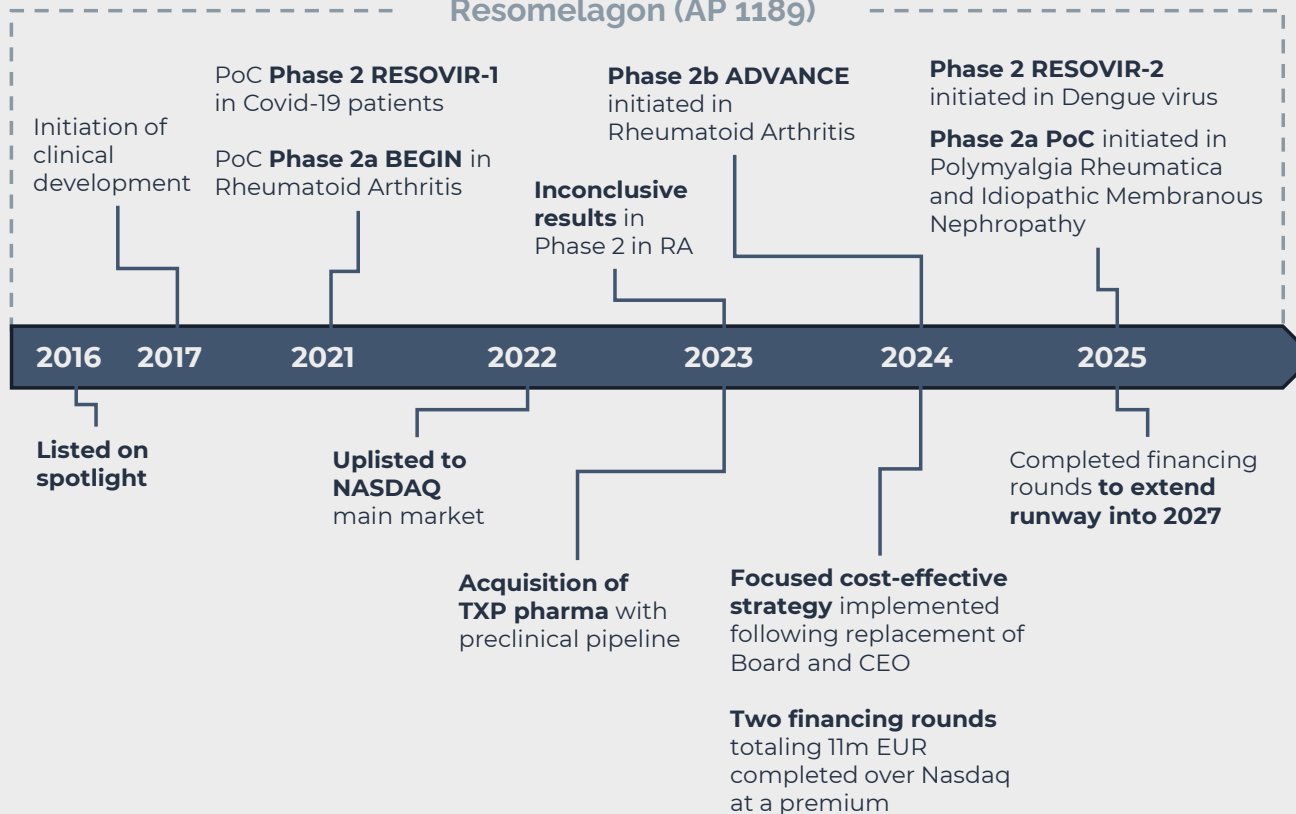
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Company in a brief

Resomelagon (AP 1189)



SynAct Pharma highlights

- Resomelagon: a novel approach in inflammation resolution – Phase 2b ADVANCE results in RA in early 2026
- Dual development strategy: Chronic/Autoimmune and Acute Hyperinflammation (Host Directed Viral Infections)
- TXP preclinical pipeline
- Financial runway into 2027

Synact Pharma

Lead compound Resomelagon (AP1189)

Parallel development tracks

Inflammatory and autoimmune diseases

- Novel mode of action to induce disease control through inflammatory resolution
- Potential to be a new patient friendly first line treatment in RA and other autoimmune and inflammatory diseases
- Phase 2b development based on positive data in newly diagnosed Rheumatoid Arthritis (RA) patients
- The ADVANCE study is a Phase 2b study (n=240) ongoing at sites in Europe and US planned to be completed in Q4 2025

Host-directed therapy in viral infections

- Novel treatment approach to control hyperinflammatory responses in viral infections
- Clinical proof of concept in Phase 2 study in severe COVID-19 with faster recovery and shorter hospitalization
- Phase 2 development in dengue fever initiated at sites in Brazil in Q2 2025- the RESOVIR-2 study
- Potential to run parallel development track in respiratory infections associated with hospitalization

Once a day tablet to induce pharmacological resolution -thereby bringing the immune system to a new, for the patient, beneficial homeostatic setting

Executing strategy – Strong news flow for 2025

Recently executed:

Focused development plan of resomelagon in RA – First step the ongoing ADVANCE Ph2b study

Continued development of resomelagon as host-directed therapy in virus infections - initiated RESOVIR-2 study in Dengue

Successful financing of more than 137m SEK / 12,5m EUR in the past 12 months - extending runway into 2027

Strengthened management and BoD

Plan ahead:

Complete and report the ADVANCE study- First line treatment in RA

Conduct and report RESOVIR-2 study at next epidemic outbreak at sites

Complete preclinical development of TXP-11 – and plan for Ph1 to be conducted in 2026

Business development – Pharma Co's

Lead the development of inflammation resolution therapeutics










Prioritized development on key indication (-s)

Find partnerships and/or business deals

Effective use of funds

Highly skilled management

Development Programs

COMPOUND	INDICATION	PRE-CLINICAL	PHASE I	PHASE IIa	PHASE IIb	STATUS & NEXT MILESTONE
RESOMELAGON	Rheumatoid Arthritis (RA)					ADVANCE Phase IIb study - ongoing
RESOMELAGON	Host-derived therapy in viral-infections					Phase IIa – Proof of Concept study PoC in Arboviral infection - Dengue fever
RESOMELAGON	Idiopathic Membranous Nephropathy					Phase IIa study – ongoing (rare disease potential)
RESOMELAGON	Polymyalgia Rheumatica (PMR)					Phase IIa study – to be initiated
TXP-11	Organ protection – surgery/acute care					Preclinical pharmacology to support Phase I CTA ongoing – aim to be phase I ready in 2025
Next generation	Autoimmune & inflammatory diseases					Discovery



Completed phase



Ongoing phase

Inflammatory and autoimmune diseases

Early intervention in active inflammation

Lead compound **Resomelagon (AP1189)**

Rheumatoid Arthritis (RA) in newly diagnosed patients given in combination with methotrexate (MTX) – positive **Phase II data - phase IIb study ongoing**

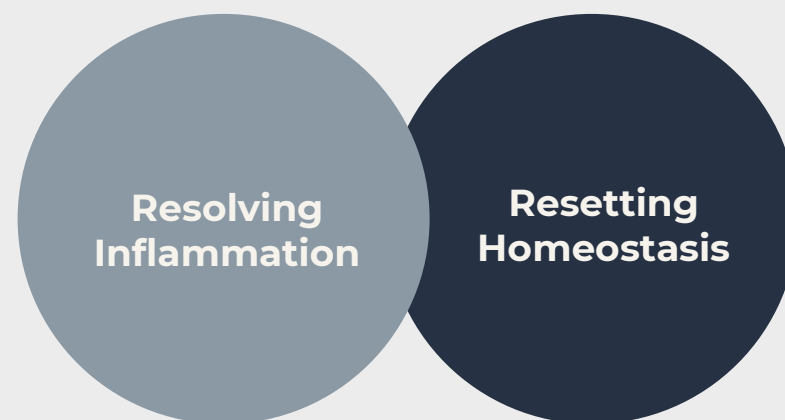
Potential to setup additional cost- effective proof of concept studies in rheumatic diseases as

Polymyalgia Rheumatica (PMR) – to reduce use of glucocorticoids (GC)/ reduce relapses following GC tapering

Axial spondylitis (AS)- possibility to apply early intervention in NSAID non-responders with active diseases

Additional opportunities in **RA flares, Psoriasis arthritis (PsA), Active Intestinal Bowel Diseases (IBD)**, ophthalmological indication as **Uveitis** and **DYD**, among other

Ongoing **phase 2a study** in Idiopathic membranous Nephropathy (**IMN**) (Nephrotic syndrome) - rare **disease-**



Once a day tablet to induce pharmacological resolution

- balancing the immune system at a new beneficial homeostatic setting

Resomelagon (AP1189) has the potential to be a novel oral treatment option in RA

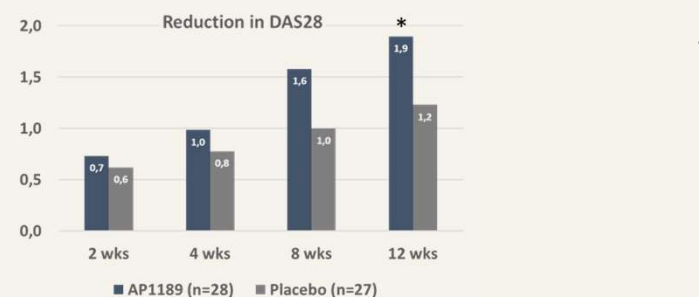
In newly diagnosed RA patients with high disease activity CDAI>22, hsCRP>3 mg/L the compound shows significant treatment effects in combination with MTX –

In combination with MTX, resomelagon has the potential to reduce the use of GC = GC-sparing effect

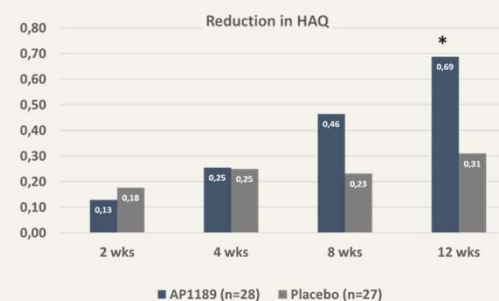
In combination with MTX as first line treatment, the compound has the potential to delay/reduce the use of second line as the bDMARDs (TNF-blockers)

Following dosing of more than 75 healthy volunteers and 200 pts (RA and Covid-19) the compound shows a **very favorable safety profile**- no dose limiting adverse events identified including no signs of immuno-suppression

Significant reduction in clinical disease activity



Significant improvement in health assessment and quality of life



Data from pt with newly diagnosed RA (EXPAND Study)

Arthritis Rheumatol. 2024; 76 (suppl 9)- ACR convergence 2024 abstract no 2274.

Host-directed therapy in viral infections

-Once a day tablet to induce pharmacological resolution -

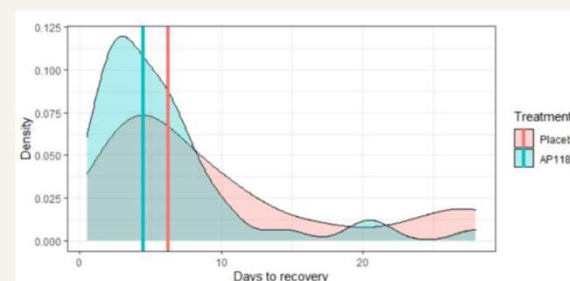
Severe COVID-19 – positive Phase 2 data – **finalized**- first ever published (BJP 2024) demonstration of the effects of a pro-resolving molecule in the context of severe infection in humans

Arboviral infections with focus on **Dengue Fever** – Opportunity to run PoC study as part of the **RESOVIR** collaboration -- **Study initiated (RESOVIR-2 study) at sites in Brazil** - recruitment on next epidemic outbreak at sites

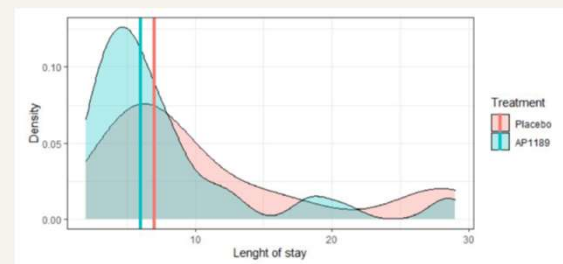
Other Arboviral infections of interest **Chikungunya** (supported by preclinical data), **Zika virus** – **future**

Respiratory infections as **Influenza** and **RS** other where a subset of patients are at risk for hospitalization (ARDS) - **future**

Faster respiratory recovery

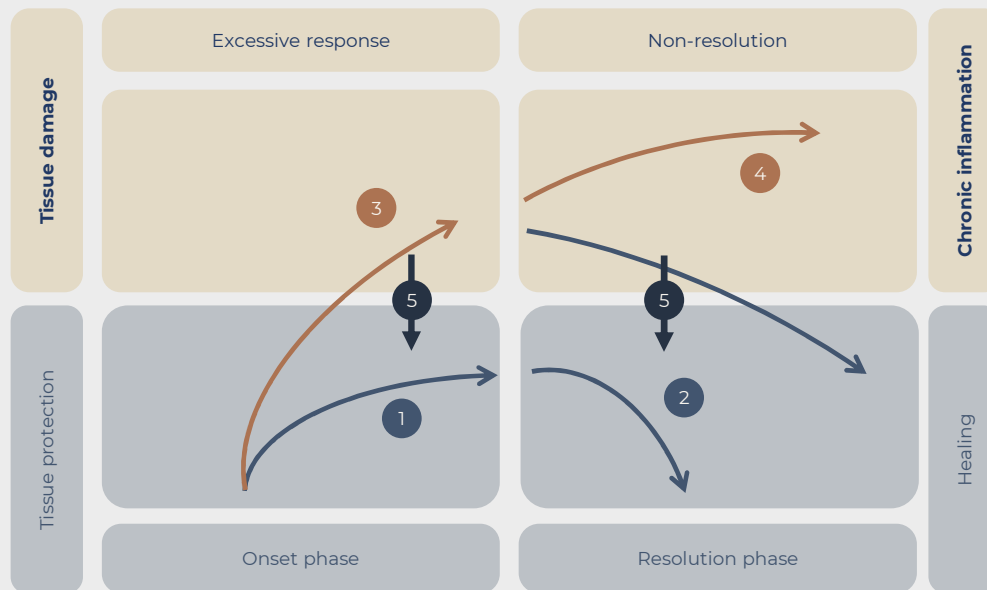


Reduced time at hospital



Almeida et al, Br J Pharmacol, 2024 - PMID: 39159951

Our compounds promotes resolution of inflammation



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

The inflammatory response

Physiological immune response:

- 1 Inflammatory response effectively controlled in extent and time – protects tissues and limits damage
- 2 Pathways activated (normal physiology) to safely terminate the inflammatory response and promote healing

Pathological immune response:

- 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 (irreversible loss of function)

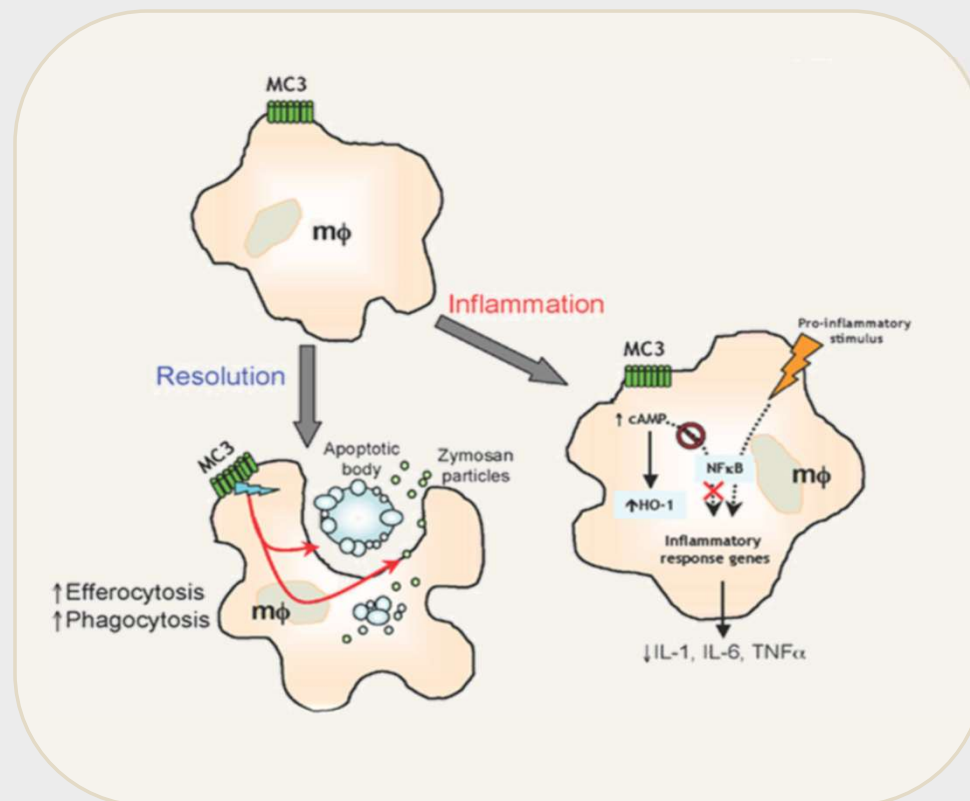
SynAct Pharma compounds:

- 5 Activation of the immune system to limit inflammatory response and promote endogenous resolution pathways has the potential to restore tissues and function

SynAct compounds promote resolution of inflammation through stimulation of melanocortin receptors (MCR's) on key cells in the immune system

Exhibits anti-inflammatory activity via MC1r and MC3r stimulation on target cells – such as lowering the release of pro-inflammatory cytokines

Promotes pro-resolution pathways following stimulation of MC1R and MC3R on target cells – such as increasing efferocytosis in macrophages



Newly diagnosed Rheumatoid Arthritis patients

Resomelagon –lead indication

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

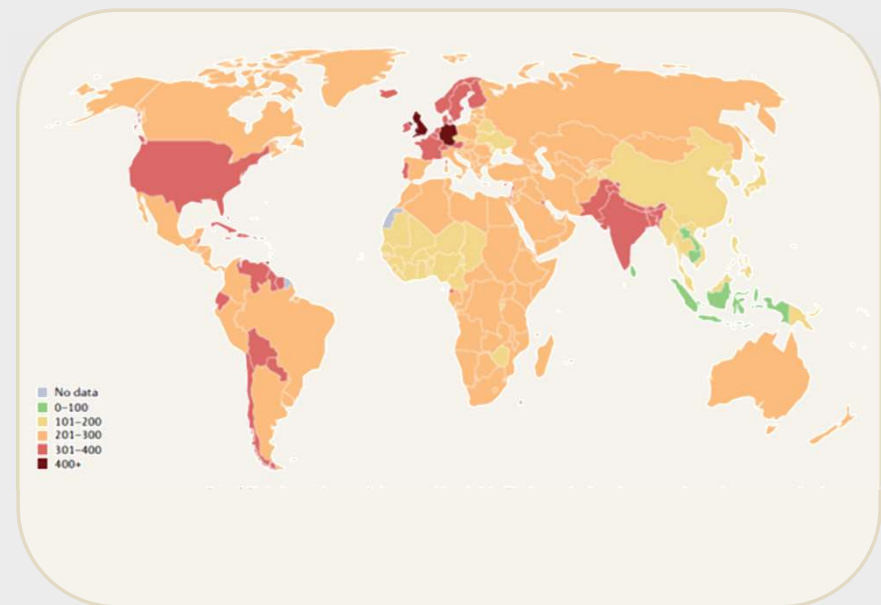
Is Prevalent in Developed Countries
Prevalence is between 0.2-1.0%, larger in industrialized countries

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.



Source: Global Burden of Disease Collaborators. Global, regional, and national burden of rheumatoid arthritis, 1990–2020, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021. Lancet Rheumatol 2023 Finckh A et al. Global epidemiology of rheumatoid arthritis. Nat Rev Rheumatol 2022. Global Data, 2023

Why is early treatment in RA so important

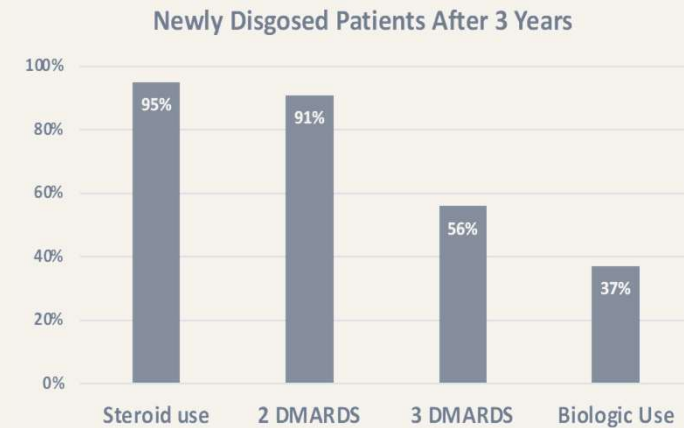
Patients presenting with high disease activity have a poorer disease prognosis and can be less responsive to MTX-

Highly active disease is the key poor prognostic indicator¹

“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 RA tend to be more difficult to treat -6mo response rates ranging from 33% to 52%³

Logic conclusion is to apply intervention with well tolerated treatment as early as possible



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

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

The EXPAND study

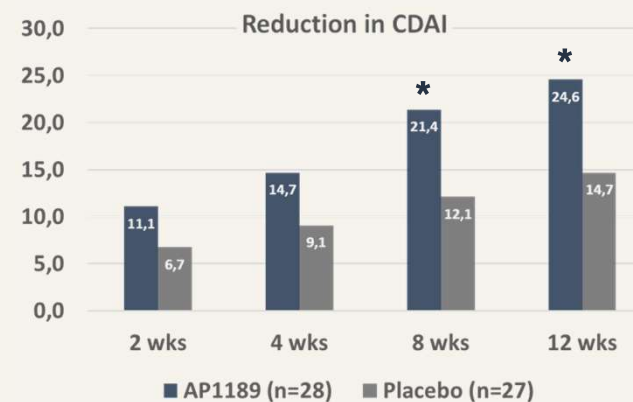
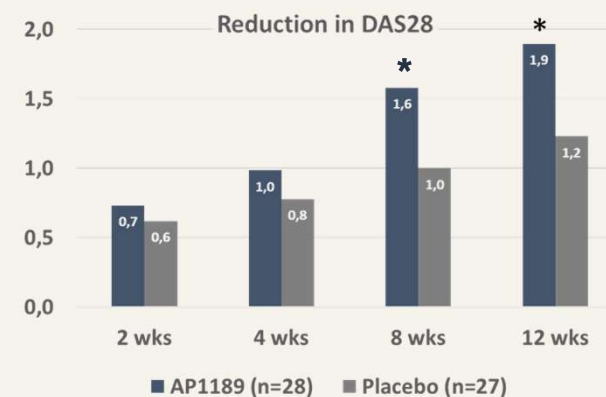
Significant treatment effect in subset of patients defined as newly diagnosed with sign of systemic inflammation

Support continued development in RA

BL CRP>3_ RA diagnose within 6 months from BL



∴ p<0.023 vs placebo (Fischer exact test).



Mean per group ∴ p<0.01 vs placebo

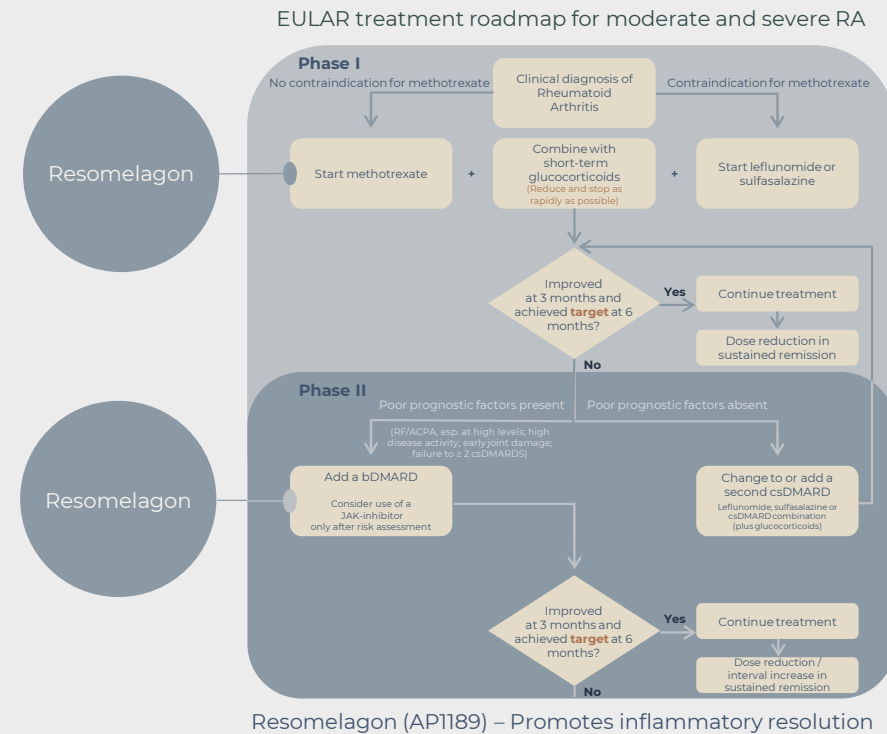
Resomelagon (AP1189) in the current treatment roadmap

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)



Advance Study P2b

Dose-range study in newly diagnoses treatment naive RA patients with high disease activity - Ongoing

Patient Population:

Newly diagnosed treatment naive 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

Intervention:

Resomelagon (AP1189) 3 dose levels in combination with MTX

Placebo, combination with MTX

————— 12 Weeks dosing —————

Dosing
and
Duration

12 weeks of once-daily dosing of resomelagon (AP1189) tablet or placebo- conducted at sites in US and Europe

Study Size
and Sites

Designed to recruit 60 patients per group – dose levels: 40, 70 and 100 mg once daily
+20 sites in US and Europe

Primary
Endpoints

Safety and Tolerability
Change in **DAS28 –CRP** during the 12 weeks treatment period

Secondary
Endpoints

ACR20/ACR50/ACR70;
CDAI score;
HAQ/RAQoI

Resomelagon (AP1189)

Early intervention in Rheumatoid Arthritis

Key take home points

Resomelagon complements the current treatment options

- with once daily oral treatment with a tablet

Resomelagon is developed to be given in combination with first line compound methotrexate (MTX)

- fits into current treatment guidelines in US and EU

Resomelagon has an attractive safety profile

- mild transient, primary gastrointestinal, adverse event
- no signs of immunosuppression

Resomelagon has early onset of action making it as an attractive treatment option in patients with high disease activity

- potentially as an alternative to glucocorticoids

Attractive business case +2 US\$ even with medium set pricing

- premium to cDMARD, discount to bDMARD and JAK- inhibitors

Rheumatoid Arthritis

>900.000 new cases per year
Current market >20B\$
Estimated annual growth rate
>5%

Arboviral infections

Dengue -

Resomelagon –Host-directed therapy to control hyper inflammation

Dengue Virus- Distribution and Incidence

- Three-month dengue virus disease case notification rate per 100 000 population, January 2025-March 2025

According to the World Health Organization (WHO), dengue is now endemic in over 100 countries

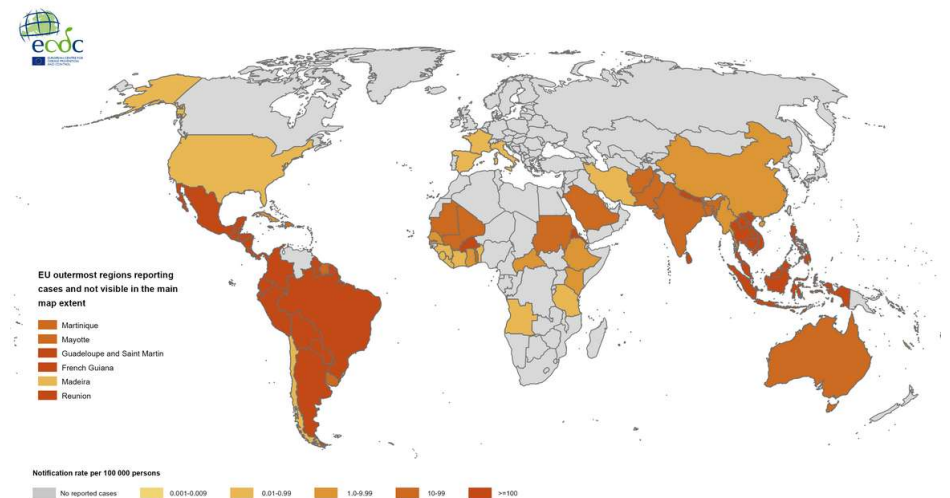
As many as 3.6 billion people, or 40% of the world's population, reside in dengue-endemic areas

Each year:

~400 million people are infected

100 million become ill

21,000 deaths are attributed to dengue



Arboviral infections-

A new problem for our societies

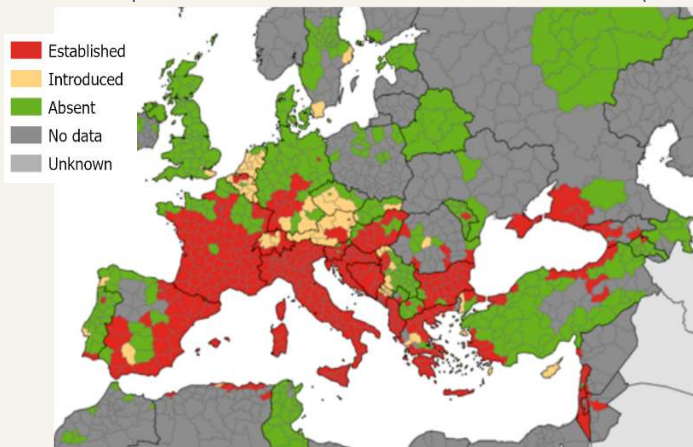
Arboviral infections is caused by a group of viruses spread to people by the bite of infected arthropods (insects) such as mosquitoes and ticks

Presence of Female *Aedes aegypti* mosquito in Europe (both southern and northern Countries) due to the global warming and cross-continent travels

This infection brings serious morbidity in a proportion of patients and can be lethal on re-infection.

Presence of the mosquito as of July 2024

Source: European Centre for Disease Prevention and Control (ECDC)



Arboviral infections are no longer an exclusive of the Global South, but are going to become more common also in the Global North

Serious complications post-infections are due to a deregulated response of our body classified as hyper-inflammation

Indigenous Dengue is reported in Southern Europe Italy, France, Spain and Greece. In France alone 78 cases from May to October 2024. In addition, around 4,000 imported cases has been reported in France alone.

The RESOVIR-2 study

Phase 2 proof of concept- initiated in Brazil- recruitment to be conducted and next epidemic at site(s):

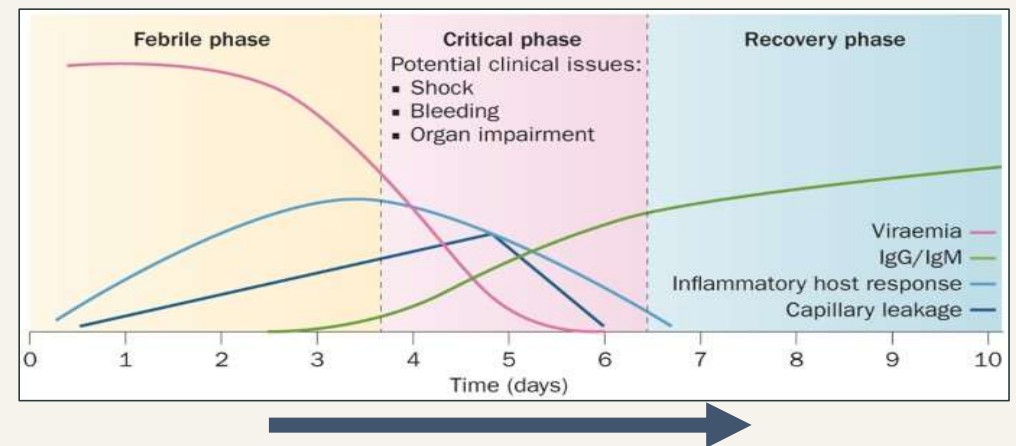
Double-blind placebo controlled once daily dosing for 5 days.

Treatment initiation: more than 36 and less than 72 hours of symptoms

Primary clinical read out(s): reduction in composite disease score at treatment day 0-10.

Once daily 100 mg resomelagon (AP1189) tablets vs placebo tablet as add on to standard treatment.

N= 60 per group



Treatment period

Leadership

Dedicated and Experienced Top Management Team



Jeppe 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



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



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



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



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



Mads Bjerregaard, MSc

CBO

Over 20 years of experience in the pharma, biotech, and med-tech industry, commercial leadership and business development roles.

Held various CxO, VP and GM positions.

Very experienced Board of Directors



Anders Kronborg

Chairman of the Board

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

Shareholder

Company or management dependent

Independent to major shareholders



Sten Scheibye

Board Member

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

Shareholder

Company independent

Independent to major shareholders



Sten Sørensen

Board Member

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

Shareholder

Company or management dependent

Independent to major shareholders



Jeppe Ragner Andersen

Board Member

Extensive financial and leadership experience spanning around 20 years.

CEO of Sanos Group A/S and NBCD A/S (Part of Sanos Group). Board member in Arctic Therapeutics (IS) .

Shareholder

Company independent

Dependent of major shareholders