SYNACT PHARMA

INFLAMMATION RESOLUTION

SynAct Pharma - EXPAND Study Update

Redye Theme: Autoimmune and inflammatory disease

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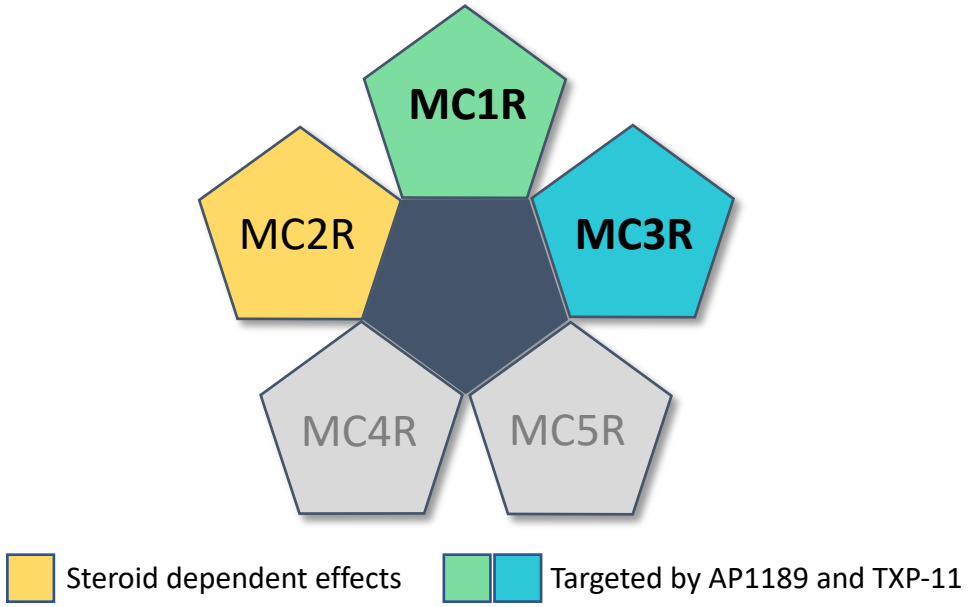
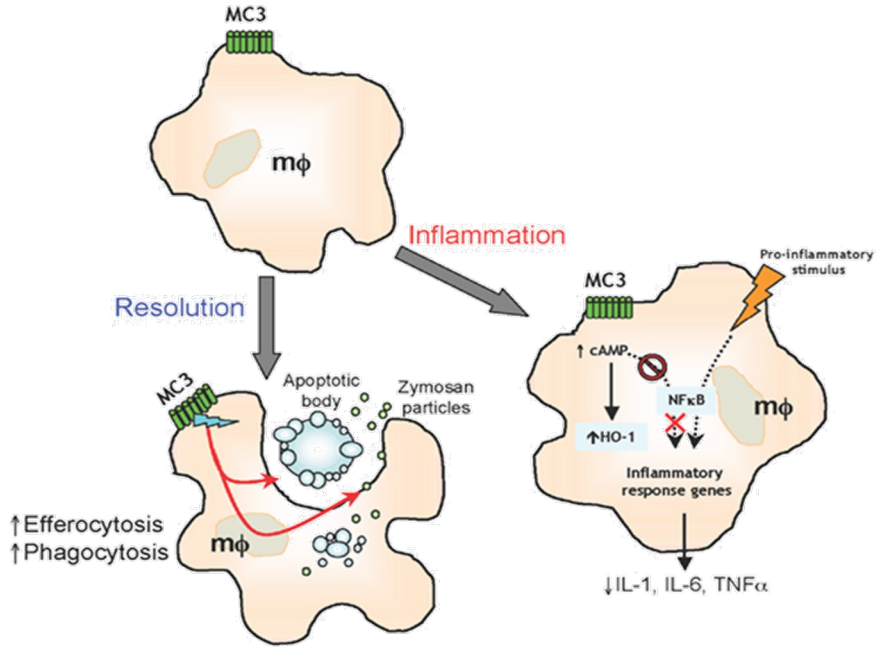
Additional data from EXPAND trial demonstrates clear and consistent efficacy in patients with evidence of systemic inflammation at study entry

- **Data supports resomelagon efficacy and activity in patients with evidence of systemic inflammation – consistent effect seen across all outcome measures**
- **Data indicates that in patients with elevated CRP at baseline (>3mg/L), resomelagon treated patients had:**
  - Biggest improvements in the HAQ-Disability Index (HAQ-DI) in areas indicating increased hand strength and dexterity
  - MRI data sub study of wrist and hand joints indicate a reduction in inflammation intensity as compared to placebo supported by matched reductions in tender and swollen joint counts
  - Significant decrease in plasma levels of C4M in the resomelagon group, a biomarker of synovial collagen 4 degradation, indicating a higher reduction in synovial inflammation

Resomelagon (AP1189) is a selective melanocortin agonist 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

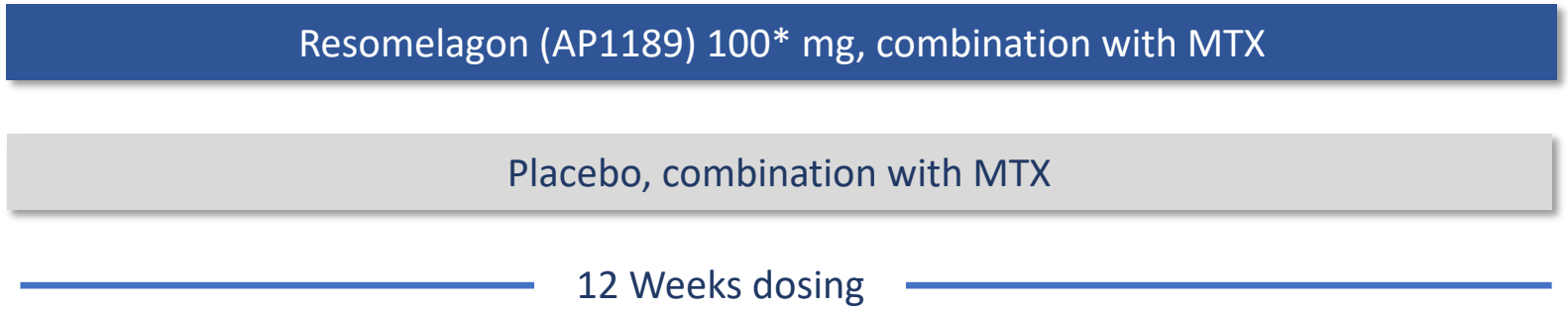
- **Exbibits anti-inflammatory activity** via MC1R and MC3R stimulation on targets cells – such as lowering the release of pro-inflammatory cytokines
- **Promotes pro-resolution pathways** following stimulation of MC1R and MC3R on targets cells – such as increasing efferocytosis in macrophages

ACTH: adrenocorticotropic hormone; MCR: melanocortin receptor

EXPAND STUDY P2b study in treatment naive RA patients.

Patient Population:

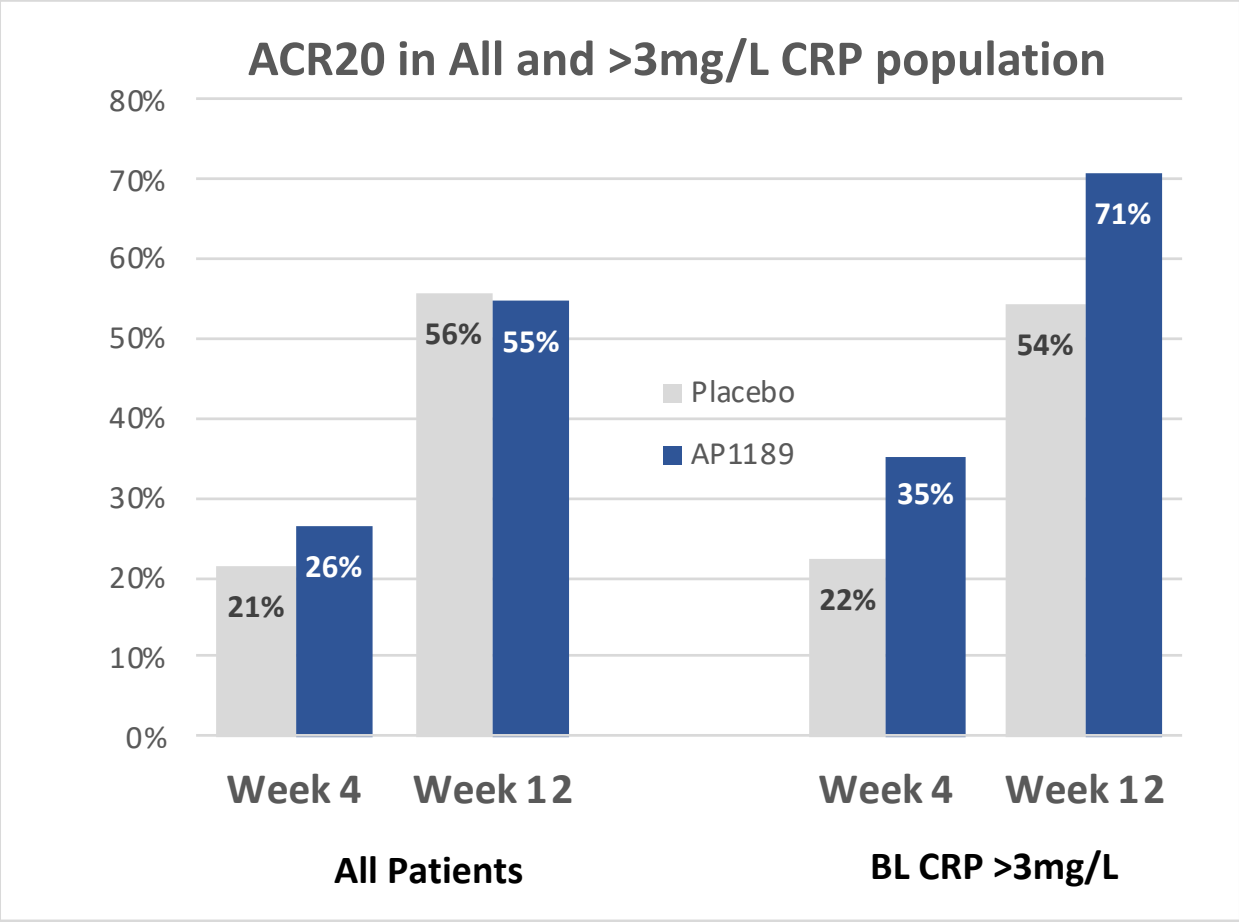
- Treatment naïve, eligible for initiation of DMARD treatment (MTX)
- CDAI >22 at baseline – min of 6 swollen and tender joints
- Glucocorticoids only allowed as rescue medicine



Key Study Parameters	
Dosing and Duration	▪ 12 weeks of once-daily dosing of solid tablet AP1189 or placebo- conducted at sites in Eastern Europe-
Study Size and Sites	▪ Designed to recruit 60 patients per group – actual number randomized is 127
Primary Endpoints	▪ Safety and Tolerability ▪ ACR20 response rate at 12 weeks as compared to placebo
Secondary Endpoints	▪ CDAI score; ACR50/ACR70; DAS28 score; FACIT-Fatigue; HAQ/RAQol
MRI- Sub Study	▪ Evaluation of Synovial inflammation using Dynamic Contrast Enhanced MRI Quantification (DEMRIQ)- potential effects on early structural changes (RAMRIS)

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

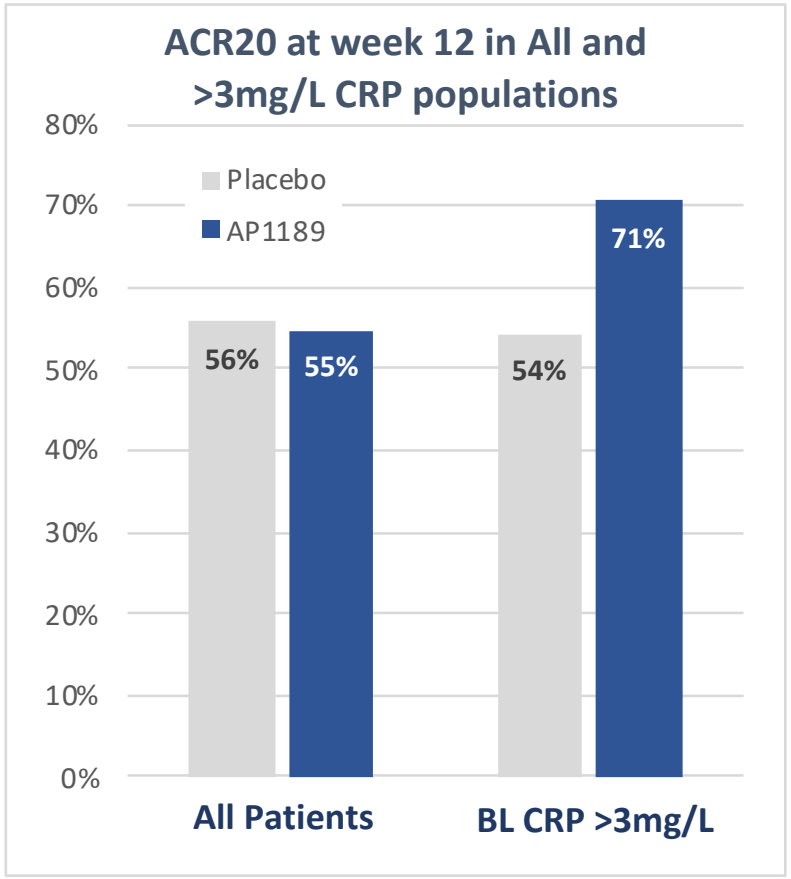
In EXPAND baseline CRP >3mg/L identified as a positive selection factor for resomelagon responsiveness

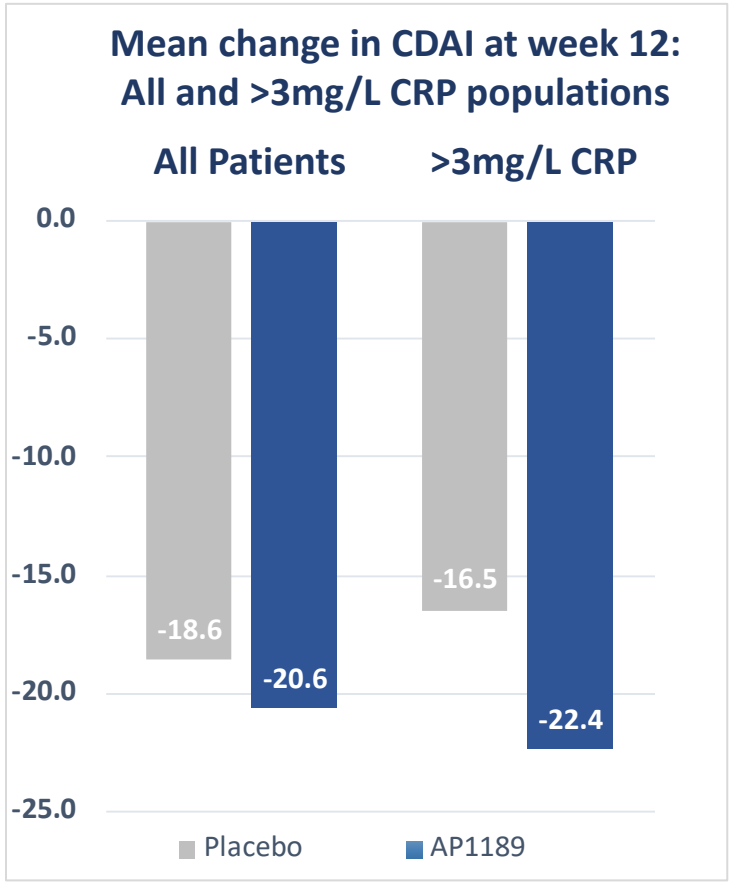


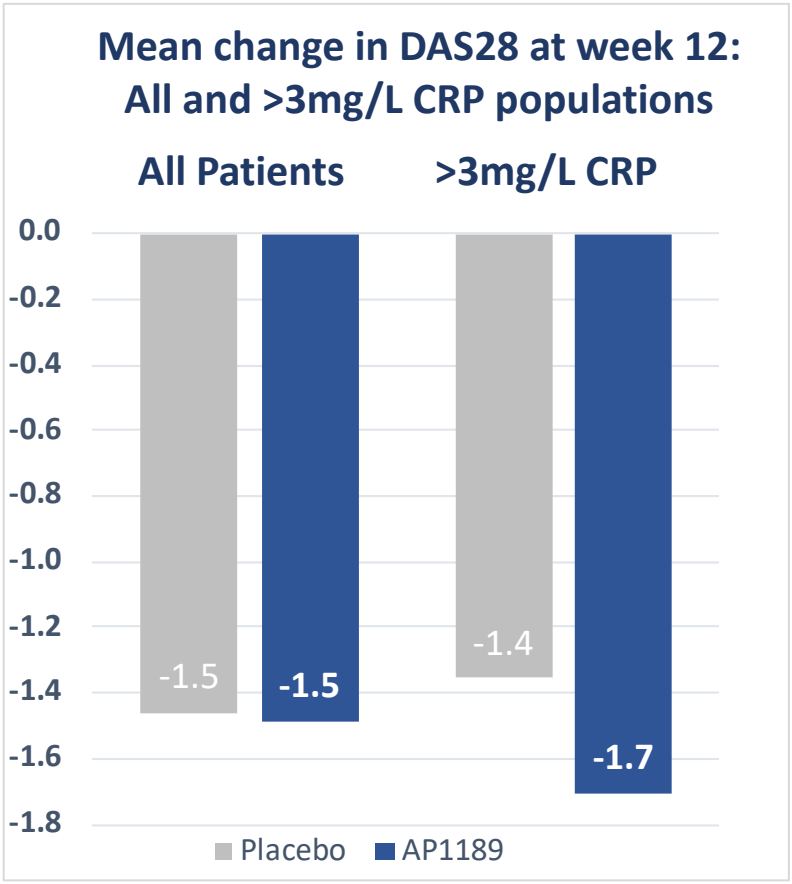
- The use of baseline CRP >3mg/L as a positive selection factor increases the probability of an AP1189 ACR20 response by 16% from 55% in all patients to 71% in the elevated CRP population at 12-weeks
- While the 4-weeks response rates favor AP1189, there is an overall lower response rate that we attribute in part to to a high level of site-to-site variability early in the study
- However, the ACR20 response rate at 12-weeks, while on the lower-end of the range, is in-line with expectations
- Improvements favoring resomelagon were also seen in the CDAI and DAS28 scoring systems
- RA patients with active disease and elevated CRP comprise up to 75% of the patients being studied in DMARD-IR trials - this is a very relevant population with evidence of systemic inflammation

Patient numbers: All patients (placebo n=61, AP1189 n=53);elevated CRP >3mg/L (placebo n=35, AP11989 n=34)

ACR20 responses seen in >3mg/L CRP population are consistent through CDAI and DAS28-CRP outcome measures



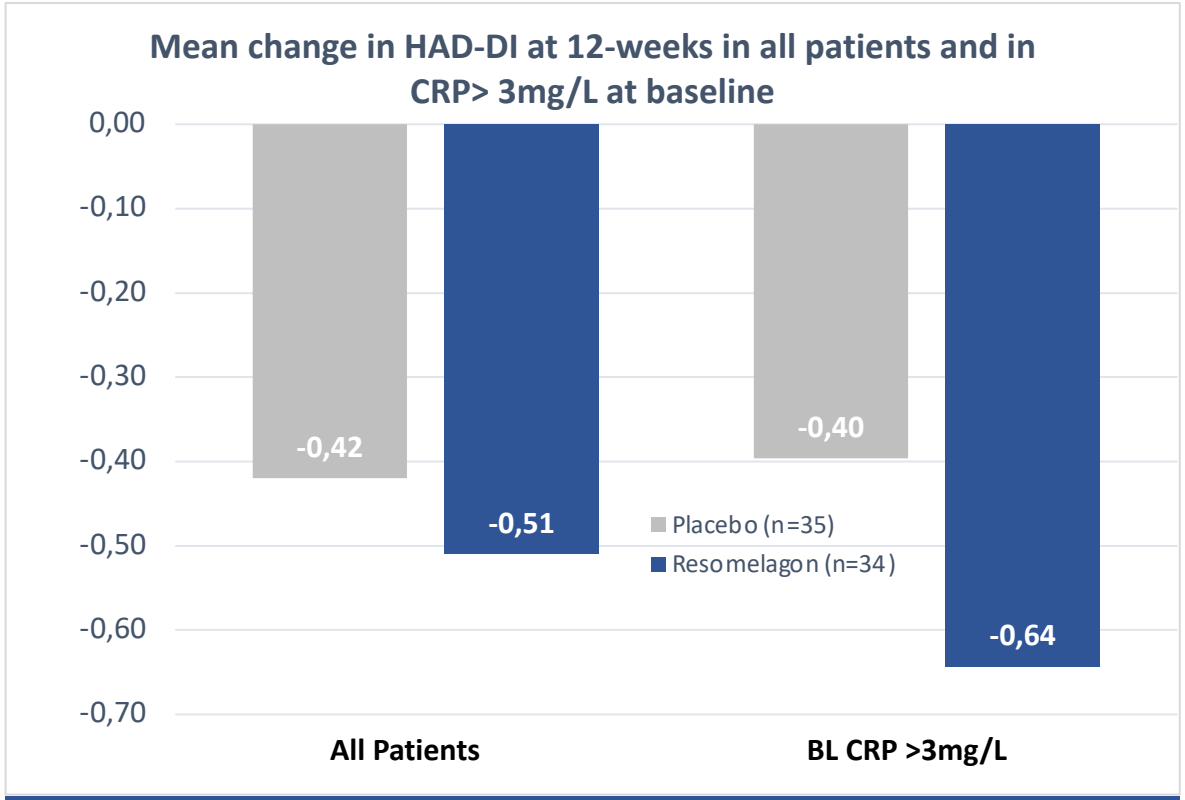




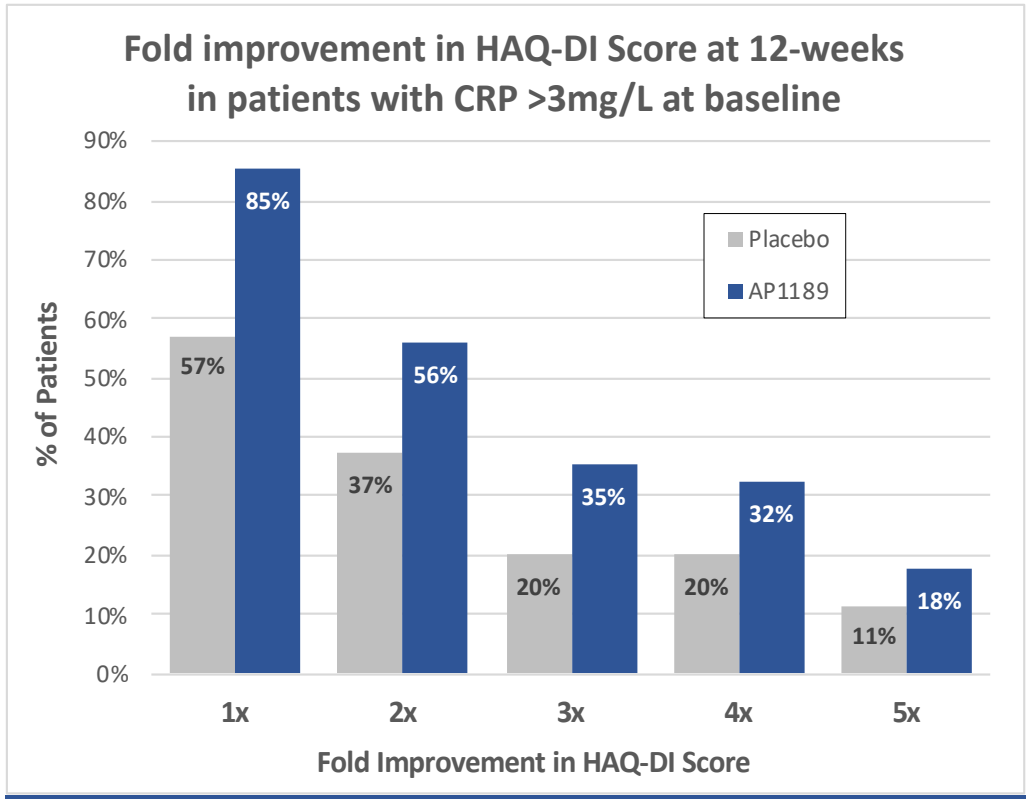
SYNACT PHARMA INFLAMMATION RESOLUTION

Patient numbers: All patients (placebo n=61, AP1189 n=53);elevated CRP >3mg/L (placebo n=35, AP11989 n=34)

The HAQ Disability Index (HAQ-DI), a quantification of current disability attributed to RA, strongly favored resomelagon in the elevated CRP population



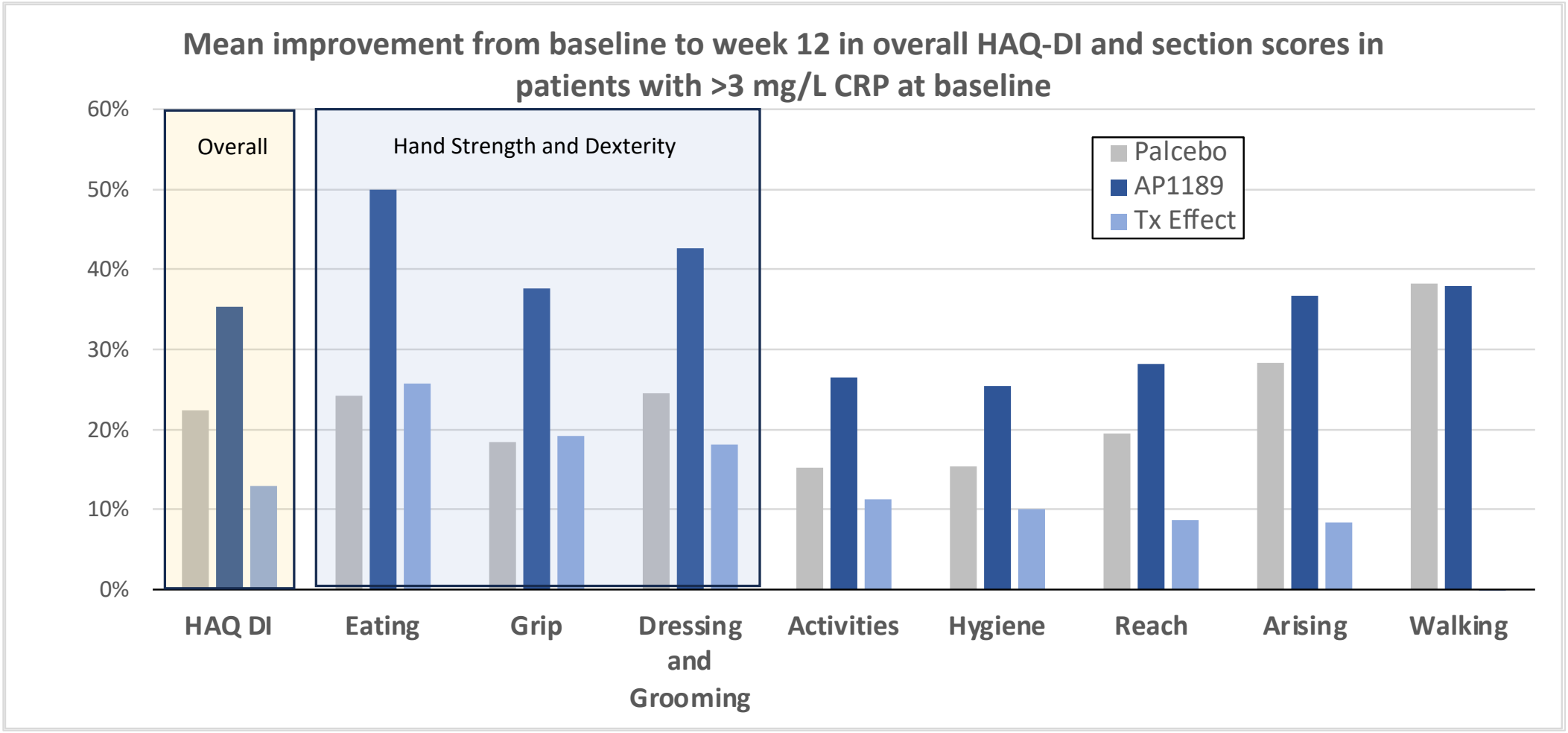
Mean decrease in resomelagon group almost 3x MCID



85% of patients achieved at least 1 MCID

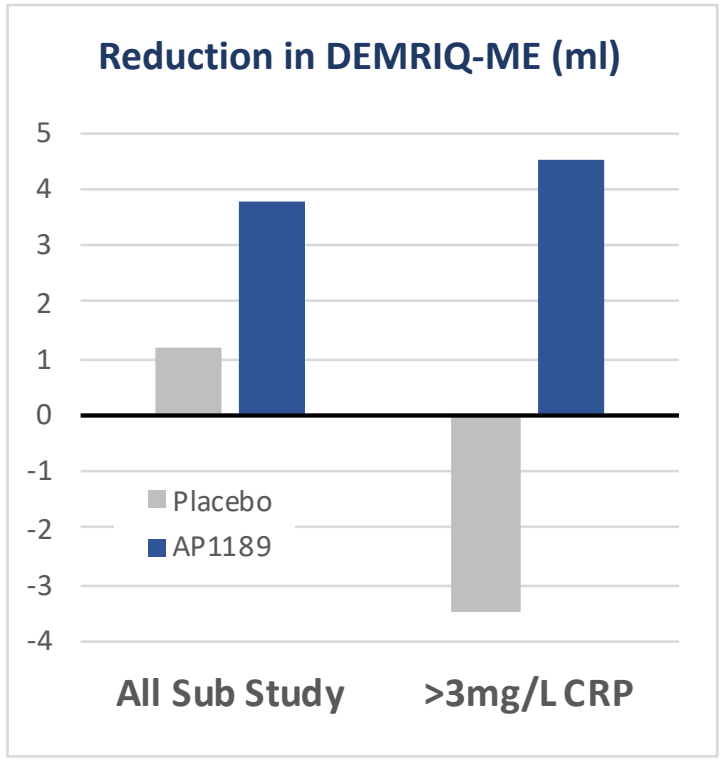
Patient numbers: All patients (placebo n=61, AP1189 n=53);elevated CRP >3mg/L (placebo n=35, AP11989 n=34)

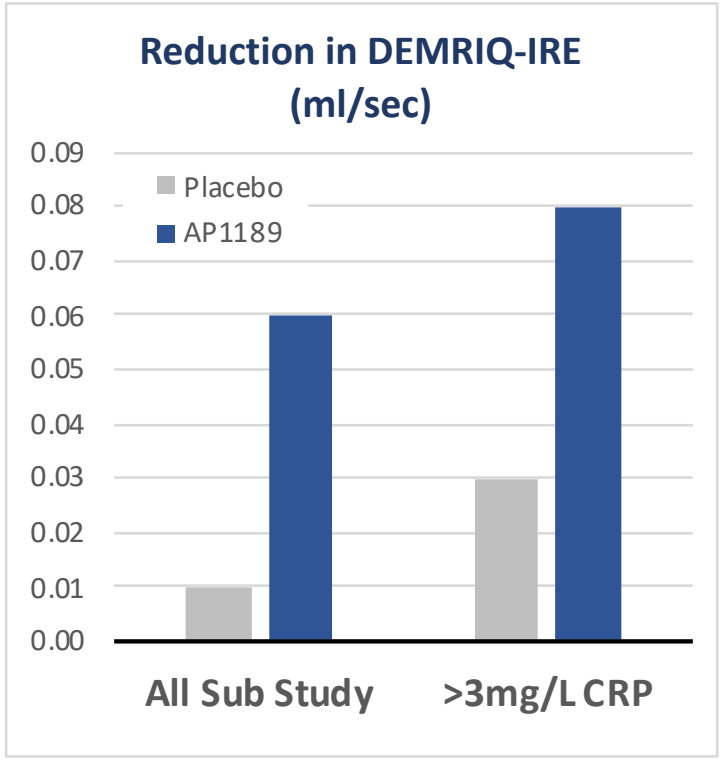
The HAQ-DI section scores show disability improvements in areas requiring hand strength and dexterity

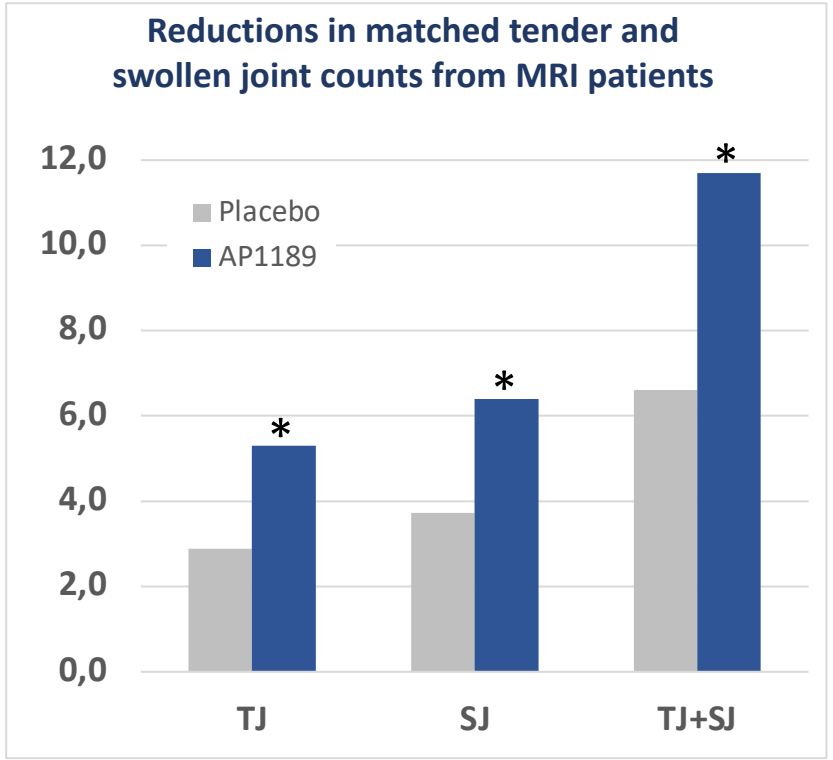


elevated CRP >3mg/L (placebo n=35, AP11989 n=34)

Results from MRI sub study of wrist and hand joints indicates a reduction in assessed joint inflammation that is supported by tender and swollen joint counts





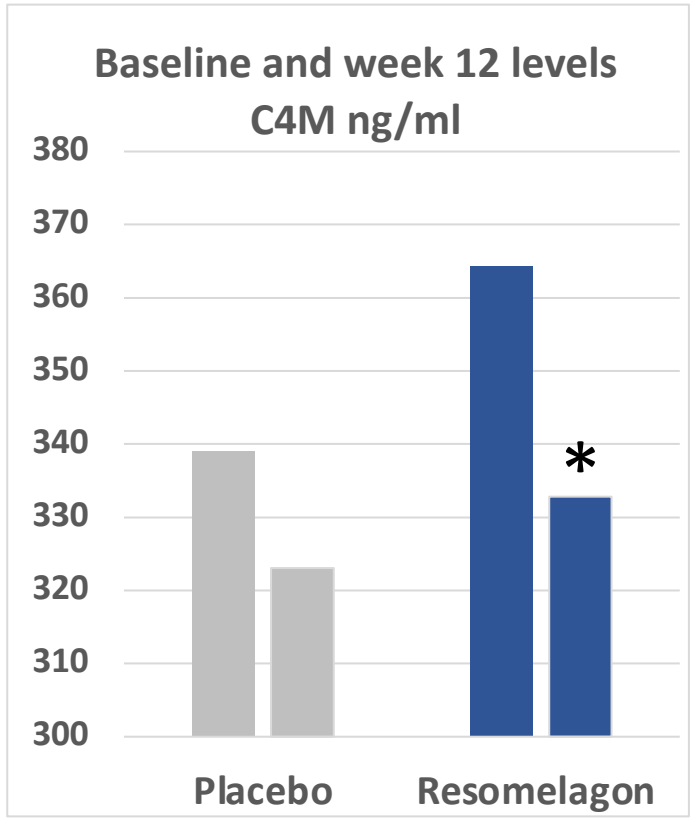


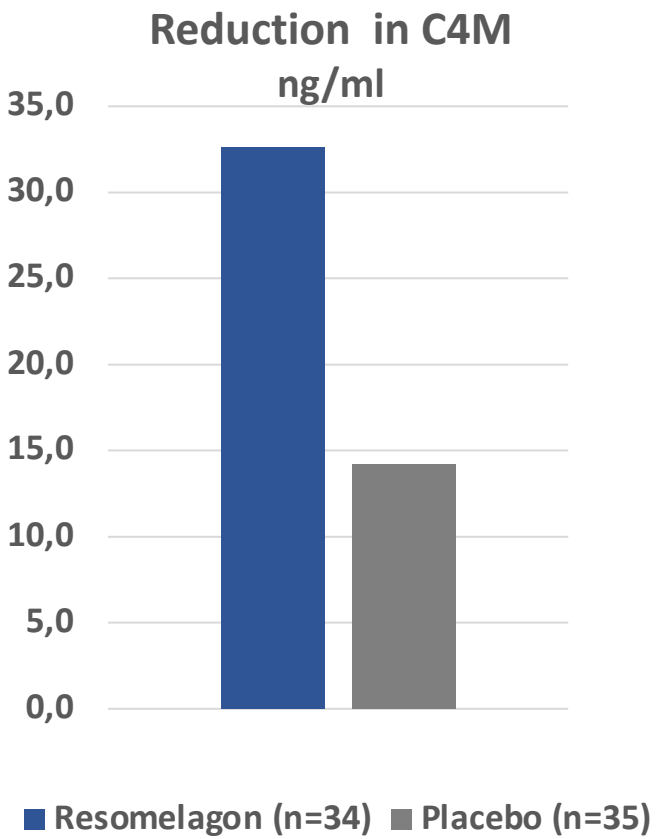
- DEMRIQ uses the peak intensity and rate of contrast agent uptake as indicators of the intensity of synovial inflammation
- Resomelagon treated patients both in the full sub study and as well as those with elevated CRP showed a lower peak intensity as well as a lower rate of agent uptake than placebo indicating a larger reduction in synovial inflammation
- This reduction in assessed joint inflammation is supported by significant decreases in tender and swollen joint counts of the assessed joints in these patients

* p<0.001 vs Baseline

Lower levels of systemic biomarker C4M indicate decreased collagen IV degradation in resomelagon treated patients with elevated CRP

- Collagen type IV is a structural matrix protein which contributes to the structural organization of the synovia
- In RA degradation and loss of C4M is correlated with increasing inflammation
- Resomelagon treated patients with elevated CRP had a larger reduction in circulating C4M than placebo indicating a larger reduction in inflammation





Mean per group- *: p<0.001 vs Baseline

EXPAND Safety: Resomelagon continues to exhibit a favorable safety profile

Treatment Emergent Adverse Events (TEAE)

Group (n)	Placebo+ MTX (64)	AP1189 100mg + MTX (63)	Overall (127)
Serious Treatment Emergent AEs			
Patients with ≥ 1 Serious AE n (%)	1 (1.6)	1 (1.6)	2 (1.6)
Non-Serious Treatment Emergent AEs			
TEAEs n (%)	43	45	88
Mild/Mod/Severe	24/19/0	25/20/0	49/39/0
Patients with ≥ 1 TEAE	28 (44.4)	27 (42.2)	55 (43.3)
Patients with ≥ 1 TEAE leading to study discontinuation	1 (1.6)	5 (7.9)	6 (4.7)
Patients with 1 or more TEAE leading to death	0	0	0
TEAEs in ≥ 5% of patients n (%)			
Overall infections	10 (15.6)	7 (11.1)	17 (13.4)
Elevated liver enzymes	6 (9.4)	3 (4.8)	9 (7.1)
Headache	6 (9.4)	0	6 (9.4)
Abdominal pain	2 (3.1)	4 (6.3)	6 (4.7)
Nausea	2 (3.1)	4 (6.3)	6 (4.7)
Vomiting	2 (3.1)	4 (6.3)	6 (4.7)

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Next clinical study read-out for Synact Pharma is the Resolve Part A later in October