

SynAct Pharma AB

Treating Inflammation through Resolution Therapy

EXPAND phase 2b - top-line data

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Top-line data EXPAND phase 2b study

Primary end point was not achieved

- 54.7% for AP1189 vs 55.7% for Placebo in ACR20 score
- Subjective assessment very much different from the BEGIN study
- Objective parameters more in line with the BEGIN study

Good safety profile

Very favorable safety profile after 3M therapy

Top-line data only

- Unusually high placebo effect and differences between sites
- Further analysis of all data to be completed

EXPAND vs RESOLVE

- Different patient population RESOLVE patients has longer disease duration
 - Documented incomplete response to MTX

Geographical split

RESOLVE also includes US sites





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

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 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- SubStudy	 Evaluation of Synovial inflammation using Dynamic Contrast Enhanced MRI Quantification (DEMRIQ)- potential effects on early structural changes (RAMRIS)

The EXPAND study – 12 weeks dosing in treatment naïve RA pt with high disease activity

127 Patients Randomized

Resomelagon=63

Completed n=53

Discontinued n=10

Withdrawal of content n=5 Adverse event n= 5 Lost in follow up n=0 Placebo n=64

Completed n=61

Discontinued n=3

Withdrawal of content n=1
Adverse event n=1
Lost in follow up n=1

The EXPAND study – 12 weeks dosing in treatment naïve RA pt with high disease activity

Baseline Characteristics

	Resomelagon (n=63)	Placebo (n=64)
Age mean	58.0	55.2
Gender % Females	85.7	87.5
RA- history Weeks (Mean)	42	19
RA % Sero Negative	25.3	17.2
CRP % above normal range	39.6	35.9
CDAI	42.0	40.3
ARC class (I/II/III in %)	3.2/77.8/19.0	7.8/71.9/20.3
Corticosteriod treatment %	0	0





Safety: Treatment emergent events in the EXPAND study

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 Emergen	t AEs		
TEAEs n (%) Mild/Mod/Severe	43 24/19/0	45 25/20/0	88 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 \geq 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)

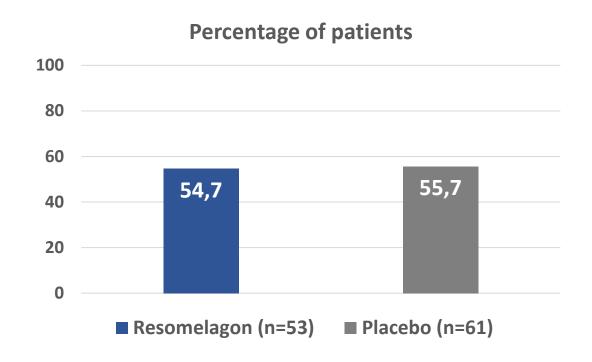


EXPAND Primary Efficacy Endpoint

Effect of 100 mg resomelagon (AP1189) against placebo in subjects with RA, evaluated by the American College of Rheumatology 20% (ACR20) response rate at week 12

The EXPAND study – 12 weeks dosing in treatment naïve RA pt with high disease activity

ACR Scores following 12 weeks treatment



The study could not identify treatment related effects of resomelagon relative to placebo on the primary endpoint





ACR scoring system – both subjective and objective read-outs

Subjective read-outs

Objective read-outs

- Investigator assessment of disease activity (VAS)
- Patient assessment of disease activity (VAS)
- Patients Pain assessment (VAS)
- Health Assessment Q. (HAQ) of physical functioning

Tender Joint Swollen Joints CRP

To qualify for improvement in ACR score reduction in tender and in swollen joints has to be present – and in addition, improvement 3 out of 5 of the other readouts, 4 of which are subjective.

EXPAND Study – observations

- In the EXPAND study reduction in tender and swollen joints in the resomelagon group seems to have been reduced to a degree we could expect from the BEGIN study
- The patient and investigator assessment of disease activity in the EXPAND study did not reflect the reduction seen in tender and swollen joint counts
- This is surprising as the reduction in joint counts is in favor of resomelagon rather than placebo – and that nothing in the adverse event profile indicates that the compound is less well tolerated
- Between sites variability in clinical scores was high, which most likely contributed to the ability to discriminate between resomelagon and placebo treatment. This variability seems to be driven mainly by the subjective measures.

RESOLVE Study - Adaptive P2a/b trial in DMARD-IR patients Sites in US and Europe under an US- IND- P2a data expected in October

Part A – 4 weeks dosing

Part B – 12 weeks dosing

3 dose levels of Resomelagon (AP1189) cont. MTX

Placebo, cont. MTX

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) and RAMRIS 	

Key differences between RESOLVE and EXPAND studies

Disease duration:

- Tx naïve <1yr since diagnosis
- **DMARD-IR** years since diagnosis

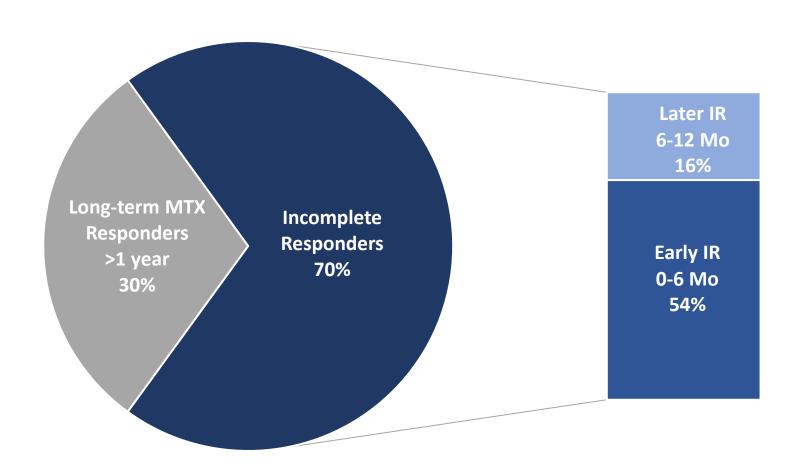
Previous methotrexate use:

- Tx naïve no previous methotrexate use
- **DMARD-IR** patients have a documented incomplete response to MTX after an adequate course of therapy of at least 3mo (many have 1+ year of exposure) at a dosage higher than was used in EXPAND

Concurrent steroid use:

- Tx naïve No use of steroids at study entry, steroids only used for rescue therapy
- DMARD-IR Steady doses of steroids below 10mg allowed
- RESOLVE is approved under new US IND with US sites recruiting approximately 25%

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 loose responsiveness²
- Up to 22% of patients experience intolerance even with long-term MTX usage³

DMARD-IR: High unmet need and significant commercial opportunity

- Currently, DMARD-IR patients are not well served by existing therapies
 - Advanced therapies like biologics and JAK inhibitors come with serious safety concerns
 - Payors and insurers can deny and delay access to these very expensive therapies
 - In the US, JAK inhibitors have been restricted due to safety concerns by the FDA to use only after a TNF blocker meaning the next therapy after DMARDs is likely an injectable or an infused product
- Approximately 40% of global RA patients (~8M) are managed on DMARD therapy alone and can have long-lasting side effects even after years of continued use
- With the global RA market expected to reach up to \$30B dollars by 2030, a successful, convenient and safe oral medication could be established in a market position with multi-billion-dollar potential

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