



New treatment for inflammatory diseases

September 2016

SynAct Pharma - Introduction

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 - First indication: Psoriasis arthritis
 - Big medical need and market potential
 - **First product AP1189** is expected to move into first human trial late 2016:
 - Phase I data H1 2017
 - Phase II data i 2018
 - The company is financed until end 2018
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 - Experienced management and board that has “been there and done this before”
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SynAct Pharma – Aktietorget



Psoriasis Arthritis

– a chronic inflammatory disease with disease progression

125 M psoriasis patients - a chronic skin disease with systemic complications

- appr 30% develop psoriasis arthritis

Symptoms: from affection of a few joints to more severe joints affection and systemic symptoms as anemia and fatigue

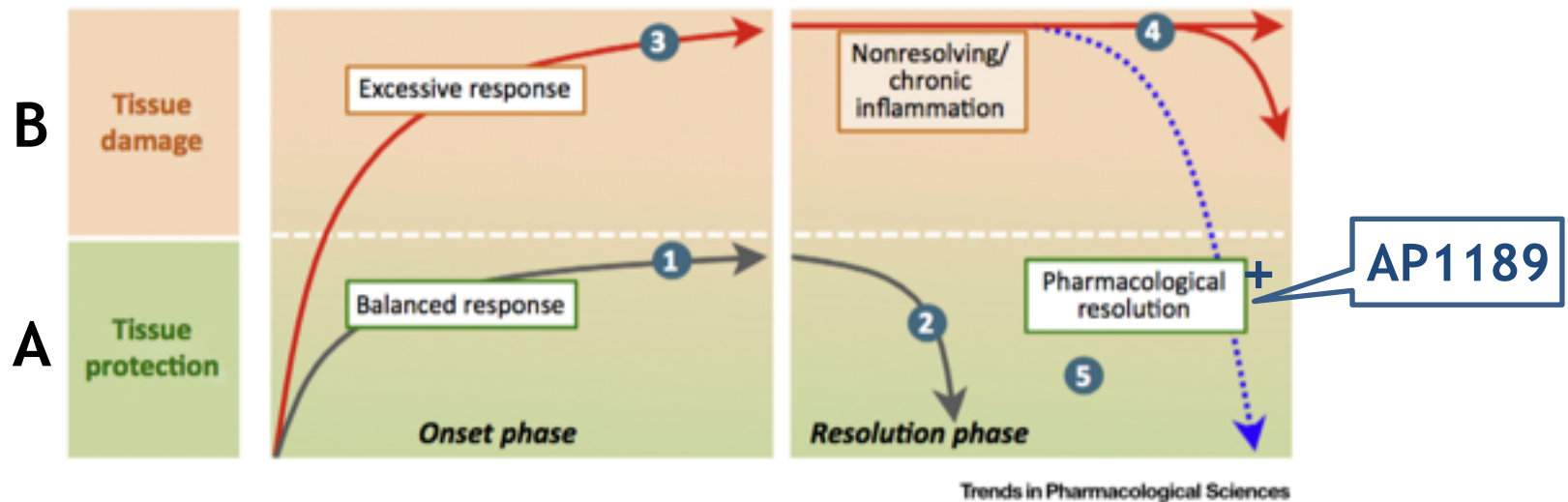
Standard care:

- Anti-inflammatory compounds, including biologics
- Immundepressive compounds
- Large fraction of patients suffer from insufficient treatment effect as well as drug induced side effects

Market: Growing global market, currently around \$2,5-4 B



The inflammatory process



A) Balanced Inflammatory response :

1. The Bodies answer to injuries in order to protect tissue function
2. Activation of specific resolving pathways

→ **Tissue resolves***

B) Excessive Inflammatory response:

3. Inappropriate resolution
4. Risk for chronic inflammation

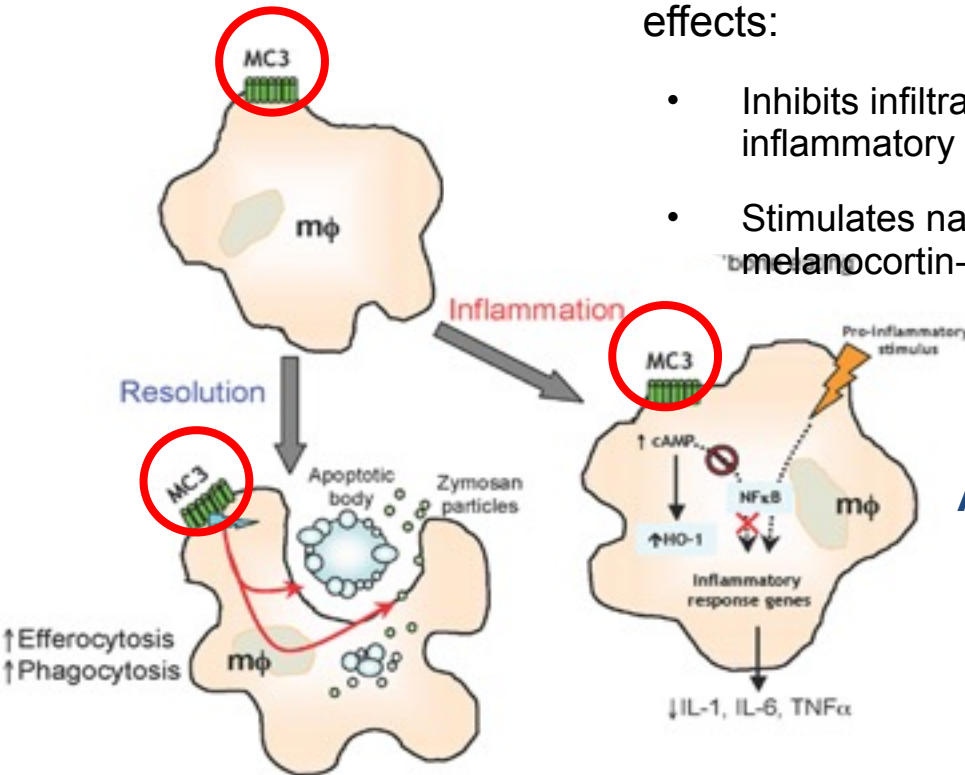
→ **Tissue damage, reduced functionality, pain**

SynAct Pharms antiinflammatory compounds reduce the inflammatory response and stimulates the bodies own resolution processes*

The Melanocortinsystem is activated in inflammatory conditions

Melanocortins are endogenous peptides with anti-inflammatory effects:

- Inhibits infiltration of white blood cells and release of pro-inflammatory mediators
- Stimulates natural occurring resolution processes through specific melanocortin-receptors



A drug that activates melanocortin receptors facilitates the bodies own systems to fight excessive inflammatory processes

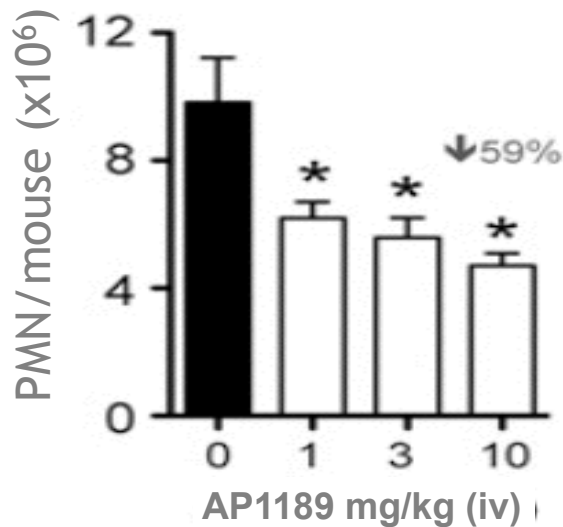
AP1189 is a small molecule acting on the melanocortin-receptor type 3 (MC3r) through a novel mechanism called "biased" agonism

AP1189 – Double anti-inflammatory effect

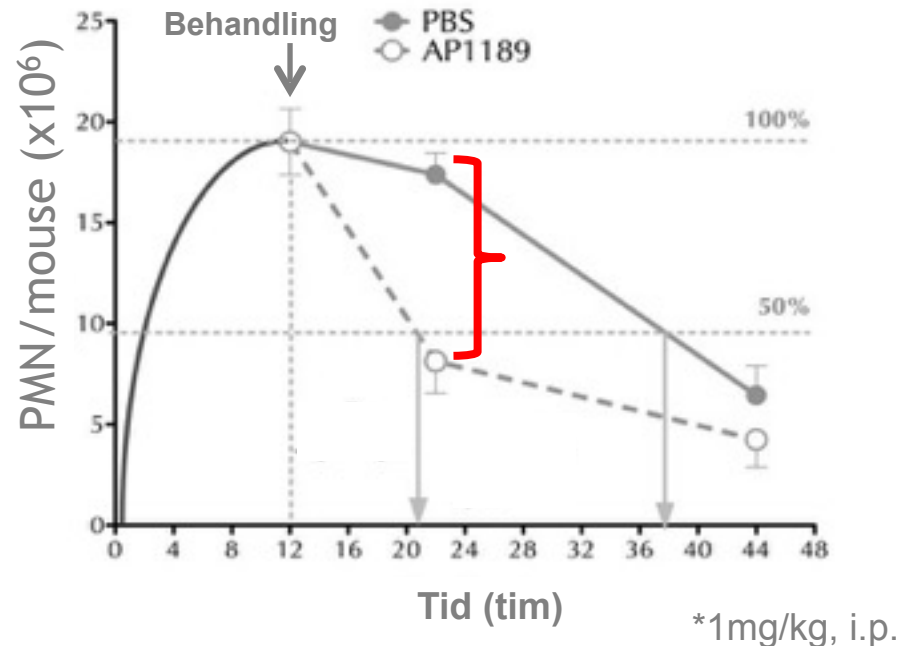
Zymosan induced peritonitis – a model of acute neutrophil driven inflammation

- Treatment with AP1189 before (left) or 12 hrs after (right) initiation of the inflammatory process

AP1189 treatment inhibits the inflammatory response

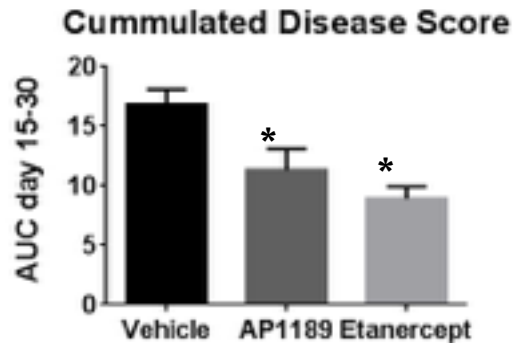


AP1189* treatment induce faster recovery



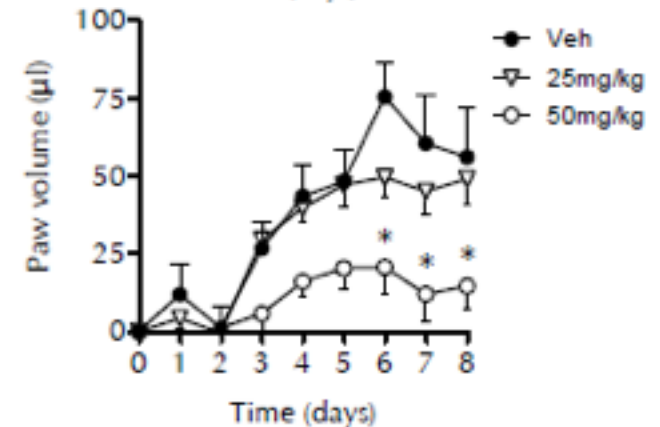
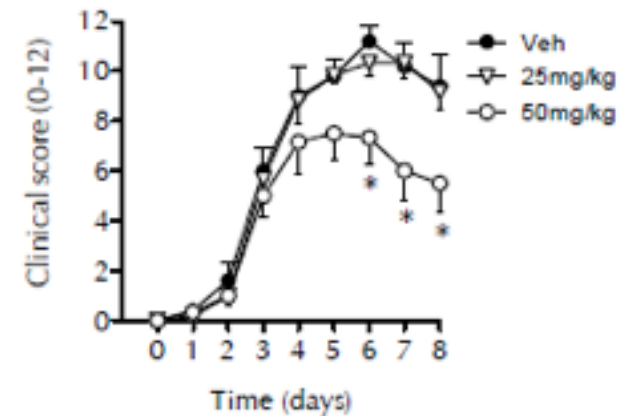
AP1189 – Treatment effect in inflammatory disease models

Collagen-induced arthritis (30mg/kg, p.o.)

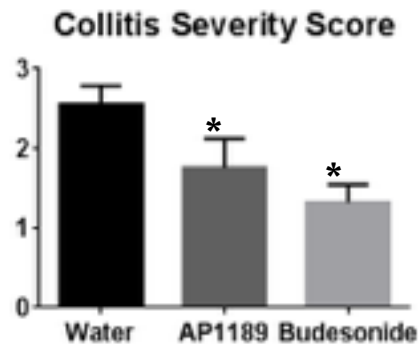


Unpublished data: n=10, *: p < 0.05 vs Vehicle

K/BxN-induced arthritis



Model of intestinal bowel disease (40mg/kg, p.o.)



Unpublished data: n=8, *: p < 0.05 vs Vehicle

Montero Melendez et al J Immunol 194, 3381-8, 2015

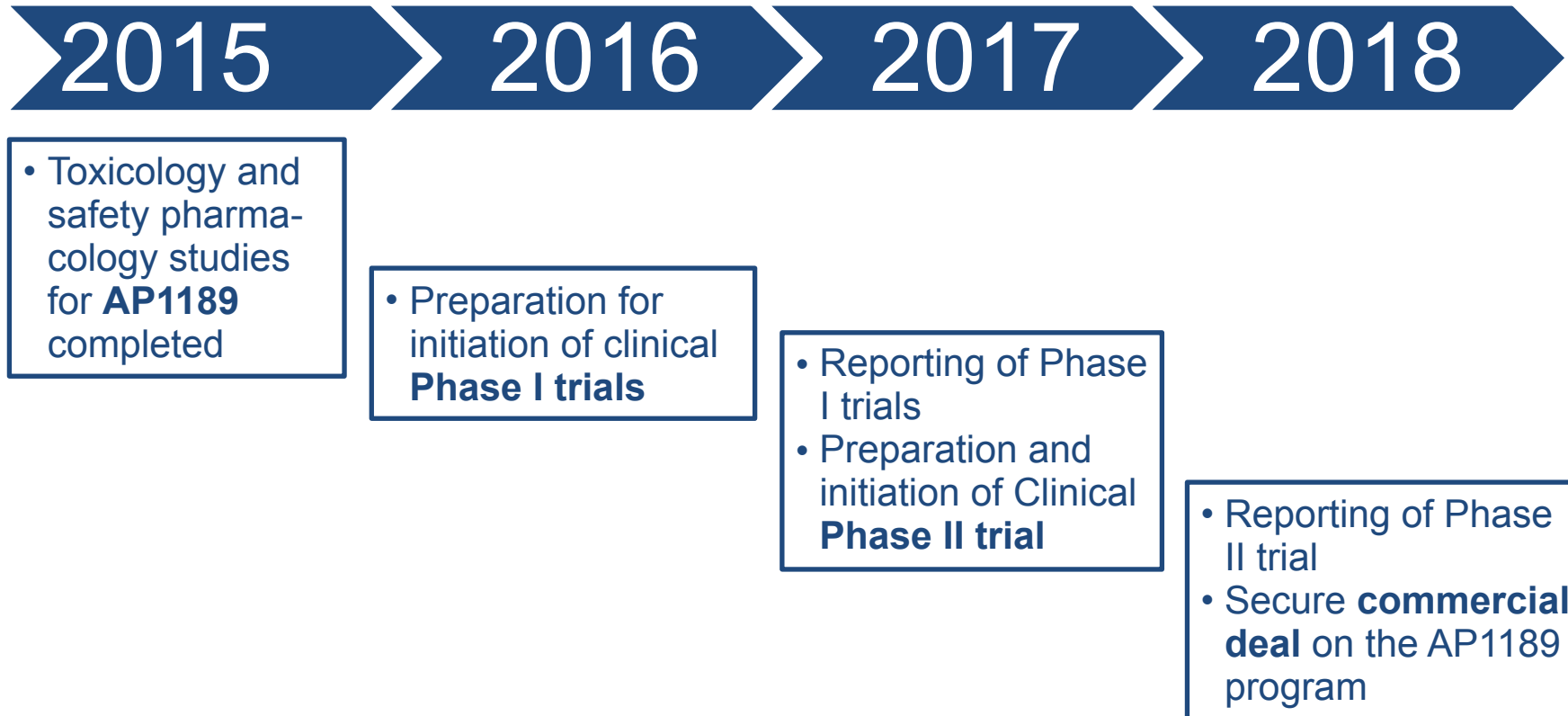
AP1189 – Ready to enter clinical development

Competitive edge:

- **New mode of action** – “Biased Agonist” on melanocortin-receptors
- Acts by stimulation of classical anti-inflammatory processes AND through potentiation of **natural occurring recovery processes**
- **Add on treatment** during acute exacerbations “flairs” in chronic inflammatory conditions- first indication: **psoriasis-artrit**
- **Oral available with possibility to apply once aily dosing**
- Potential for **low cost** large scale production

AP1189: “First in class, small molecule” with unique anti-inflammatory effects ready to enter *clinical development*

AP1189 – Planned development activities



Relevant deals within the inflammation field

Deals with SynAct Pharma Board and/or Management involvement:

- 2005: Biolipox and Boehringer Ingelheim: totalt deal value **250 M €** plus royalties
- 2011: Orexo abd J&J: totalt value up to **650 M US\$**, plus royalties
- 2012: Action Pharma, main project AP214 sold to AbbVie - **110 M US\$** cash, Phase II-projekt, indication "organ protection"
- 2013: Questcor Pharmaceuticals aquires rights to TXP Pharmas deal value – **100 M US\$** ("upfront and milestone")
- 2014: Questcor sold to Mallinckrodt Pharmaceuticals for **6 BN US\$**

Other recent relevant deal:

- 2015: Galapagos and Gilead: **725 M US\$** upfront and up to **1.35 BN US\$** ("milestones") and royalties from 20%

Vitae Pharma Inc – Just acquired for USD 635 M



- Small US biotech company within the inflammation/psoriasis space
- Medical Need, great innovation and large market potential
- Lead program has shown proof-of-concept in psoriasis with lead drug candidate
- Announced on September 14th 2016: Allergan to acquire Vitae for USD 635m in cash – Approx. 160% market premium in order to strengthen AGN dermatology franchise

Experienced management and board

More than 100 years of drug development and business development in private and public life science companies.

- Examples of deals:



SynAct Pharma – Management and board

- Management
 - Jeppe Øvlesen, MBA , CEO
 - Henrik Stage, MSc, CFO
 - Thomas Jonassen, MD, CSO
- Board of directors
 - Torbjorn Bjerke, MD, Chairman
 - Charlotte Edenius, MD, Phd
 - Lars Adlersson
 - Thomas Jonassen, MD,

Management and board has a broad expertise within drug development and business development

SynAct Pharma - Summary

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