

# Synact Pharma AB

# A new medicine to treat inflammatory diseases

Jeppe Øvlesen, MBA CEO

Thomas Jonassen, MD

**CSO** 

Sedermera Dagen Copenhagen, March 13, 2018

# SYNACT PHARMA – OVERVIEW



- Synact Pharma AB listed at Aktietorget in July 2016
- Ticker SYNACT; Aktietorget
- Introduction price at 6.40 SEK per share
- Current (March 6) 14.35 SEK per Share
- Marked cap (March 6) of 178.0 SEK





- Main strategy is to develop lead compound AP1189 into Phase II clinical development in inflammatory joint diseases
- Investigate opportunities in additional indications with the possibility to setup development path in second indication (ACTH).
- Strong IP position
- Business model to sell or out-license the project after clinical PoC to bio pharma or big biotech
- Current market for lead indication is several Bn \$ annually and growing

AP1189 Clinical development Phase I 2017/18 (Healthy volunteers )

Phase II 2018 (Patients)

**Commercial agreement** 

# SYNACT PHARMA TEAM





#### Jeppe Øvli Øvlesen, MBA

- CEO
- > 15 years of CEO experience
- Investor and founding Board Member at a number of Biotech/Medtech companies
- Co-founder of TXP Pharma
- Former CFO & VP BD of Action Pharma



#### Thomas Jonassen, MD

- Co-founder and CSO,
- Member, Board of Directors
- Associate Professor, KU in Denmark
- Honorable Professor, WHRI, United Kingdom
- Co-founder of TXP Pharma
- Co-founder and former CSO of Action Pharma



#### Henrik Stage, MsC

- CFC
- Former CEO and CFO at Santaris Pharma
- >25 years experience from Biotech and financial industry



#### Torbjørn Bjerke, MD

- Chairman, Board of Directors
- Co-founder and Chairman in TXP PHarma
- > 25 years track record from Pharma industry as Head R&D and CEO.
- Co-founder of Action Pharma A/S
- Member, BoD for DBV Technologies



#### **Lars Adelsson**

- Member, Board of Directors
- Former GM, GlaxoSmithKline Sweden; Austria
- Former CEO, Medivir
- Member, BoD for Evolan Pharma; Swedish Pharmaceutical Manufacturers Association

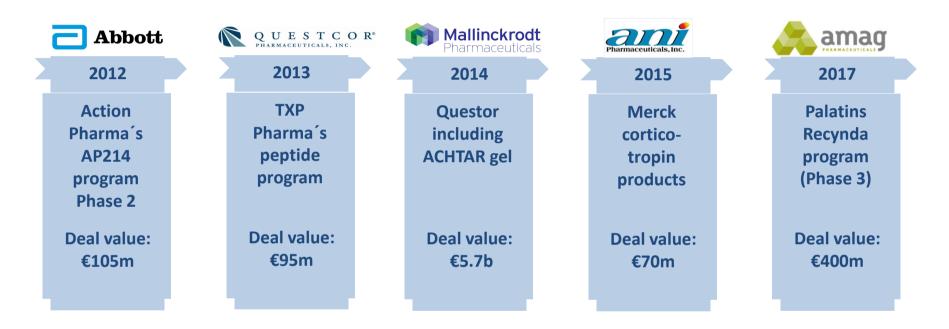


#### Charlotte Edenius, MD, PhD

- Member, Board of Directors
- Former Executive Vice President for R&D, Medivir AB; Senior Vice President for R&D Orexo AB, Vice President and CSO Biolipox AB and various roles AstraZeneca Clinical R&D
- Member, BoD for Kancera, Immunicum and Gesynta

# MELANOCORTIN THERAPY – RECENT DEALS





Also worth mentioning is Rhythm Pharmcaeuticals - targeting the MC4r in POMC defiance Obesity patients- who recently went public-current market cap: in excess of 700 M US\$

All specialized programs focused on peptide derived therapy

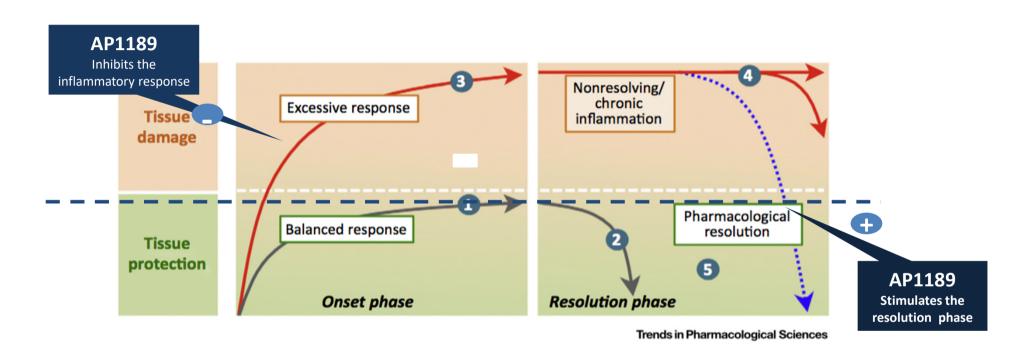
## SYNACT PHARMA - STATUS - TODAY





- AP1189 SynAct Pharma's lead project is in clinical development for active joint disease

   ie rheumatoid and psoriatic arthritis
- Status from ongoing Phase 1 studies shows
  - Well tolerated with attractive safety profile
  - Promising pharmacokinetics profile, supporting once daily oral dosing
  - Tablet for once daily dosing is currently tested in repeat dosing regiment
- Filing of Phase IIa clinical application is scheduled for Q2 2018
- The potential of the compound in additional high-value indications -includes systemic lupus (SLE), multiple Sclerosis (MS), nephrotic syndrome (NS) and Intestinal bowel disease (IBD) is exploited in ongoing experimental studies.



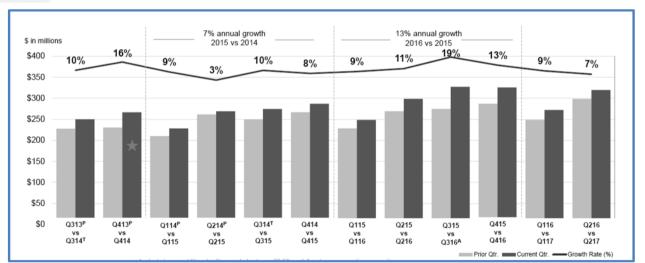
 Resolution therapy holds promise to correct overshooting/ongoing inflammation typical of several pathological settings.

# MELANOCORTIN DERIVED THERAPY- CURRENT MARKED

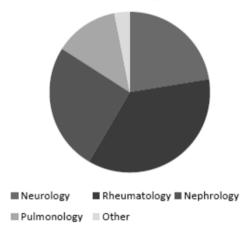




- ACTH (ACHTAR gel) is a potent anti-inflammatory compound that mediates it antiinflammatory effects through melanocortin receptor activation
- Current annual sale of around \$ 1.25 Bn -



### 2016 Net Sales by TA

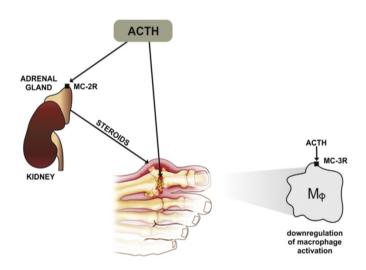


Source: Mallinckrodt Pharmaceuticals Investor Briefing October 4, 2017

# MELANOCORTIN DERIVED THERAPY-



- ACTH (ACHTAR gel) has potent anti-inflammatory effects in a variety of severe autoimmune and inflammatory disorders
- Two-way mode of action:
  - 1. Melanocortin receptor activation (non-selective)
  - 2. Release of steroid hormones
- Route of administration: subcutaneous injections

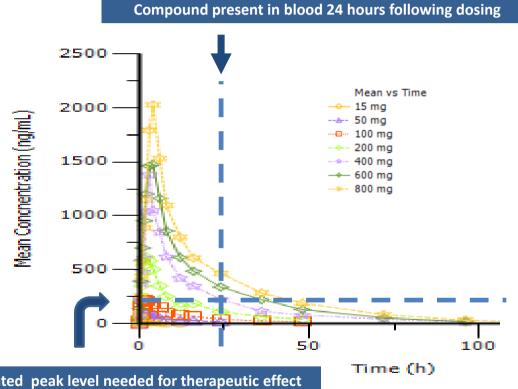


Limited for <u>difficult to treat patients</u>, due to side-effect profile with unwanted steriod hormone effects and stimulation of dermal pigmentation

AP1189 has the beneficial therapeutic effects related to melanocortin receptor stimulation- AP1189 does not have steriod hormone effects and does not induce dermal pigmentation – in addition AP1189 is oral available



- Dosing completed in 64 healthy volunteers (male as well as post menopausal women)
- In general well tolerated up to highest dose level, where peak exposures reached > 10 times the efficacious concentrations
- Long elimination half life support once daily administration
- Repeat dosing with newly developed tablet is ongoing



Anticipated peak level needed for therapeutic effect

- PsA and RA patients present with comparable clinical symptoms and respond to similar treatment modalities, despite different etiologies of disease
- Both the RA and PsA treatment markets are dominated by high priced biologics providing feasibility for novel oral entrants like AP1189 with moderate-high price levels
- Both the RA and PsA markets are growing at double digit rates due to aging populations and novel market entrants
- The RA market is roughly 10x larger than the PsA market in \$ terms



- Patients with active inflammatory joint disease are currently treated with Methotrexate (MTX)
- Around 40% of these patients have an inadequate response to MTX
- Next line compounds are expensive and often associated with unwanted side effects
- Even among patients treated with the expensive biologics, up to 30% of the patients still suffer from inadequate treatment effects



A compound given as early add-on to MTX that could reduce the need for second line treatment and/or reduce the dose levels of MTX to option remission of symptoms would have major impact in active joint disease



Phase I

- Part 1 and 2 completed
- Part 3 to be completed Q2, 2018 followed by reporting

Phase II

- Preparation of Phase II Clinical trial in lead indication Q2,2018
- Trial application to be filed in Q2, 2018
- Study to be initiated in Q3, 2018
- Study to be completed in Q3, 2019

**Pre-Clinical** 

- Testing of compound in additional disease models H2, 2018
- Evaluate potential new business opportunities emerged from new data

Continuous business development discussions with potential partners



# **AP1189**

- excellent oral PK and can be developed as a once-daily tablet formulation
- very well tolerated in ongoing Phase 1 clinical testing
- robust efficacy in preclinical models of arthritis, IBD and peritonitis
- Ongoing studies evaluate additional development opportunities
- potential to be a first-in-class treatment option for inflammatory diseases with big medical needs



CEO, Jeppe Øvlesen

## joo@synactpharma.com

Tel.: + 45 2844 7567

CFO, Henrik Stage

### hs@synactpharma.com

Tel.: + 45 4026 0900

www.synactpharma.com