

# AP1189 - A new medicine to treat inflammatory diseases

Thomas Jonassen, CSO

Jeppe Øvlesen, CEO

Sedermeradagen Malmø 2018

#### AP1189 – a melanocortin receptor agonist to reduce inflammation and "boost" healing

- → First indication: active inflammatory joint diseases (rheumatoid and psoriatic arthritis)
- → Opportunity: additional indications based on Mode of Action (ACTH-like properties)

#### **Current market for arthritis indications**

→ several Bn \$ annually and growing

#### **Attractive Business Model**

→ sell or out-license the project after clinical PoC

#### **Strong IP position**

→ Approved patents in US, EU and Japan

#### **Experienced Management and Board**

→ Expertise in melanocortin research, clinical development and global deal making

AP1189 Clinical development

Phase | 2017/18 (Healthy volunteers )

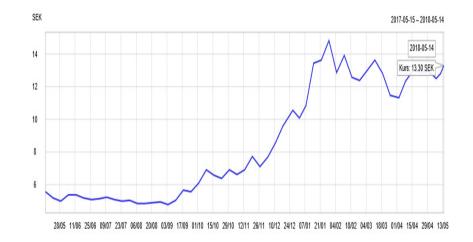
Phase II 2018/19 (Patients)

Commercial agreement

# THE SHARE (Ticker SYNACT)



- Listed at Aktietorget in July 2016
- Introduction price at 6.40 SEK per share
- Current (Maj 2018) app. 13.50 per Share
- Market cap (Maj 2018) of app. 160 MSEK
- Right issue of 2 257 718 shares subscribed with 196% - closed yesterday
- Lock up for 12 months (Management and Board)



# **EXPERIENCED 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

- CFO
- 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 Adlersson**

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



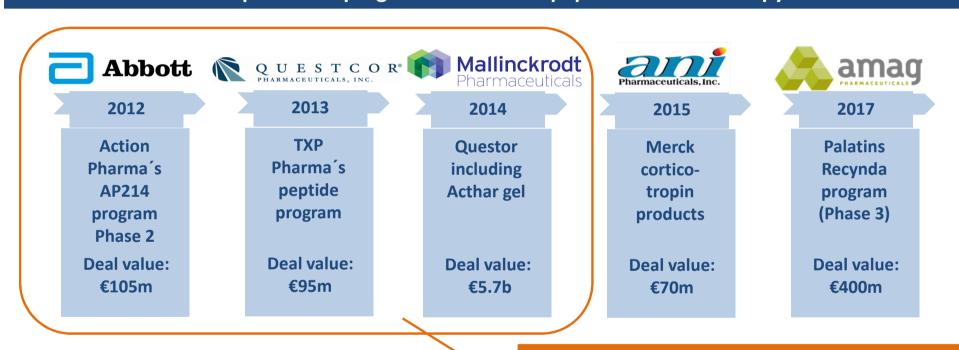
#### Charlotte Edenius, MD, PhD

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

#### **MELANOCORTIN THERAPY – RECENT DEALS**



# Specialized programs focused on peptide derived therapy



**Projects/deals delivered by SynAct Pharma founders** 

AP1189 is an oral, once daily, small molecule melanocortin receptor agonist

- DEVELOPMENT OVERVIEW



2017 > 2018 > 2019

- ✓ Start of clinical phase I study (healthy)
- ✓ Planning for clinical phase IIa study (patients)
- Report phase I study
- Start of clinical phase IIa study
- Continued preclinical studies with AP1189 in additional indications
- Report phase IIa study
- Evaluate potential in additional indications
- Commercial partnership/deal

Preparatory activities for future commercial deal with AP1189 after Phase IIa

- IN CLINICAL DEVELOPMENT FOR ACTIVE JOINT DISEASE



# Broadening indication from flares in PsA to active inflammatory joint disease, both RA and PsA



- ✓ Both RA and PsA treatment markets are dominated by high priced biologics – room for novel oral entrants
- ✓ The RA and PsA market reached global sales in 2015\* of:

Psoriatic Arthritis: 4.53 billion USD

• Rheumatoid Arthritis: 19.5 billion USD

 Combined patient population will allow fast and efficent enrollment of patients into clinical studies

Increased market potential by broadening indication to active inflammatory joint diseases

IN CLINICAL DEVELOPMENT FOR ACTIVE JOINT DISEASE



#### Rheumatoid and psoriatic arthritis have overlapping characteristics

- ✓ autoimmune diseases where the immune system "wrongly" attacks joint tissues
- ✓ similar symptoms with swelling, pain, stiffness and in severe cases joint destructions
- ✓ available antiinflammatory treatments:
  - are not effective enough in all patients and/or cause severe side effects
  - reduce inflammation by inhibiting the immune system

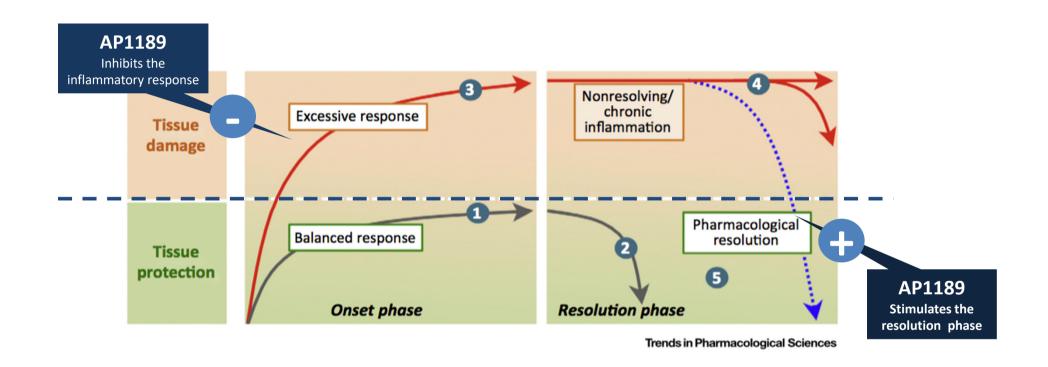


AP1189 – activates certain immune cells with a unique potential to reduce inflammation and support resolution

#### **RESOLUTION OF INFLAMMATION**

- A NEW THERAPEUTIC FRONTIER





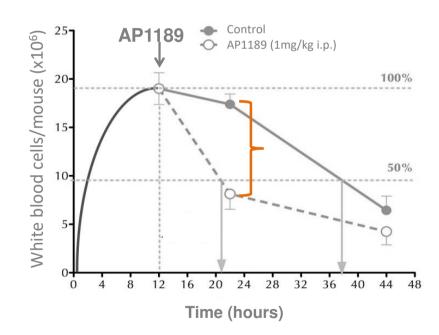
Resolution therapy holds promise to correct overshooting/ongoing inflammation typical of many pathological settings

#### - TREATMENT EFFECTS IN DISEASE MODELS



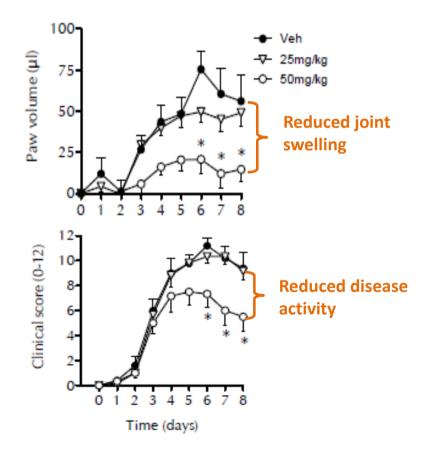
# Increases clearance of apoptotic cells

#### → Stimulates resolution of inflammation



Montero Melendez et al J immunol 194, 3381-8, 2015 In-house data

# Efficacious in arthritis model in mice (joint inflammation)



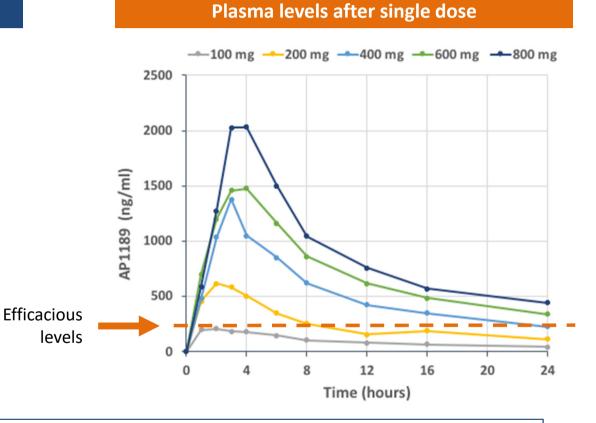


# **Clinical Phase I study is ongoing**

- Single dose completed in 64 healthy volunteers
- Well tolerated up to dose levels where peak exposures reached > 10 times the efficacious concentrations
- Data support once daily dosing
- Newly developed tablet is now used in 14 days study

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Top line data available Q2-2018



Filing of Phase IIa clinical application is scheduled for Q2 2018

- POSITIONING AS AN ADD-ON IN ACTIVE JOINT DISEASE



- Patients with active joint disease are treated with methotrexate (MTX)
- Approx. 40% have inadequate response
- Next line treatments are more efficacious, but often have side effects
- Even with expensive injectable biologics, up to 30% still suffer from inadequate treatment effect





# AP1189 is developed as an add-on to MTX to reduce inflammation and support resolution

- → attenuate symptoms and decrease time to resolution
- → reduce need for second line treatment and/or reduce MTX dose

- DEVELOPMENT OVERVIEW



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#### **MELANOCORTIN DERIVED THERAPY**

- AP1189 OPPORTUNITY IN ACTH SPACE



#### **ACTH** based therapy

- ACTH has potent effects in autoimmune and inflammatory disorders via:
  - **1. Melanocortin receptor activation** (non-selective)
  - 2. Release of steroid hormones
- Limited to difficult to treat patients, due to unwanted steroid hormone realated side effects (systemic lupus (SLE), multiple sclerosis (MS) and nefrotic syndrom)
- Injections (s.c.)
- Annual sales: around 1.25 Billion USD\*



Preclinical studies
ongoing to evaluate other
indications in the ACTHtherapy area

AP1189 - an oral melanocortin receptor activator with beneficial therapeutic effects without specific steroid hormone effects → opportunities in ACTH space

# **THE OPPORTUNITY - 2018/2019**



- New Share issue facilitates broader approach
- Increased market potential by broadening the indication from flares in PsA to active inflammatory joint diseases in both RA and PsA (2015 sales: 19.5 and 4.53 billion USD, respectively)
- Complete an expanded Phase IIa (clinical PoC) in patients with active arthritis in 2019
- Explore additional indications to complement the package for business development ("ACTH indications")





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#### **ERBJUDANDET I SAMMANDRAG**



Teckningstid: 19 april – 8 maj 2018.

**Teckningskurs:** 9,90 SEK per aktie.

Emissionsvolym: Cirka 22,4 MSEK.

Antal aktier innan nyemissionen: 12 417 449 stycken.

Marknadsplats: AktieTorget.

Värdering (pre-money): Cirka 123 MSEK.

**Teckningsförbindelser:** Bolaget har erhållit teckningsförbindelser om totalt cirka 9,1

MSEK, motsvarande cirka 41 procent av emissionsvolymen.

Bolagets styrelse och ledning har förbundit sig att teckna för 1,1 MSEK och har ingått ett "lock up" avtal med SynAct Pharma som

sträcker sig under en tolvmånadersperiod avseende hela

aktieinnehavet.