

Swiss-Scandinavian Bio-Business Seminar



February 12, 2013

fighting inflammation

Avexxin's Pipeline

PRODUCT	Disease	Target					
			In-Vitro	In-Vivo	Preclinic	Phase I/II	Phase II/III
AVX001	Psoriasis	gr.IVaPLA2	[Progress bar spanning In-Vitro, In-Vivo, Preclinic, Phase I/II, and Phase II/III]				
AVX002	Rheumatoid arthritis	gr.IVaPLA2	[Progress bar spanning In-Vitro, In-Vivo, and Preclinic]				
AVX003	Glomerulonephritis	gr.IVaPLA2	[Progress bar spanning In-Vitro]				

50,000 Feet Overview

Company

Founded 2005 – Spinout based on basic research at the Norwegian University of Science and Technology

Therapeutic Target

Group IVa Phospholipase A2

Drug Candidates

Small, novel molecules against psoriasis, rheumatoid arthritis and glomerulonephritis and other chronic inflammatory disorders

Lead Indication Status - Psoriasis

Danish Medicine Agency approved testing of AVX001 in mild to moderate psoriasis - clinical phase I/IIa

Trial start February 2013 - Proof-of-Concept in man data expected mid 2013

Funding

Completed Series B November 2012

Intellectual property

Five patent families; two classes of molecules; issued patents in psoriasis

AVX001 - Product Target Profile

*A topically applied drug with a direct anti-inflammatory effect
– equivalent to steroids but without the side effects*

Clinical Target Product Profile

- Direct effect on the diseased keratinocytes within a week leading to more than 50% reduction in PASI score
- Mild-to-moderate psoriasis is a pathway to treating other skin disorders (dermatitis)

Pharmacodynamics

- Substantial effect (57%) in oxalazone-challenged mouse ear model at low dose (0.05%); therapeutic administration mode

Toxicology

- NOAEL at 0.2% in mini-pig skin
- Local irritation in mini-pig skin seen at high concentrations well above efficacy level

Regulatory

- Bioanalytical results: no systemic exposure found at clinically relevant doses
- Histopathology: no treatment related pathological findings at clinically relevant doses

CMC

- A 9-step GMP synthesis
- Formulated in an ointment for topical application
- Lipophilic compound – efficient cellular uptake

Non-Clinical - Efficacy

Oxazolone-induced Contact Hypersensitivity in Mice

- **Protocol**

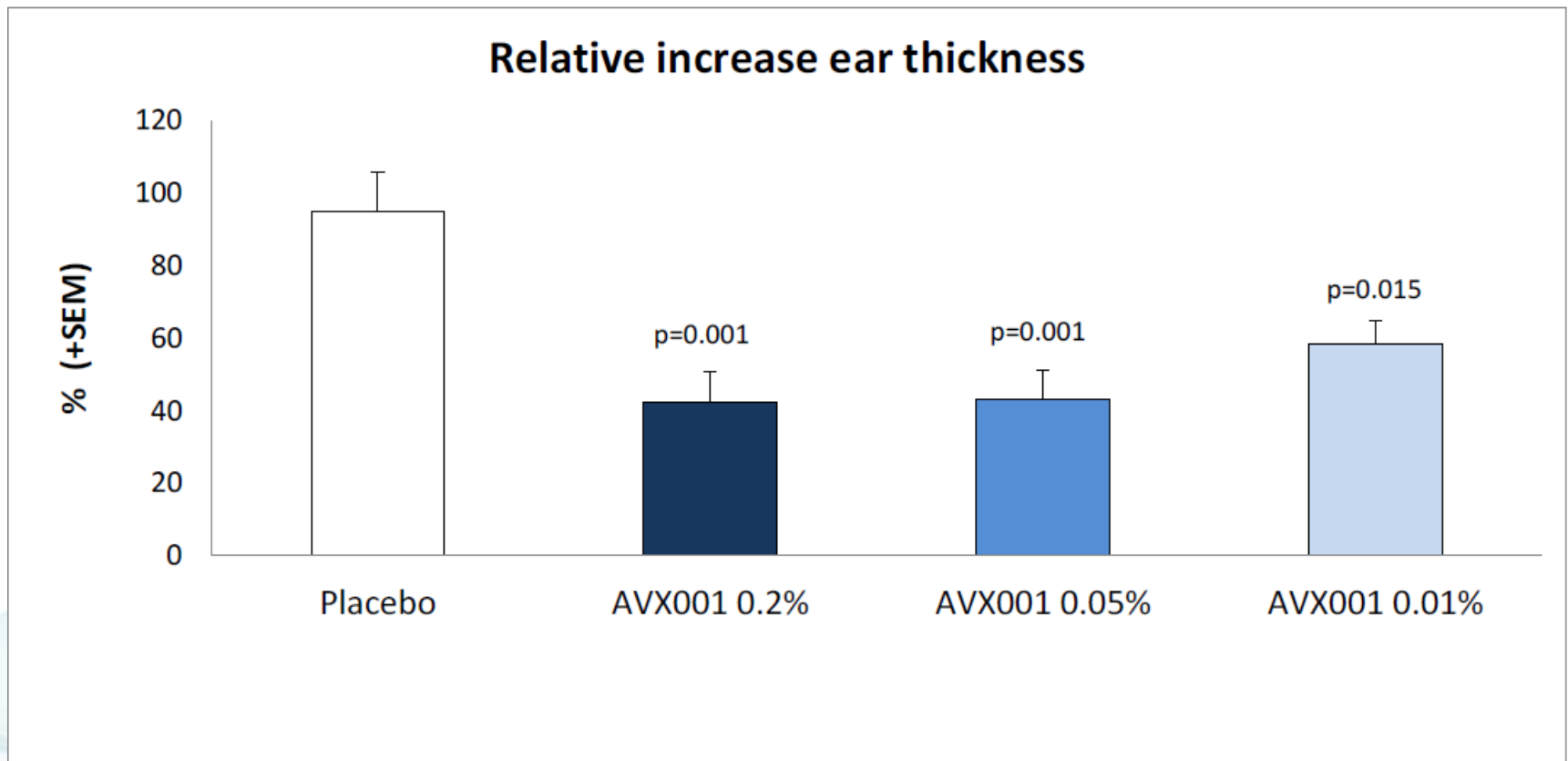
- AVX001 Placebo Ointment
- AVX001 0.2% Ointment
- AVX001 0.05% Ointment
- AVX001 0.01% Ointment

- **Conclusion**

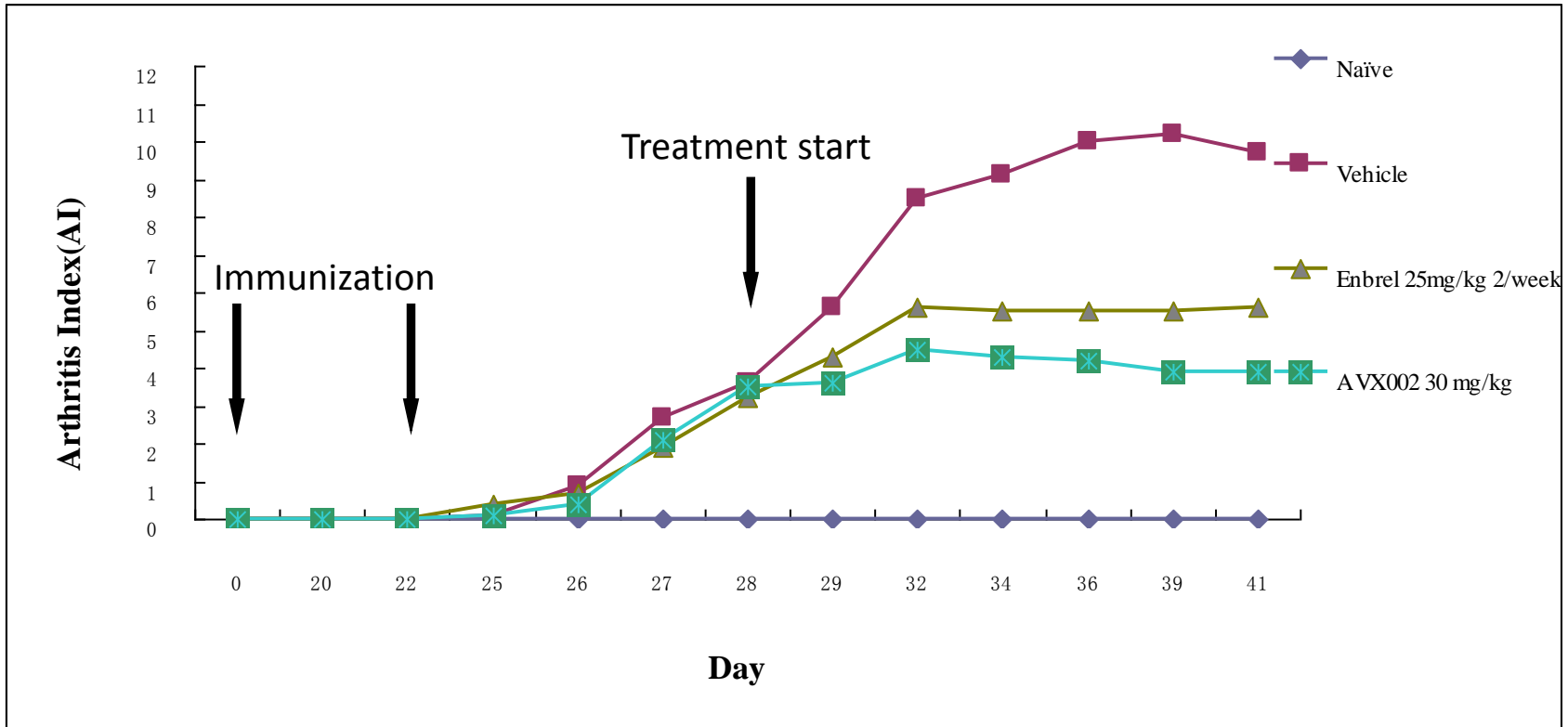
Compared with placebo, AVX001 is able to significantly reduce the increase in ear thickness at all concentrations when administered both 1 hour and 7 hours after challenge.

Non-Clinical - Efficacy

Oxazolone-induced Contact Hypersensitivity in Mice



AVX002 in Therapeutic Efficacy Study in Collagen-Induced Arthritis in DBA/1 Mice



Enbrel (Eterncept) was given two times per week; IP administration

AVX002 was given daily for four days, and then every second day; IP administration

Commercialization Strategy

- Out-licensing/partnering for AVX-compounds within dermatology
- Out-licensing/partnering for AVX-compounds in other chronic inflammatory disorders

Priority

1. World-wide license partner
2. Territorial license partners

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