



Non-Confidential Presentation

January 2012

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Mission

Delenex discovers and develops next-generation antibodies

short-acting and fast-clearing

**delivered locally for chronic diseases
administered systemically for acute events**

The Case for Short-Acting & Fast Clearing Antibodies

- **Antibodies are a great class of drugs**

In the last ten years, therapeutic antibodies have revolutionized the treatment of major diseases (most notably in oncology and autoimmune conditions). 2010 sales: \$51.6 bn*.

- **State of the art: systemically administered, with long half-lives**

The ability of therapeutic antibodies to be injected to patients infrequently (typically once every few months) offers high convenience in many diseases.

But: in less severe diseases, the accumulation of side-effects from such long residence time leads to unfavorable risk/benefit (boxed warnings for Remicade, Humira, Actemra, etc.)

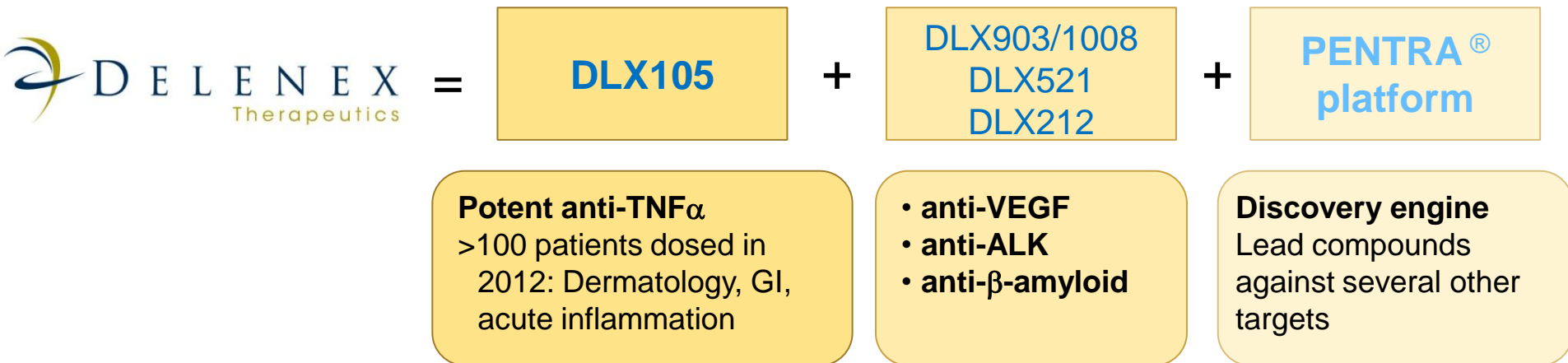
- **NEW Short-acting antibodies: clinical efficacy and higher safety**

Much safer daily topical dosing for chronic diseases opens new perspectives. Short-acting, fast-clearing drugs are necessary for acute inflammatory conditions (flares). Short residence time => favorable risk/benefit in mild/moderate patients.

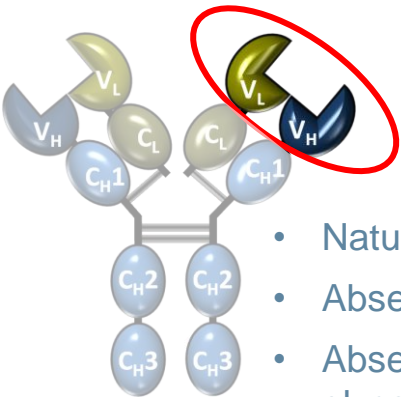
Delenex is committed and funded to conduct studies proving the short-acting antibody concept in patients for multiple indications.

Delenex: From Platform to Clinic

- Clinical lead compound (multiple indications)
- Pre-clinical pipeline
- Discovery platform for rapid production of antibodies against new targets



PENTRA[®] : Optimized Single-Chain Fragments



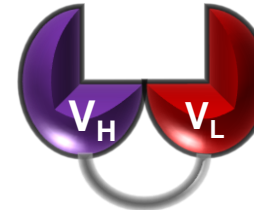
First-generation single-chain Fv fragments

- Natural frameworks
- Absence of Fc-functions
- Absence of glycosylation/heterogeneity
- Low cost production in yeast/bacteria
- Short half-life in circulation
- Excellent tissue penetration

BUT

- Difficult to produce and purify in monomeric form
- Insufficient stability
- Strong monovalent potency requires significant optimization

=> No scFv compound achieved clinical PoC



PENTRA[®] antibodies

Obtained through 10 years of research to select the best human scFv scaffolds.

Enjoy all the attributes of scFvs **PLUS**

- Low risk of immunogenicity
- Excellent stability (T_c up to 86°C)
- Strong monovalent potency before affinity maturation (low picomolar IC₅₀)
- Excellent production of monomers

=> Positioned to achieve clinical PoC

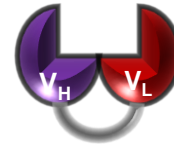
PENTRA[®] Antibodies Are Highly Tissue-Penetrant

Skin penetration of DLX105 has been observed. This data is preliminary and is currently being confirmed.

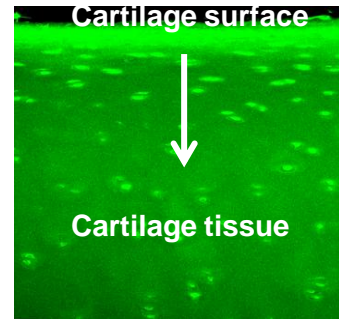
4-hour diffusion (top to bottom) of FITC-labeled compounds into *ex vivo* bovine cartilage at physiological pH. Intensity of green fluorescence is proportional to compound concentration.

24-hour diffusion of Cy5-labeled compounds into *in vivo* mouse rectal mucosal tissue (ulcerative colitis model). Intensity of yellow fluorescence is proportional to compound concentration. Compounds were dosed in the lumen, situated on the right-hand side. The lumen was washed before taking the biopsy.

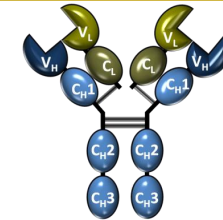
(Courtesy of Prof. G. Rogler, University Hospital Zurich)



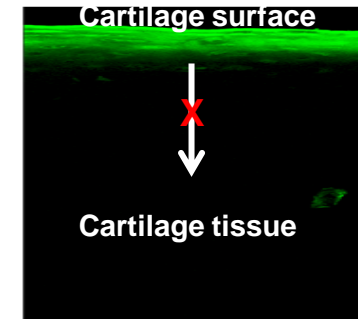
DLX105
PENTRA[®] scFv, 26 kDa



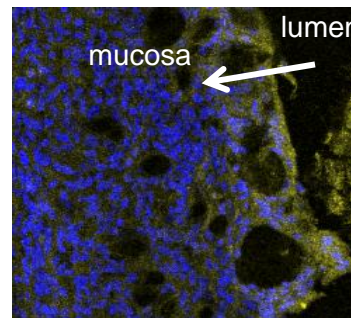
200 μm



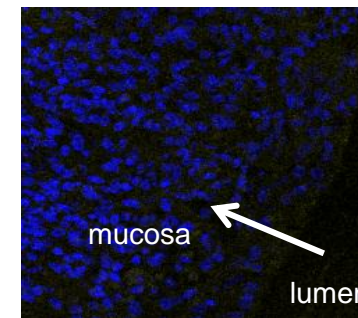
Infliximab
IgG, 145 kDa



200 μm



200 μm

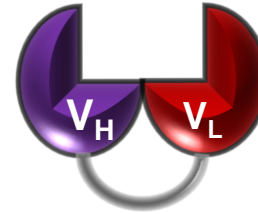


200 μm

PENTRA®

Drug-like

- Ease of manufacturing/purification
- High stability (ease of formulation)
- Low immunogenicity
- High monovalent affinities



PENTRA® antibody
~ 25 kDa

Ideal for acute indications

- Rapid action (excellent tissue penetration, large volume of distribution)
- Fast clearance (<8h in plasma)

⇒ **complementary to existing mAbs**

Pioneering ‘topical antibody therapy’

Excellent tissue penetration, leading to:

- Topical formulation for dermatology
- Gel formulation for mucosal tissue

DLX105

A CLINICAL-STAGE ANTI-TNF α ANTIBODY

DLX105 is A Differentiated Anti-TNF α Antibody

- **Short half-life in circulation (<8h in non-human primates)**
A significant advantage for local dosing: any compound that gets into general circulation rapidly disappears. Risk of toxicity is vanishingly small.
- **Excellent tissue penetration**
DLX105 rapidly penetrates eye and cartilage thanks to its small size and favorable physical properties.
- **Validated target**
TNF blockade has demonstrated therapeutic effect in a range of inflammatory conditions, in millions of patients.
- **High affinity**
DLX105 has sub-nanomolar affinity for human TNF α .

Therapy Areas Delenex Will Bring to PoC

- **Dermatology**

Clinical trials will be run in psoriasis to test skin penetration and plaque clearing. Follow-up with other dermatology indications, notably with anti-VEGF compound.

- **GI inflammation**

PoC in local treatment of rectum/anus area. Follow-up with oral (enteric coated) formulation for general IBD.

- **Acute inflammation**

PoC via intravenous administration in flares of known TNF-driven diseases. Follow-up with acute inflammatory diseases such as severe asthma exacerbations, acute kidney injury or others.

Current Partnering Opportunities

- **Cartilage inflammation**

Phase 1b study of DLX105 administered via intra-articular injections in the knee of osteoarthritis patients.

Excellent safety and favorable pharmacokinetics demonstrated.

Delenex is open for partnerships to set up Phase 2 trials in OA.

- **CNS**

PK and PD have been demonstrated in rodents

1. *Furrer, E., Hulmann, V., Urech, D.M. (2009) Intranasal delivery of ESBA105, a TNF-alpha-inhibitory scFv antibody fragment to the brain. J. Neuroimmunol Oct 30;215(1-2):65-72.*
2. *Cattepoel S, Hanenberg M, Kulic L, Nitsch RM (2011) Chronic Intranasal Treatment with an Anti-A β ₃₀₋₄₂ scFv Antibody Ameliorates Amyloid Pathology in a Transgenic Mouse Model of Alzheimer's Disease. PLoS ONE 6(4): e18296. doi:10.1371/journal.pone.0018296*

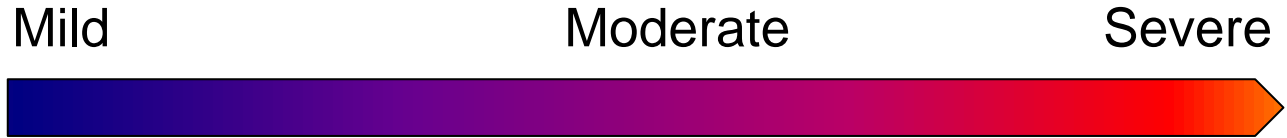
Delenex is looking for a partner to translate these findings to the clinic.

Clinical Projects

Psoriasis Development Plans for DLX105

- **PD study in psoriasis patients (Phase 1b)**
To demonstrate safety and show a clinical effect in a short-duration intradermal injection trial.
- **Topical formulation**
To discover a topical formulation of DLX105 with the appropriate skin penetration properties.
- **Topical proof of concept (Phase 2a)**
To demonstrate clinical effectiveness in psoriasis for the chosen topical formulation of DLX105.

DLX105 Positioning in Plaque Psoriasis



Mild

Moderate

Severe

Mildly effective, chronic use limited by tolerance/side effects

Topicals
anti-itching, moisturizers, keratolytics, tar-based, corticosteroids, vit. A derivatives, vit. D derivatives

Mildly effective, impractical as chronic therapy

Phototherapy
UVA, PUVA, UVB

Very effective, use limited by high cost and rare but severe side effects

Medical Need
A therapy that would be topical, safe, and effective

Systemics
Retinoids, cyclosporin, methotrexate, anti-TNF, anti-Tcell, anti-IL12/23

IBD Development Plan

- **Pre-clinical PK study**
To show mucosal penetration of our gel formulation in rodents.
- **Topical proof of concept**
To show clinical effectiveness in a rectal gel formulation.
- **Oral formulation development**
To develop an enteric-coated formulation suitable for oral dosing of the PENTRA® antibody.
- **Oral proof of concept**
To show clinical effectiveness for the broader population of IBD patients.

- **Intravenous proof of concept**
To show clinical effectiveness in an 'inflammatory flare' indication.
- As soon as PoC is obtained with the i.v. formulation, a subcutaneous formulation project and/or follow-up trials in other indications will be decided upon.

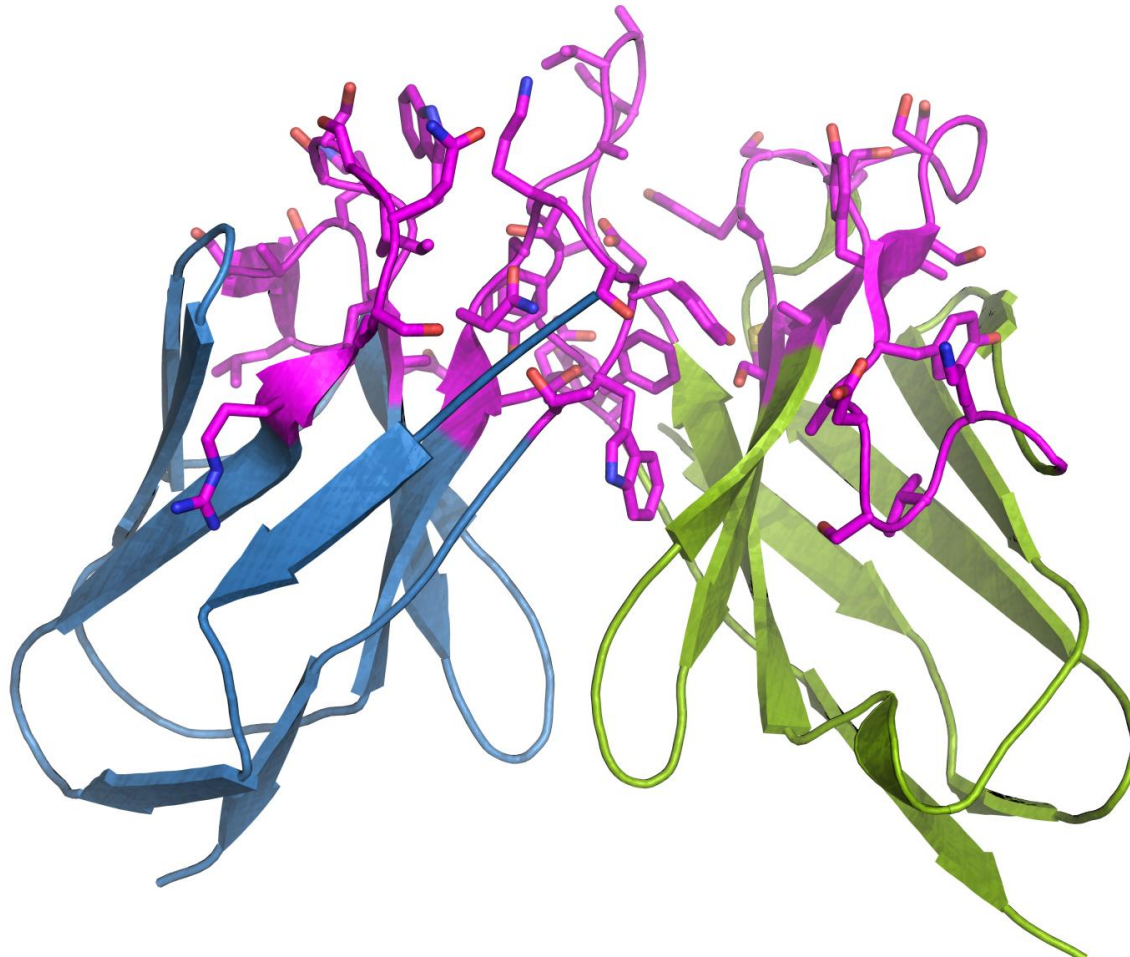
NOAEL in rhesus monkeys (intravenous administration) has been measured at 22.5 mg/kg/day. This supports the concept of exposing patients to high doses for a short time.

Technology Platform:

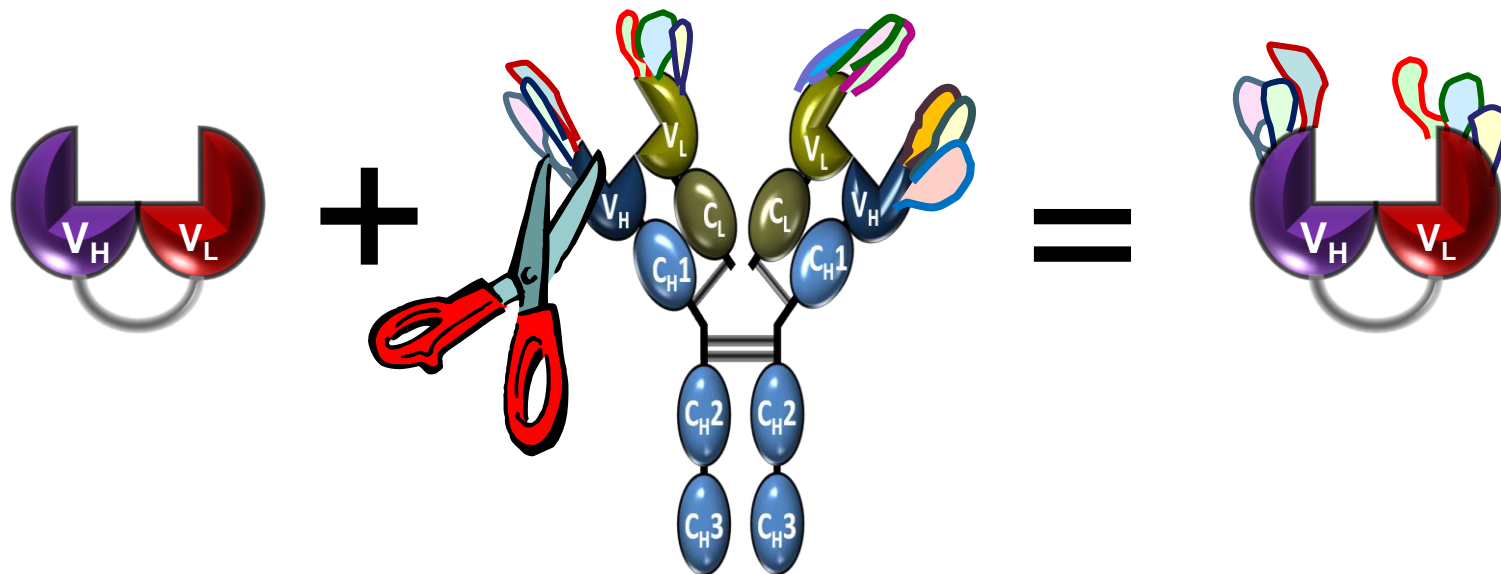
PENTRA® antibodies have unique properties that maximize drug-likeness and tissue penetration

PENTRA[®] Technology Platform

CDRs magenta
V_L blue
V_H green



Scaffold + CDRs = Drug Candidate



PENTRA® scaffolds

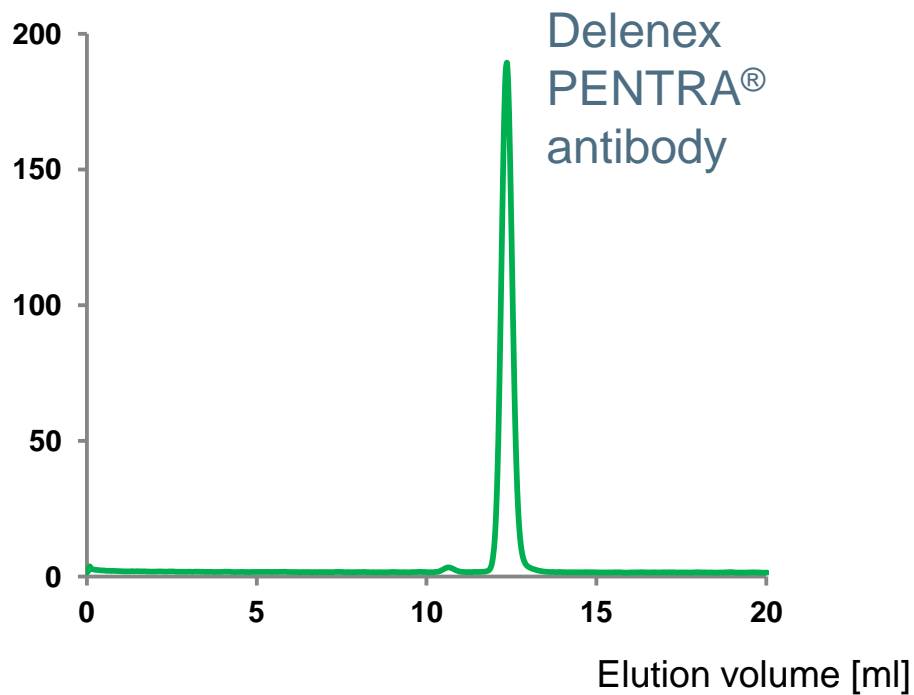
**CDRs from
standard antibodies
(human or animal)**

**Genetic grafting
of CDRs provides
lead compound**

→ Excellent Stability

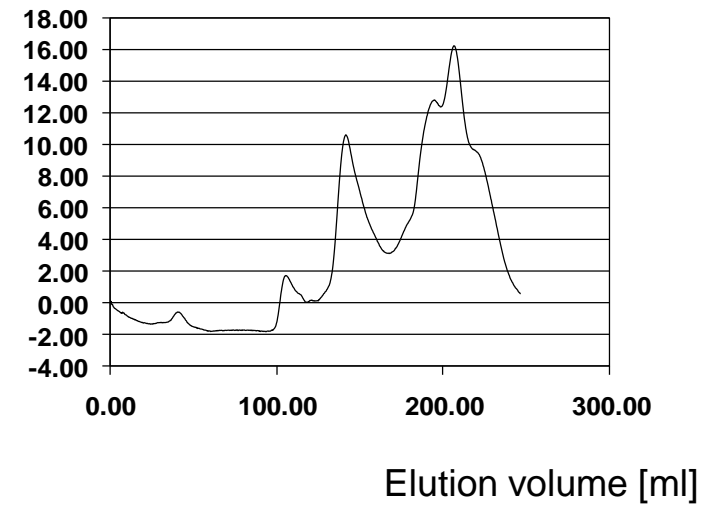
Comparable analytics performed via size-exclusion chromatography

Absorbance 280 nm [mAU]



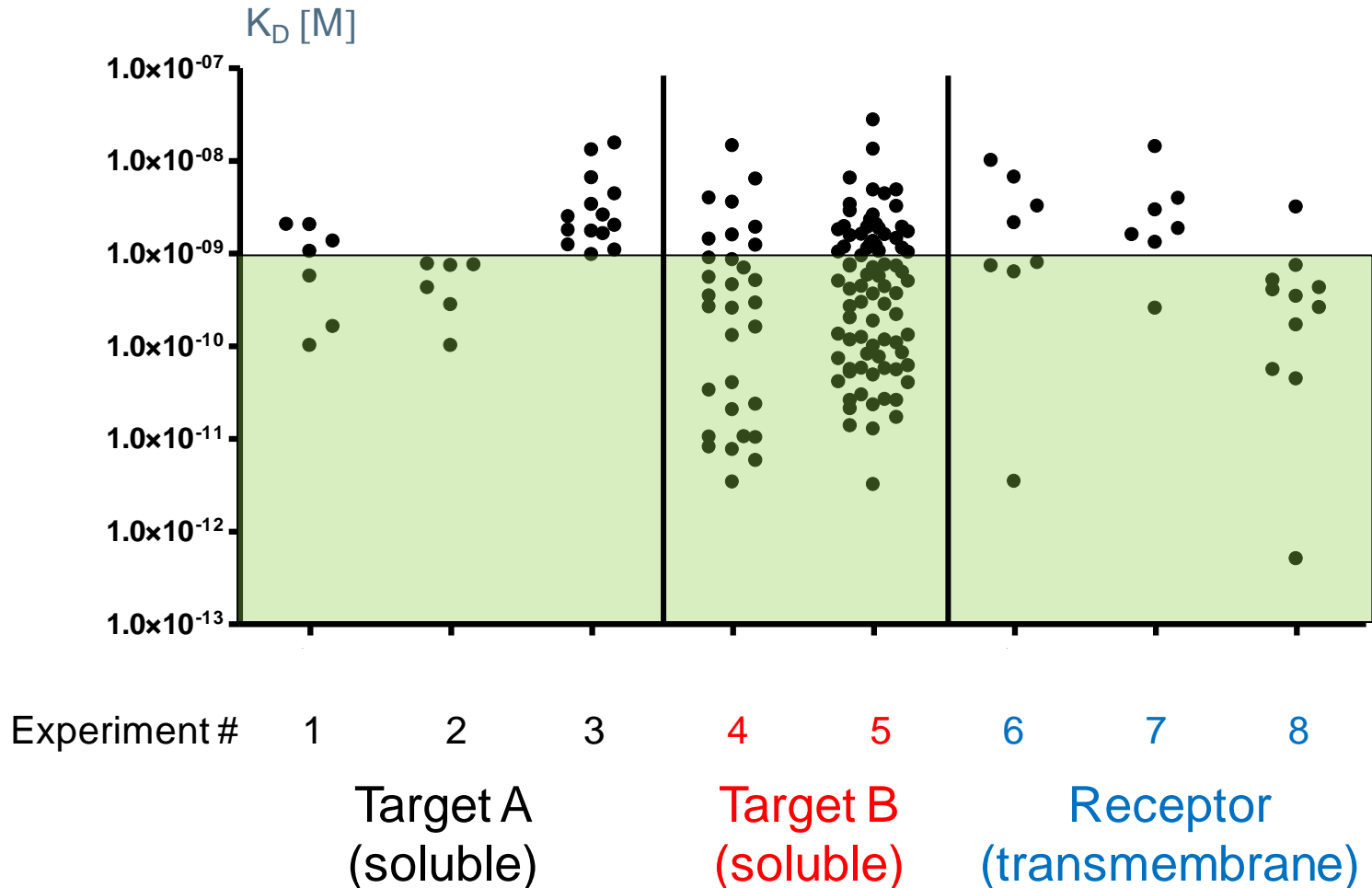
[mAU]

“Standard” scFv



→ Excellent Monovalent Affinities

Each dot represents one candidate PENTRA[®] antibody raised against the target



More Examples

scFv	K_D [M]	Relative Potency (EC_{50} Control / EC_{50} scFv)	Thermal Stability
anti-VEGF			
511	5.7×10^{-10}	0.6	72-86°C
578	3.9×10^{-11}	1.7	76-81°C
anti-TNF α			
34	$< 1.8 \times 10^{-12}$	5.7	77-82°C
43	1.0×10^{-10}	3.8	66-69°C

Adapted from Borrás L et al. J Biol Chem 2010, 285(12):9054-66

Conclusion

An Experienced Management Team



CEO Eric de La Fortelle, PhD, MBA

- 10 years research in protein structure determination (Paris XI, BMC Sweden, MRC UK)
- 12 years leading pharma/biotech deal teams (SGX Pharmaceuticals, Roche)
- Previous position: global head, external research and technologies, Roche



CMO Thomas Jung, MD

- Board-certified dermatologist
- 10 years immunology research experience (DNAX, U. Göttingen, Novartis Research Institute, Vienna)
- 9 years development experience (Novartis, Basel)
- Previous position: head translational medicine EU, Novartis



CSO Titus Kretzschmar, PhD

- 20 years experience in novel antibody discovery, protein evolution and leadership of scientific organizations (Ciba-Geigy, Novo Nordisk, MorphoSys, Lonza/ex-amaxa)
- Previous position, CSO and head of the Lonza initiative for future technologies



CFO Jakob Schlapbach, lic. rer. pol., MBA

- 18 years experience as CFO of public and private companies (Ascom, Cytos Biotechnology)
- Previous position, CFO of Cytos Biotechnology

Strong Intellectual Property

5 layers of IP protection, 9 patents granted.

- **Layer 1**: composition of matter IP on compounds against TNF α , VEGF-A, ALK, Amyloid β + RabTor framework. 2 patents granted, 3 patent applications.
- **Layer 2**: supplementary IP on all key elements of its PENTRA[®] platform. 2 patents granted, 2 patent applications.
- **Layer 3**: additional IP on other elements of the PENTRA[®] platform. 1 patent granted, 2 patent applications.
- **Layer 4**: key IP outside Delenex' core business. 2 patents granted, 4 patent applications.
- **Layer 5**: IP providing additional protection and FTO. 2 patents granted.

Outlook: Business Development / Partnering

- Series A round financing recently closed (CHF 30.2 Mio, May 3 2011)
 - Clinical development of PENTRA[®] therapeutic antibodies with focus on
 - (i) dermatology
 - (ii) gastro-intestinal disease
 - (iii) and acute inflammatory eventsPoC expected by end 2012
 - Phase 2-ready osteoarthritis project available for partnering
 - Developments in the CNS area are open for a research partnership with option to license
-

PENTRA® Antibodies ...

- **... aim at underserved markets**
 - Highly efficacious topical treatments
 - Acute diseases
- **... cannot be easily imitated**
 - Significant improvements on traditional scFv format
 - Large IP estate
- **... will yield clinical results in 2012**
 - Psoriasis
 - IBD
 - Acute inflammation



Changing the Game in Immuno-Inflammation

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