

P.L.E.A.S.E.®

Skin matters

BioPharm America Partnering Conference, September 08, 2011




pantec
biosolutions

Disclaimer

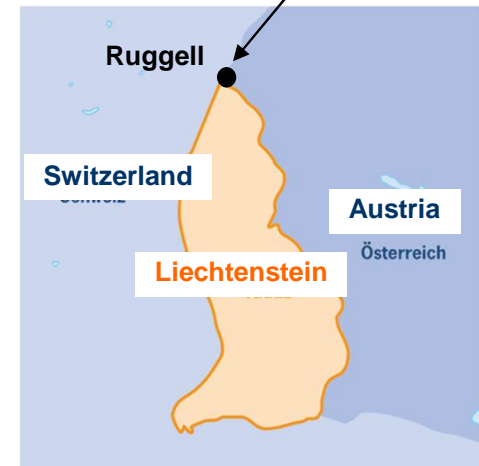
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About Pantec Biosolutions – a Specialty Pharma/Medtech Company

Location	Pantec Biosolutions AG Privately-owned Ruggell, Liechtenstein
Foundation	2005
Products	P.L.E.A.S.E.® Professional for dermatology applications P.L.E.A.S.E.® IVF (Hormone patches for IVF therapy in combination with P.L.E.A.S.E.®)
Employees	20 FTEs within Pantec, 10 FTEs in strategic partnerships



The P.L.E.A.S.E.® Platform:

- ✦ The P.L.E.A.S.E.® platform is based on Pantec's proprietary diode-pumped laser technology, forming compact and powerful class 1 laser devices.
- ✦ P.L.E.A.S.E.® stands for Precise Laser EpidermAI SystEm
- ✦ Painless, needle-free intraepidermal drug delivery system
- ✦ P.L.E.A.S.E.® can be used for:
 - Therapeutic skin treatment => target aesthetic and medical dermatology
 - Therapeutic proteins and small organics => target dermatology
 - Therapeutic peptides and proteins => first target infertility
 - Therapeutic proteins and antibodies => target immunology

Intraepidermal Delivery with P.L.E.A.S.E.®

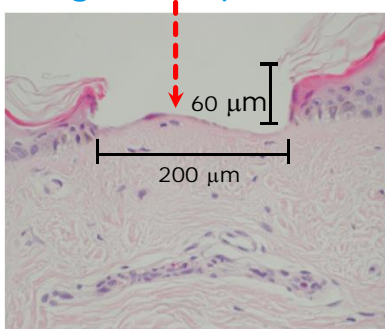
Delivery of large drug molecules using a hand-held laser device combined with an optimized patch formulation

- # Precise, reliable and painless drug delivery
- # Simple convenient use by patient or professional
- # Tailored and flexible dosing by variation of pore numbers
- # Accurate dose delivery or removal of drug
- # Independent of individual skin condition

Laser for skin microporation



Target compartment



Drug patch onto microporated skin

One P.L.E.A.S.E.® Platform - two Devices

P.L.E.A.S.E.® Private

For IVF therapy and other applications

- Device for use at home, class 1 laser
- Easy to use by patients
- First generation has CE-mark



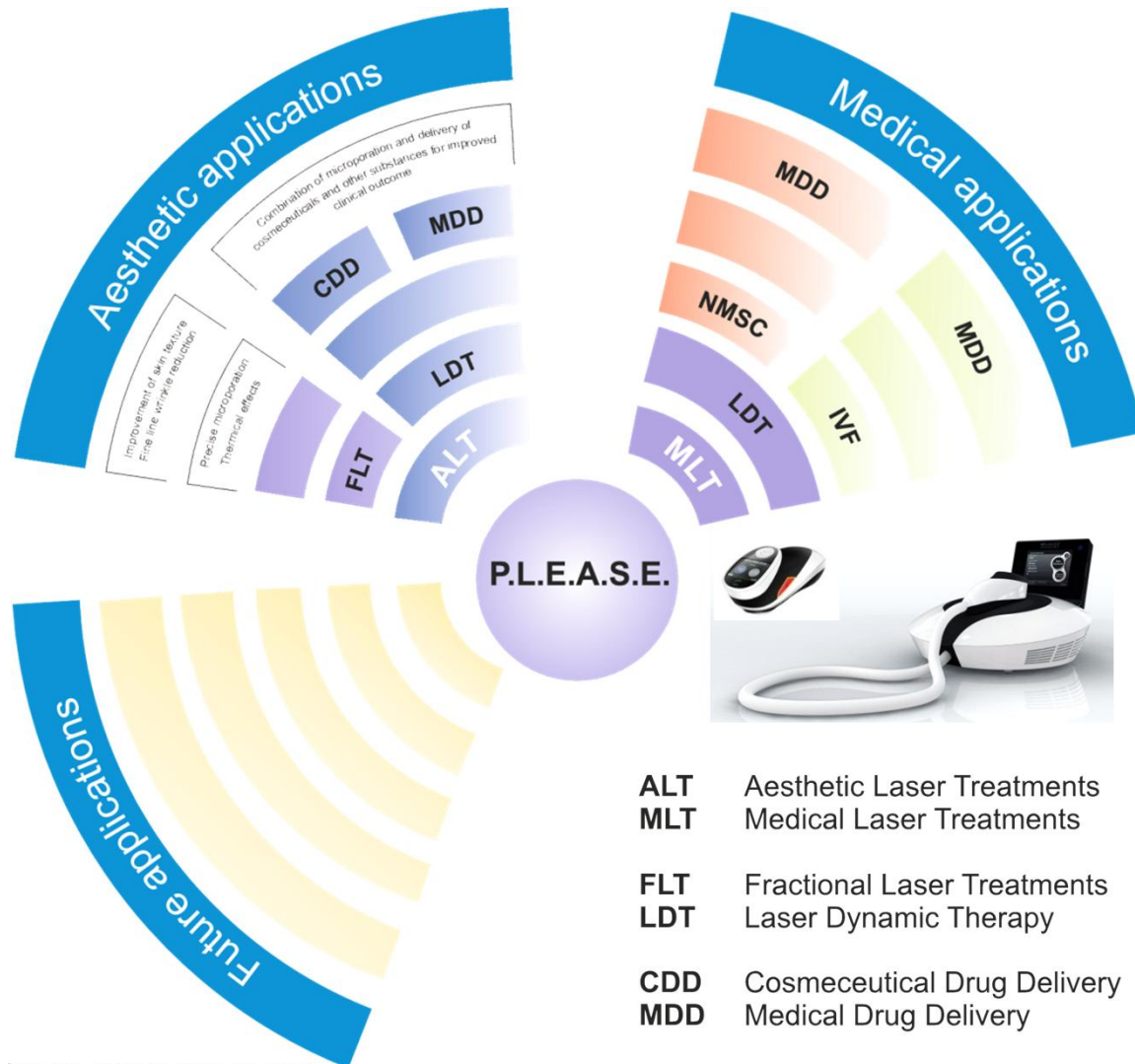
P.L.E.A.S.E.® Professional

For medical and aesthetic dermatology

- Device for medical professionals, class 1 laser
- Can run all day
- Multipurpose dermatology device
- CE-marked
- Market launch started



The P.L.E.A.S.E.® Universe – Next Level Therapies

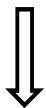


The P.L.E.A.S.E.[®] Universe - From Drug Delivery to Dermatology Applications

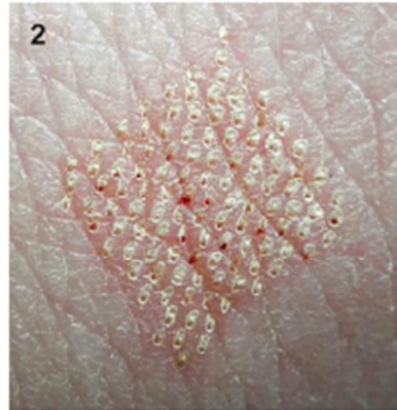
P.L.E.A.S.E.[®] Professional – variety of parameter settings



1
short pulses, low energy density per pulse



Drug delivery applications



2
longer pulses, high energy per pulse, pulse stacking



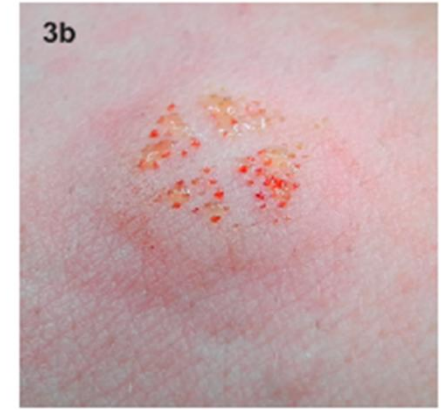
Dermatology applications



3a
longer pulses, higher energy per pulse, higher pulse stacking



Diagnostics applications



3b
immediately after no carbonization

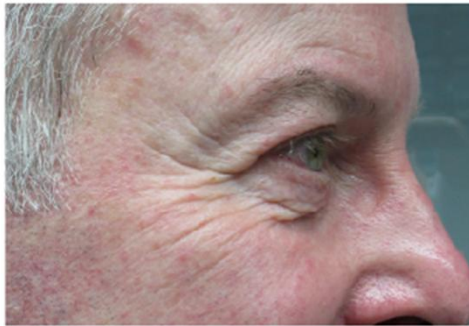


Immunology applications

Dermatology Applications with P.L.E.A.S.E.®

Aesthetic Dermatology Applications

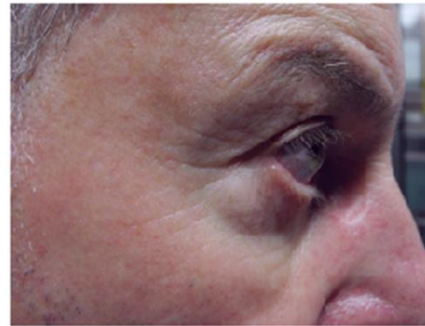
P.L.E.A.S.E.® Professional Mild parameter setting for fractional skin resurfacing



Before



Immediately after
fractional ablation



3 months after
one single treatment

- Appearance of wrinkles is greatly reduced
- Skin texture and structure is improved
- Skin color tonality is even and skin looks fresh and homogenous
- Very pleasing results after only one treatment with less than 5 days downtime
- Neo-Collagenesis is't fully active yet. Results should further improve after > 3 months

Successful treatment of scars (keloids)



beginning of a possible
keloid formation



controlled microporation with
P.L.E.A.S.E. Professional

application of only one drop low
molecular hyaluronic acid followed
by ~ 8 hour total occlusion covered
with „Tegaderm“



a few days later



more than two months later

Laser Treatment of Topical Non-Melanoma Skin Cancer

Old treatment strategy

Several weeks to months of daily cream application => low compliance

Actinic keratosis

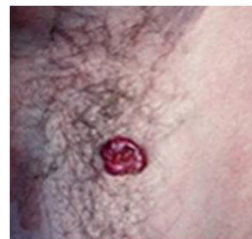


Topical
imiquimod
cream

Basal cell
carcinoma

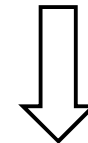


Topical
imiquimod
cream



New treatment strategy

P.L.E.A.S.E.[®] treatment plus cream application, goal 1-2 weeks to healing

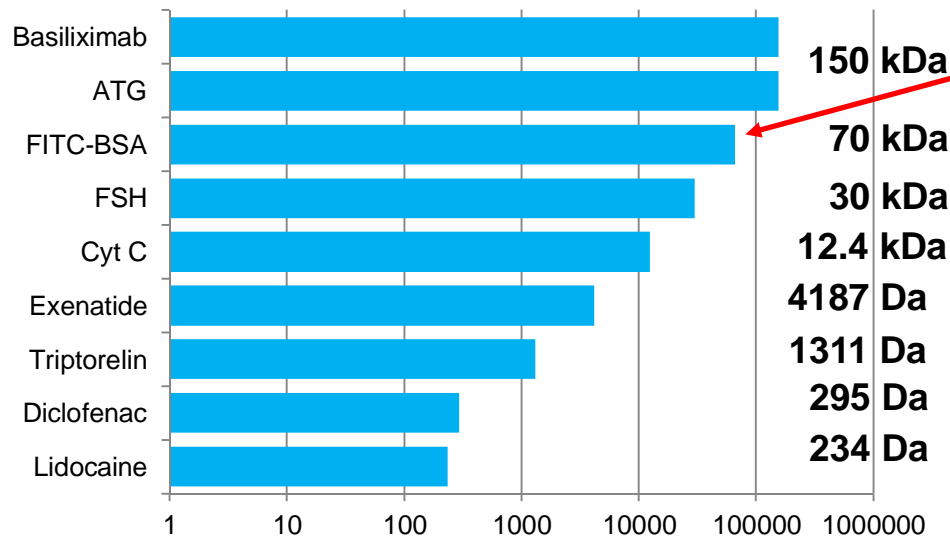


Topical
imiquimod
cream

Drug Delivery Applications with P.L.E.A.S.E.®

Delivery of Drugs with High Molecular Weight

- ✦ P.L.E.A.S.E.® can deliver drugs up to a molecule weight of 150 kDalton
- ✦ The system demonstrated intraepidermal delivery of small organic molecules, peptides, proteins and functional antibodies *in vitro*



Delivery of large proteins feasible in the range of milligrams

Status PBS pipeline

Name	Category	Drug	Preclinical	Phase 0	Phase I	Phase II	Phase III	Reg.	On the market
P.L.E.A.S.E. Professional	Medical device	none	market launch preparations						
P.L.E.A.S.E. Professional NMSC	Medical device + branded procedure	Imiquimod	own programme						
P.L.E.A.S.E. IVF001	Medical Device + New Drug	Triptorelin	own programme						
P.L.E.A.S.E. IVF002	Medical Device + New Drug	FSH	own programme with partnered API						
P.L.E.A.S.E. IT	Medical device + New Allergen	Allergen	partnered						
P.L.E.A.S.E. RNAi	Medical device + New Drug	RNAi	partnered						
P.L.E.A.S.E. Diclofenac/lidocaine	Medical device + branded procedure	Diclofenac Lidocaine	own						

- ✦ P.L.E.A.S.E. Professional: Full focus on market launch (Aesthetic dermatology)
- ✦ P.L.E.A.S.E. NMSC: Basic proof of concept for Actinic Keratosis shown
- ✦ P.L.E.A.S.E. IVF: Follicle growth shown through patch and first pregnancy achieved
- ✦ P.L.E.A.S.E. IT: Immunotherapy proof of concept shown in mouse asthma allergy model (partnered)
- ✦ P.L.E.A.S.E. RNAi: Delivery shown in human skin and uptake into fibroblasts achieved (partnered)

Global *In Vitro* Fertilization (IVF) Market

A premium product \$2 billion market with 5-10% annual growth depending on cumbersome and painful injections of infertility drugs

- ✦ Currently, injections are used for IVF
- ✦ 1 to 2 months of daily self-administration of drugs



Pantec's market research:

- ✦ ~80% of IVF patients have negative feelings about injections and their frequency
- ✦ Overwhelming proportion of patients would welcome P.L.E.A.S.E.® based delivery:
 - 73.2% "very probable"
 - 15.5% "probable"
 - 11.3 % "it depends"

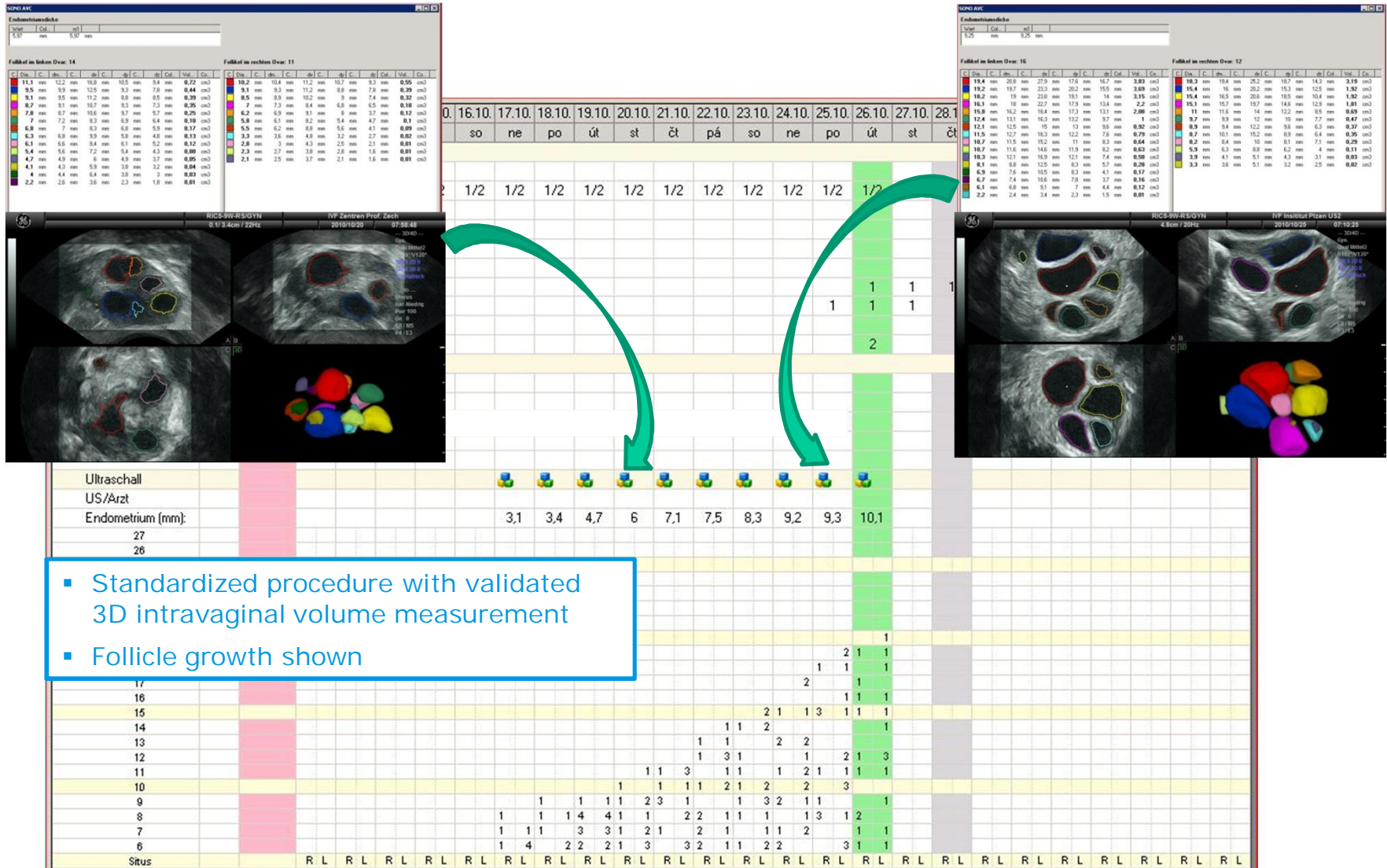
Pantec Biosolutions' Novel IVF Drug Products

Painless, Safe and Accurate Application Using P.L.E.A.S.E.®

Product	Indication	Clinical Status
IVF001 Triptorelin patch	Infertility (IVF) Downregulation prior to stimulation	Phase I completed <ul style="list-style-type: none"> ▪ Demonstrated safety, bioavailability, tolerability endpoints
IVF002 Follicle Stimulating Hormone	Infertility (IVF) Stimulation of follicle growth	Phase II ongoing, exploratory proof-of-concept successful <ul style="list-style-type: none"> ▪ Demonstrated follicle stimulation ▪ First pregnancy achieved

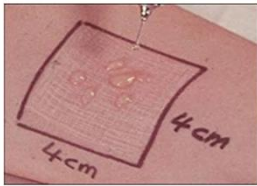


Successful Follicle Stimulation with IVF002



- Standardized procedure with validated 3D intravaginal volume measurement
- Follicle growth shown

P.L.E.A.S.E. Immunotherapy - animal proof of concept



- Blamoutier (1959): specific immunotherapy by epicutaneous application of allergen extract after scarification of the skin
- Clinical study of epicutaneous immunotherapy using tape stripping and vaseline patches (Senti et al., 2009. JACI 124(5), 997-1002.)

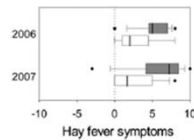
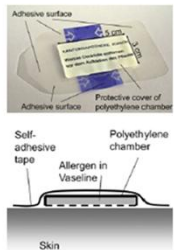
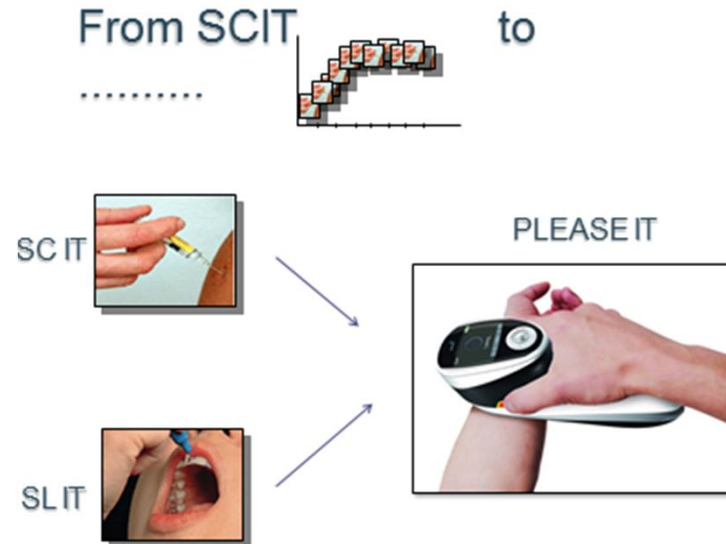


FIG 5. Patient-recorded hay fever symptoms. Patients compared symptom severity during seasons 2006 and 2007 (posttreatment) with 2005 (pretreatment) and recorded scores between -10 (worst possible deterioration) and +10 (best possible improvement). Patients receiving verum (filled boxes) reported better improvement than placebo patients (open boxes; 2006, $P = .02$; 2007, $P = .009$). Box plots show median; 10th, 25th, 75th, and 90th percentiles; and outliers.



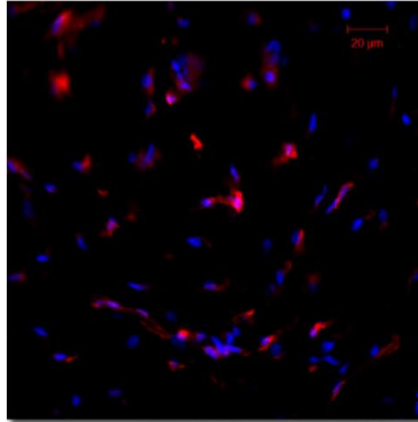
Mouse model of allergic asthma (rec. grass pollen) n=18 in 3 groups: control, 6 injections SCIT, 6 P.L.E.A.S.E. treatments

Results

- Transcutaneous Immunotherapy via P.L.E.A.S.E. generated micropores equals SIT in efficacy
- Transcutaneous Immunotherapy induces a different systemic immune profile than SCIT
- P.L.E.A.S.E. IT induces a decrease of pro-inflammatory cytokines
- SCIT induces an unwanted boost of Th2 cells

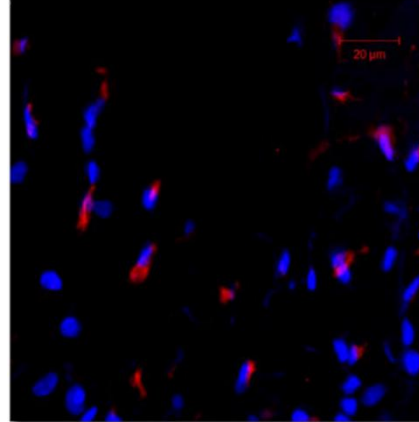
P.L.E.A.S.E. sd-rxRNA™ - delivery into cells shown

sd-rxRNA™ = novel, small asymmetric, hydrophobically modified RNAi compound developed by RXi Pharmaceuticals

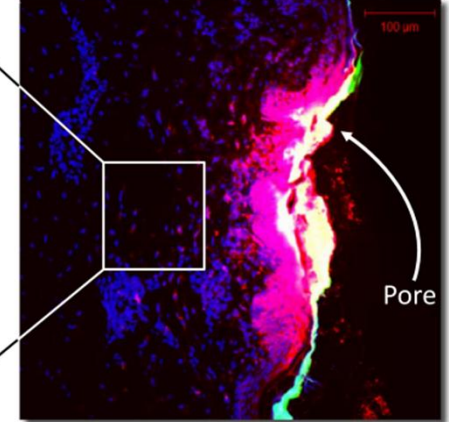


©2011 - I. Alberti - Study 6 - 5B(4) - Injected (2D-3x of 5B3)

Pig skin ex vivo, fibroblast transfection following ID injection



©2011 - I. Alberti - Study 6 - 3B(7) - Porated 5-250 (2D-3x of 3B5)



©2011 - I. Alberti - Study 6 - 3B(5)-Pored5-250(2D)

Evidence of dermal fibroblast transfection in P.L.E.A.S.E. microperated pig skin

Skin scar keloids: dermal fibrosis due to excessive expression of a protein, CTGF (connective tissue growth factor)

- Positive in vivo tests, sd-rxRNA™ uptake and gene silencing achieved by partner company
- Limitation: sd-rxRNA™ must currently be injected into scars
- P.L.E.A.S.E. is a less invasive method of delivery
- US potential market: up to \$4 billion

Conclusions - in vitro skin

- There is qualitative evidence for dermal siRNA delivery following skin microporation
- Cellular transfection patterns appear comparable to those obtained by ID injection

⇒ **Basic proof of concept shown**

Summary and Partnering Strategy

- ✦ Pantec dispatches P.L.E.A.S.E.® Professional directly or to partners for dermatology applications (conventional and aesthetic)
 - Distribution agreements for P.L.E.A.S.E.® Professional device in progress

- ✦ Pantec develops its product portfolio for the core indication of IVF
 - Proof-of-concept: achieving therapeutic levels with triptorelin and FSH; follicle growth and first pregnancy achieved from stable FSH (32kDa) patch
 - Co-development / co-marketing deals in our core indication

- ✦ Pantec partners P.L.E.A.S.E.® with companies with small molecule, peptide or protein-based products to address unmet medical needs (i.e. immunology, immunosuppression, allergy vaccines and orphan diseases)
 - Partnering includes out-licensing for our non-core indications

Pantec Biosolutions - Skin matters

Contact Information



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