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21-23 May, 2019 | Frankfurt, Germany
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Dermatology Drug Development Summit *Europe*

Innovating & Accelerating the Development & Commercialisation of Dermatology Drugs

20 Expert Speakers Including:



Lee Heeson
President for
Worldwide
Markets,
Inflammation &
Immunology
**Celgene
Corporation**



Tita Ritsema
Vice President of
Dermatology
**ProQR
Therapeutics**



Dhaval Patel
Executive Vice
President & CSO
UCB



Elena Rizova
Vice President &
Head of Medical
Affairs, Immuno
Inflammation
Sanofi



Ernst Kriehuber
Vice President
- Translational
Sciences
**Glenmark
Pharmaceuticals**

Partners:



Welcome to Dermatology Drug Development Summit Europe

Enhancing development efforts and bringing better and more efficient dermatological medicines to market

The dermatology space continues to undergo huge therapeutic innovation, driven by a transformative evolution in the understanding of the pathophysiology of skin diseases, as well as in the available treatment options for chronic, moderate to severe dermatological conditions and high unmet need that affects the lives of millions of patients worldwide.

The Dermatology Drug Development Series is a unique industry-focused, dedicated discussion and networking forum committed to **addressing the key challenges and advances in dermatology drug development and commercialisation.**

Following two successful editions in Boston, this series now makes its debut in Europe, to provide the European dermatology community with a unique end-to-end platform to discuss and learn about the latest insights on **how to accelerate preclinical and translational research, clinical development, approval and commercial activities of dermatological therapeutics.**

Join your peers and hear from a faculty of expert leaders including Sanofi, LEO Pharma and UCB, who will be sharing their learning and latest case-studies. You'll leave this meeting with the knowledge and connections to successfully advance your work in dermatology drug development at your own organisation.

What previous attendees have said about meetings in this series

💧💧 All of the speakers did a great job. This was a really good conference – both size-wise and the quality of attendees 💧💧

Immune Pharmaceuticals

💧💧 I was able to get something out of each presentation. It was a total success in my opinion 💧💧

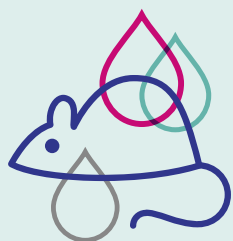
GlaxoSmithKline

💧💧 A very good meeting in terms of presentation topics, interactive workshop, and networking 💧💧

Celgene



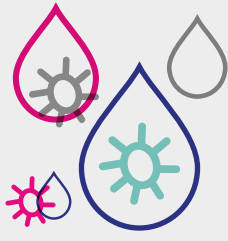
Key Highlights You Cannot Miss



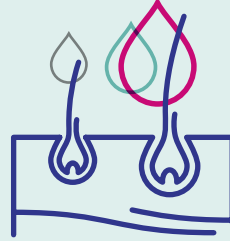
Glenmark Pharmaceuticals and **LEO Pharma** explore key translational challenges in dermatology, including *in-vitro* systems and animal models.



Kymab and **Temesis Therapeutics** share their experience with new target development in atopic dermatitis and psoriasis, respectively.



ProQR Therapeutics and **University of Modena and Reggio Emilia** address the development of innovative treatments targeting dermatological rare diseases.



Sanofi, Celgene and **Galderma** discuss the current landscape in dermatology drug development, including the latest biologic approaches, unmet needs, value demonstration and commercial hurdles.



Sol-Gel Technologies, Sienna Biopharmaceuticals and **Botanix Pharmaceuticals** share their latest advances into topical development and formulation approaches.

Expert Speaker Faculty



Anton Stuetz
Founder & CEO
Pharma R&D Consulting Stuetz GmbH & Akribes Biomedical GmbH



Betsy Hughes-Formella
Independent Consultant
Dermatology Drug Development



Bill Bosch
Executive Director & CSO
Botanix Pharmaceuticals



Carlo Pincelli
Professor of Dermatology
University of Modena and Reggio Emilia
& CEO
PinCell



Dhaval Patel
Executive Vice President & CSO
UCB



Dogan Fidan
Head of Global Strategic Franchise, Immunology & Inflammation
Galderma



Elena Rizova
Vice President & Head of Medical Affairs
Immuno Inflammation
Sanofi



Ernst Kriehuber
Vice President - Translational Sciences
Glenmark Pharmaceuticals



Felicitas Thom
Director, Project Management in Autoimmunity, Transplantation & Inflammation
NIBR



Jakob Felding
Director, Skin Research
LEO Pharma A/S



Jean-Francois Ginglinger
CSO
Temisis



Kendall Marcus
Director, Division of Dermatology & Dental Products
FDA



Lee Heeson
President - Worldwide Markets, Inflammation & Immunology
Celgene Corporation



Marc Brown
Co-Founder & CSO
MedPharm



Ofer Toledano
Vice President, R&D
Sol-Gel Technologies



Paul Lizzul
CMO
Sienna Biopharmaceuticals



Rasmus Hogrefe
Head of Virtual Clinical Trials
LEO Innovation Lab



Robert Rissmann
Research Director Dermatology
Center for Human Drug Research



Silvio Traversa
CSO
Sienna Biopharmaceuticals



Sonia Quaratino
CMO
Kymab



Tita Ritsema
Vice President of Dermatology
ProQR Therapeutics

Conference Day One

Wednesday, 22 May

	9.00 Chair's Opening Remarks	
 Dhaval Patel UCB	9.15 Opening Keynote Panel Discussion: What's Next in Dermatology Drug Development? - Establishing the current therapeutic landscape and state-of-the-art in dermatology drug development – latest advances and challenges - Lessons learned for rational and effective drug development in dermatology – discussing a 'blueprint' of what success looks like in dermatology drug development - Analysing the end-to-end pain points that accompany dermatology programmes – from improving preclinical translation, to tackling late regulatory and commercial challenges - Where's dermatology going? – new indication, new targets, the next antibodies - Identifying and addressing unmet needs – defining the strategic driver for companies involved in drug development for rare and orphan dermatological diseases or moderate skin conditions (vs. standard of care) - Driving precision medicine approaches in dermatology	
 Ernst Kriehuber Glenmark Pharmaceuticals		
 Silvio Traversa Sienna Biopharmaceuticals		
 Tita Ritsema ProQR Therapeutics		
Enhancing Discovery, Preclinical Development & Translational Research in Dermatology		
Ernst Kriehuber Vice President – Translational Sciences Glenmark Pharmaceuticals	9.45 Translational Data to Guide Clinical Development & Target Discovery - Human disease derived data are discussed vis a vis <i>in-vitro</i> model systems and animal models - Examples are provided from GBR 830 program, an OX40/OX40L pathway blocking antibody in Ph2b development in Atopic Dermatitis	
	10.15 Speed Networking Session	
	10.45 Morning Refreshments	
Jakob Felding Director, Skin Research LEO Pharma A/S	11.15 Application of a Translational <i>in-Vitro</i> Assay Platform for Selection of a Highly Selective JAK1 Inhibitor - Establishing the importance of JAK1 selectivity in drug candidates for oral administration versus topical administration - Exploring <i>in-vitro</i> screening platform to address the JAK kinase selectivity - Supporting the identification of a clinical candidate by pre-clinical profiling of a highly selective JAK1 inhibitor	
Sonia Quaratino CMO Kymab	11.45 OX40L: A New Target in the Treatment of Dermatological Diseases? - Giving background on OX40L in autoimmune diseases - Introducing KY1005, a novel fully human anti-OX40L blocking antibody and preclinical data supporting the MOA - Exploring the scientific rationale for targeting OX40L in atopic dermatitis	
	12.15 Lunch & Networking	
Carlo Pincelli Professor of Dermatology University of Modena and Reggio Emilia & CEO PinCell	13.15 Addressing The Medical Need for Pemphigus: A New Biologic - Addressing the need for reliable models of complex diseases - Exploring challenges in translating pathway targets to precise human efficacy - Defining a better translatability approach for accelerating the drug development process and adding value to the project - Providing regulatory agents and investors with more appealing approaches	

Jean-Francois Ginglinger CSO Temisis	13.45 TEM1657 – A Novel Small Molecule Approach Targeting Psoriasis - Describing TEM1657, a novel small molecule asset showing unrivalled efficacy to reduce psoriasis symptoms in IMQ animal model - Analysing TEM1657's MOA – regulation of a key player in the IL-17 signalling pathway in keratinocytes - Exploring next steps into clinical trials
Advancing the Clinical Development of Dermatological Therapeutics	
Tita Ritsema Vice President of Dermatology ProQR Therapeutics	14.15 Treating Epidermolysis Bullosa by Removing Mutations from the RNA - Developing a treatment for recessive dystrophic epidermolysis bullosa (RDEB) - Translating <i>in-vitro</i> data to an easy to use therapy - Harnessing exon skipping AON's to treat skin diseases
	14.45 Afternoon Refreshments & Networking
Kendall Marcus Director, Division of Dermatology & Dental Products FDA	15.15 Regulatory Perspectives on Dermatology Drug Development More information to be provided soon
*Remote presentation & discussion	15.45 Dedicated Q&A Session
Paul Lizzul CMO Sienna Biopharmaceuticals	16.00 Bridging the Innovation Gap in the Treatment of Mild to Moderate Dermatological Diseases - Addressing the unmet need in topical drug development towards a large patient population with mild to moderate dermatological diseases, still primarily using topical steroids - Updating on SNA-120 (TrkA inhibitor) – SNA-120, a novel approach to the treatment of psoriasis, targeting NGF/TrkA and neurogenic inflammation - The important role of nerves & neuropeptides in psoriasis - Itch as a proxy clinical biomarker for high NGF/TrkA expression in psoriasis - A novel non-steroidal approach in the treatment of psoriasis and associated itch targeting the NGF/TrkA pathway
Felicitas Thom Director, Project Management in Autoimmunity, Transplantation & Inflammation NIBR	16.30 Innovative Trial Design to Determine Early Efficacy of Drugs in Translational Medicine at Novartis - Exploring different study designs for proof of concept studies in Dermatology (examples from clinical studies in Acne, Atopic Dermatitis, Hidradenitis suppurativa) - Addressing considerations of scientific aspects in drug development under various operational models - Identifying factors influencing operational setup and recruitment
Rasmus Hogrefe Head of Virtual Clinical Trials LEO Innovation Lab	17.00 Digitisation of Dermatology - Is It Happening? - Digital patient tools in dermatology - Exploring telemedicine and the fit in dermatology - Digitalisation of Clinical Trials in dermatology - Real-world data in Clinical trials gathered from digital tools
	17.30 Chair's Closing Remarks

Conference Day Two

Thursday, 23 May

The Current Landscape in Dermatology Drug Development

8.50 Chair's Opening Remarks

Elena Rizova
Vice President &
Head of Medical
Affairs Immuno
Inflammation
Sanofi

9.00 Overviewing The Latest Advances in Biologic Therapies in Dermatology

- Biologics in dermatology – when did it start?
- Exploring lessons learnt on the introduction of these therapeutics in the treatment paradigm of psoriasis and atopic dermatitis
- What is the path forward? – considerations on what the next generation of biologics look like and exploring further indications

Lee Heeson
President –
Worldwide Markets,
Inflammation &
Immunology
Celgene Corporation

9.45 Begin with the End in Mind

- Making choices – assessing the unmet needs across dermatology
- Understanding the future dermatology pricing and reimbursement dynamics in Europe
- Demonstrating clinical value against outdated regulatory endpoints – growing utility of Real World Evidence (payers and clinicians)

10.15 Morning Refreshments & Networking



Dogan Fidan
Galderma



Elena Rizova
Sanofi



Lee Heeson
Celgene Corporation

11.00 Panel Discussion: The Evolving Clinical, Regulatory & Commercial Paradigm in Dermatology



- Exploring how to overcome key challenges in dermatology clinical development
- Assessing the need for cooperation between regulators, payers and drug developers in the definition of appropriate endpoints in the development of dermatological therapies
- Supporting value-based evidence to external stakeholders – establishing the value of new therapies and effectively demonstrating improved outcomes
- Discussing the different payer requirements between Europe and US
- Navigating the challenges of a crowded development space



11.45 Mastermind Session: Supporting the Successful Development & Commercialisation of Dermatology Medicines



This session facilitates in-depth discussions among participants in an informal environment. After splitting into groups, participants will discuss key issues and common challenges regarding the current landscape of dermatology drug development.

12.30 Lunch & Networking

Developments in Topical Drug Development & Formulation Approaches

Ofer Toledano Vice President, R&D Sol-Gel Technologies	13.30 New Topical Drugs Having a Novel Silica-Based Delivery System • Overviewing Sol-gel's proprietary, silica-based microencapsulation technology platform - enhancing the tolerability and stability of topical drugs while maintaining their efficacy • Entrapping active ingredients in an inert, inorganic silica shell, creating an unnoticeable barrier between the active ingredient and the skin • Enabling the production of novel fixed-dose active ingredient combinations that otherwise would not be stable. • Discussing Sol-Gel's lead product candidate, TWIN, a novel, once-daily, topical cream containing encapsulated benzoyl peroxide and encapsulated tretinoin, for the treatment of acne vulgaris. • Demonstrating statistically significant improvements in all pre-defined co-primary and secondary efficacy endpoints, as compared to vehicle - overviewing the recently completed Phase II clinical trial designed to assess the safety and efficacy of TWIN in subjects with facial acne
Silvio Traversa CSO Sienna Biopharmaceuticals	14.00 The Topical-by-Design Technology - Defying Conventional Wisdom • Does size really matter? • Exploring an innovative way of using polymers • Bringing potent drugs to derm fruition, minimizing systemic exposure
Bill Bosch Executive Director & CSO Botanix Pharmaceuticals	14.30 Topical Formulations of Cannabidiol for the Treatment of Acne, Atopic Dermatitis, & Psoriasis • Novel formulation approaches to maximize delivery of the active ingredient • Discussion of multiple mechanisms of action for treating skin diseases • Update on clinical development
	15.00 Chair's Closing Remarks

■ Thanks for putting together a great conference! It was beneficial to bring together experts from academia, industry and health authorities ■

Sienna Biopharmaceuticals

Dermatology Drug Development Summit (Boston, 2018)

Pre-Conference Workshops

Tuesday, 21 May

Workshop A

Innovative Approaches to Early Clinical Development & Dose-Finding – Integration of PK-PD in Dermatology Drug Development

12.00-15.00

One of the biggest challenges in dermatological research today remains the development of meaningful methodologies to determine the rate and extent to which topically or systemically applied drugs reaches its site of action and engages its target in the skin.

In this workshop, learn how to make the most of early clinical development by integrating advances in techniques to quantitate dermal pharmacokinetics (PK) and pharmacodynamics (PD) measurements in model and patient settings and their role in dose finding.

Key topics to be discussed include:

- **Challenges with dermal PK – did the API reach the site of action?**
 - Stratum corneum (tape-stripping)
 - Epidermis (Raman spectroscopy)
 - Dermis (open flow microperfusion)
 - Transdermal (systemic absorption)
- **Challenge models in healthy volunteers**
 - Imiquimod
 - Wound healing after skin punch biopsies
 - Lipopolysaccharide intradermal and intravenous
 - UVB irradiation
 - Histamine
 - Capsaicin

- **Models in patients**
 - Psoriasis
 - Atopic dermatitis / contact dermatitis
 - Wound healing in ulcers, atopic dermatitis
 - Hidradenitis suppurativa, vitiligo, acne
- **The role of samples**
 - Biopsy
 - Skin surface
 - Non-invasive sampling: dry blood spot, swabs
- **Dose response relationship: Intended vs. unintended effects**
- **Toolbox**
 - Biochemistry (e.g. biomarkers in biopsy, non-invasive measurements)
 - Next generation biophysical measurements
 - Non-invasive imaging
 - Clinical assessments
 - Lipidomics
 - Patient reported assessments
 - Mobile apps

Join us in this interactive session that will bring **practical insights into the inclusion of PK and PD measurements and clinical models** in early clinical development programs, and how these can provide value and **de-risk clinical development** of dermatological drugs.



Betsy Hughes-Formella
Independent Consultant,
Dermatology Drug Development



Robert Rissman
Research Director, Dermatology
Center for Human Drug Research

Pre-Conference Workshops

Tuesday, 21 May

Workshop B

Looking Ahead – What Will Come Next in Dermatology R&D?

15.30-18.30

Within the past 10- 15 years, there has been an enormous progress in the treatment of psoriasis and atopic dermatitis. New, highly effective biologics have been registered since and new ones including small molecules like JAK inhibitors are coming up, which show promise also for the treatment of other immune-mediated skin diseases like alopecia areata and vitiligo.

However, **within the next 5 to 10 years, the number of registered and highly effective treatments for these diseases will be so high, that investments into new treatments of the same diseases or of the same classes of compounds/targets may not be considered commercially attractive any more.**

In view of encouraging forward-looking thinking on this matter, this session will aim at discussing what will come next in dermatology R&D – **are there other skin indications with high medical need and commercial attractiveness which deserve investment in future R&D?**

Key areas to be discussed include:

- Lessons learned during R&D of new therapies for treatment of skin diseases, from discovery to launch
- Options and challenges for the future in dermatology R&D (including insights in skin cancers like SCC and BCC, or chronic wounds)

- Is there high unmet medical need in dermatology beyond psoriasis and atopic dermatitis?
- New approaches in wound healing and tissue repair

Join this session and take part of an engaging discussion led by Prof. Anton Stuetz, an industry dermatology veteran and expert, and recipient of the 2011 award for Innovative Therapy of the Skin by the American Academy of Dermatology. You will also be able to hear and learn from esteemed colleagues and experts including:

- Dr. Barbara Wolff-Winiski, CSO and Co-CEO, **Akribes Biomedical GmbH**
- Prof. Georg Stingl, **Medical University of Vienna**
- Prof. Thomas Luger, **Munster University**

You will leave this workshop with information on unmet medical need, future R&D trends and approaches, which will help you support the success of the development work in your own organisation in the near future.



Anton Stuetz

Founder & CEO

Pharma R&D Consulting Stuetz GmbH & Akribes Biomedical GmbH

■ This was a great conference overall, well organised with educated speakers and relevant topics ■

FLX Bio

Dermatology Drug Development Summit (Boston, 2018)

Partners



Expertise Partner

MedPharm is the world leading specialist pharmaceutical development company, committed to

the creation and development of bespoke topical and transdermal formulations for application to the skin, nail, mucous membranes, eye, nose and lung. Alongside developing its own patented dermal drug delivery technologies, MedPharm uses its experience to support customers through regulatory approval previously resulting in biowaivers for generic submissions from regulatory authorities and marketing authorisations for over 60 products in the US and Europe.

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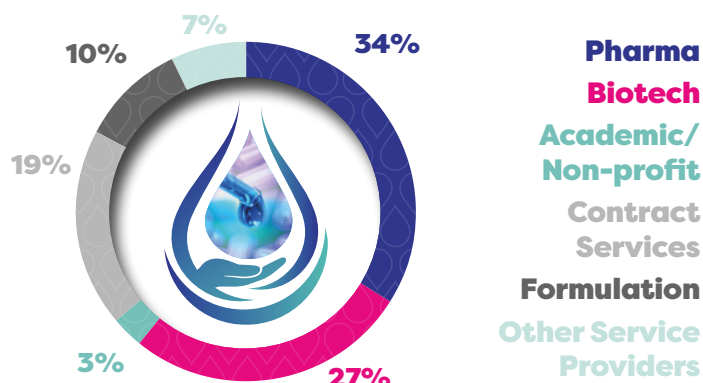
Exhibitor

Bioskin is a leading CRO with unique understanding and capabilities for both early and late phase dermatological

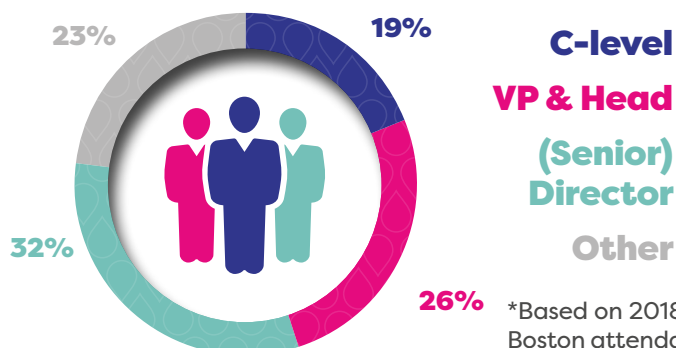
clinical trials. Recognised by global companies as a valuable partner in studies for drugs, medical devices, food supplements and advanced cosmetics since 1992, bioskin offers early phase safety and Proof-of-Concept studies, vasoconstrictor assays according to FDA guidelines, global Phase II - IV trials for NCEs, new formulations with known actives as well as consulting in the field of dermatology.

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AUDIENCE BY SECTOR*



AUDIENCE BY SENIORITY*



*Based on 2018 Boston attendance

For more information about partnership opportunities, please contact:



Jacob Roberts-Kendall
Partnerships Director
Tel: +44 (0)20 3141 8700
Email: sponsor@hansonwade.com

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- 1 Accelerate the development of innovative dermatological therapies
- 2 Be in tune with the growing excitement in the dermatology drug development space
- 3 Hear from KOLs on how to tackle the challenges to bring better dermatology drugs to market

Team Discounts*

- 10% discount – 3 delegates
- 15% discount – 4 delegates
- 20% discount – 5 or more delegates

*Please note that discounts are only valid when three or more delegates from one company book and pay at the same time. Contact: register@hansonwade.com

SECURE YOUR PLACE

Standard Rate	Register & Pay By Friday, 12 April	Standard Rate
Conference + 2 Workshops	€3,597 (save €300)	€3,697 (save €200)
Conference + 1 Workshop	€3,098 (save €200)	€3,198 (save €100)
Conference Only	€2,599 (save €100)	€ 2,699
Individual Workshops	€599	

Academic/ Start-Up Rate*	Register & Pay By Friday, 15 March	Standard Rate
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Conference Only	€1,699 (save €100)	€ 1,799
Individual Workshops	€399	

*** T&Cs Apply: Start-up rate is subject to organiser approval. Please visit the event website for more details.**

*** VAT will be charged at 19%**



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For further information or assistance, please visit

www.radissonblu.com/en/hotel-frankfurt

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