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October, 10-12 Boston, MA



Dermatology Drug Development Summit

Innovating & Accelerating the Development & Commercialization of Dermatology Drugs

Expert speakers include:



Frank Nestle
Head of Immunology &
Inflammation Therapeutic
Research Area & Chief Scientific
Officer North America
Sanofi US



Kim Domela Kjøeller
Executive VP,
Global R&D
LEO Pharma A/S



Paul F. Lizzul
Chief Medical
Officer
**Sienna
Biopharmaceuticals**



Sujatha Sonti
VP, Topical
Product
Development
GlaxoSmithKline

💧 The difference between this event and others is that this allows us to exchange ideas with those with whom we share many common challenges 💧

Abbvie, Past Attendee, Hanson Wade Event

Tel: +1 212 537 5898 Email: info@hansonwade.com
www.dermatology-drugdevelopment.com



Welcome to the Dermatology Drug Development Summit

Join the Dermatology Revolution

Treating chronic and severe dermatology conditions will improve the lives of millions of patients worldwide. With an increasingly better understanding of the pathophysiology of skin diseases, new targets and mechanistic approaches, the dermatology space is being revolutionized with innovative therapies coming to market.

The **Dermatology Drug Development Summit** provides you with a platform for discussion with other leaders in this space at a time of newly opened opportunities in dermatology pipelines, driven by heavy investment in the field.

Through sharing details of the latest success stories and evaluating solutions to existing challenges, this meeting aims to **accelerate efforts to develop and bring to market increasingly better and more efficient dermatology drugs.**

Join your peers to explore a myriad of key field-specific topics including discovery, R&D, clinical development, biologics, topical approaches, and regulatory and market access concerns.

💧💧 All speakers were highly qualified and the presentations were insightful 💧💧

Pfizer, Past Attendee, Hanson Wade Event

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

Celgene, Past Attendee, Hanson Wade Event

💧💧 The talks were high quality and the interaction among participants was excellent 💧💧

Genentech, Past Attendee, Hanson Wade Event

Key Highlights You Cannot Miss

1. LEO Pharma A/S share how they are revolutionizing dermatology R&D with precision medicine and biomarkers

2. Novartis Institutes for Biomedical Research explains how to bridge the translational gap and accelerate clinical development

3. Sienna Pharmaceuticals tackles the innovation gap in topical dermatology drug development

4. Innovation Pharmaceuticals Inc. and Exicure discuss their pioneering therapeutic approaches based on oral immunomodulators and spherical nucleic acids

5. Sanofi US explores the explosion of biologic therapies to tackle dermatological conditions such as psoriasis and atopic dermatitis, including the game-changing Dupilumab

6. Novartis demonstrate how they are using biologics to address other unmet needs in dermatology

7. GSK and Immune Pharma reveal how to optimize clinical research and development with a better definition of dermatology clinical endpoints

8. Castle Creek Pharmaceuticals address clinical development in rare and orphan diseases in dermatology

9. Almiral and Novartis assess the regulatory environment in the changing dermatology landscape

10. Galderma analyzes how the current dermatology landscape is influencing commercial decision-making and market access/reimbursement strategies

Expert Speaker Faculty



Anne Parneix
VP & Senior Global
Program Head,
Dermatology
Novartis



Braham Shroot
Dermatology
Drug
Development
**Independent
Consultant**



David Giljohann
Chief Executive
Officer
Excire



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



Ernst Kriehuber
Director
Translational Medicine,
Dermatology & Immune
Mediated Diseases
**Novartis Institutes for
Biomedical Research**



Frank Nestle
Head of Immunology
& Inflammation
Therapeutic Research
Area & Chief Scientific
Officer North America
Sanofi US



Gavin Corcoran
Chief Medical
Officer
Allergan



Geoffrey Hird
Executive
Director of
Pharmaceutics &
CMC
Liquidia



Greg P. Licholai
President & Chief
Scientific Officer
**Castle Creek
Pharmaceuticals**



**Jean-Philippe
(JP) Therrien**
VP, Skin Biology
**EnDev
Laboratories™**



**Kim Domela
Kjeller**
Executive VP,
Global R&D
LEO Pharma A/S



Krishna Menon
President & Chief
Scientific Officer
**Innovation
Pharmaceuticals
Inc.**



Marie Bernasconi
Senior Director
& Head of
Dermatology
Therapeutic Area
R&D
Almirall



Maxwell Stock
President & Chief
Executive Officer
Signum Biosciences



**Mayte Suarez-
Farinas**
Associate Professor,
Biostatistics
**Icahn School of
Medicine at Mount
Sinai**



Monica Luchi
former Chief Medical
Officer & Executive
VP
**Immune
Pharmaceuticals**



Paul F. Lizzul
Chief Medical Officer
**Sienna
Biopharmaceuticals**



Sujatha Sonti
VP, Topical
Product
Development
GlaxoSmithKline



**Tomoko Maeda-
Chubachi**
Senior Medical
Director,
Dermatology
GlaxoSmithKline

💧 This meeting brings together the best
scientists with state of the art experience.
Great job 💧

Bristol Myers Squibb, Past Attendee, Hanson Wade Event

Conference Day One | Wednesday, October 11, 2017

7.45 Registration & Coffee



8.45 Chairman's Opening Remarks



9.00 Opening Keynote Panel Discussion: A Therapeutic Revolution in Dermatology – Bridging the Gaps & Opportunities



- Addressing the evolving landscape, growing interest and developments in the dermatology drug development space
- Analyzing the paradigm shift from topical to systemic treatment approaches – tackling symptoms vs. causes
- Unmet needs – evaluating the ROI of drug development for rare dermatological conditions
- Outlining where we are and where we are going – important learnings to date and perspectives on future directions



Optimizing Discovery & Preclinical Development in Dermatology



9.45 Precision Medicine in Dermatology - Revolutionizing R&D & Providing Optimal Treatment for Patients

- Assessing how biomarkers provide a unique opportunity to improve disease understanding: Identifying distinct subtypes (different presentations and different response to treatment), unique disease signatures and early changes in biomarker profiles
- Exploring how early response prediction can reduce late stage attrition
- 2020 – the era of biologics
- Applying in-depth disease and pathway understanding to identify new biologics targets
- Addressing single gen orphan diseases with biologics
- Applying biomarkers to support precision medicine
- Creating the win-win for the Four Ps (Patient, Physician, Payer, Pharma) with Precision Medicine

10.15 Morning Refreshments & Speed Networking



11.45 Translational Research in Dermatology – Setting the Course for Successful/Accelerated Clinical Development

- Exploring how to match the right mechanism with the right indication
- Accelerating clinical development by implementing PD in FIH studies
- Exploring PK-PD for indication expansion



12.15 Skin Biology – A Valuable Tool for the Innovation & Development of Novel Therapeutic Alternatives in Dermatology



- Introducing EnDev Laboratories and the Skin Biology capabilities
- Reviewing different in vivo/ex vivo/in vitro skin models available
- Describing the pre-clinical strategy to de-risk dermal drug development
- Presenting case studies supporting the use of skin biology for innovation and drug development

12.45 Lunch & Networking

Advancing Topical & Small Molecule Drug Development

 Paul F. Lizzul , Chief Medical Officer, Sienna Biopharmaceuticals	1.45 Addressing the Innovation Gap in Topical Dermatology Drug Development - Analyzing the revolution in how moderate to severe dermatologic diseases (e.g., psoriasis and AD) are now treated in a targeted way with the biologics - Looking at the innovation gap in topical drug development with many patients still primarily using topical steroids - Describing the need for a novel targeted topical approach to fill the innovation gap in treatment for the mild to moderate (80-90%) patient population with dermatologic diseases - Modifying potent small molecules that address key immune targets of psoriasis and atopic dermatitis with a "Topical by Design" approach - Exploring how "Topical by Design" also results in a favorable safety profile with Low Systemic Exposure (LSE)
 Sujatha Sonti VP, Topical Product Development, GlaxoSmithKline	2.15 Key Considerations in Designing Topical Formulations - Exploring Target Product Profiles in dermatology applications - Discussing the latest advances in formulation, analytical and process development technologies - Analyzing formulation selection criteria
 David Giljohann , Chief Executive Officer, Excicure	2.45 Targeting Diseases Using Topical Treatments with Spherical Nucleic Acids - Treating dermatological diseases locally using topically applied drugs – analyzing the Excicure approach - Exploring Spherical Nucleic Acids – an innovative approach to treating patients using underlying biology by targeting a disease at its genetic source - Analyzing early clinical data and the shown success using this approach via a TNF pathway in patients with psoriasis - Tackling other diseases with known genetic drivers
3.15 Afternoon Refreshments & Networking	
 Krishna Menon , President & Chief Scientific Officer, Innovation Pharmaceuticals Inc.	3.45 Innovation in Oral Immunomodulators for the Treatment of Psoriasis & Other Dermatological Conditions - Overviewing Prurisol: A new small molecule under investigation for the treatment of psoriasis - Exploring HDP Mimetics: Understanding the mechanism of action of endogenous host defence peptides (HDPs) as enhancers of immunomodulatory functions - Analyzing Brilacidin as a novel small molecule for the treatment of bacterial infections, with successful Phase II b clinical trial results for acute bacterial skin and skin structure infection (ABSSSI)
 Maxwell Stock , President & Chief Executive Officer, Signum Biosciences	4.15 Identifying Therapeutic Novel NCEs Which Rival Big Pharma - Overviewing the small business perspective as they enter the drug discovery space to compete with big pharma - Analyzing next steps for a successful drug discovery program - Outlining the advantages and disadvantages of small business drug development
 Geoffrey Hird Liquidia  Maxwell Stock , Signum Biosciences  Sujatha Sonti VP, Topical Product Development, GlaxoSmithKline  Tomoko Maeda-Chubachi GlaxoSmithKline	4.45 Panel Discussion: Debating the Therapeutic Developments in Topicals - Taking risks in early stages to develop new and innovative topicals - Addressing the big pharma vs. smaller biotech paradigms and perspectives - Analyzing the next steps in developing increasingly efficient dermatological topical treatments
 Monica Luchi Immune Pharmaceuticals	5.30 Chairman's Closing Remarks

Conference Day Two | Thursday, October 12, 2017



Monica Luchi
Immune
Pharmaceuticals

8.20 Chairman's Opening Remarks

The Rise of Biologics in Dermatology



Frank Nestle, Head
of Immunology &
Inflammation
Therapeutic Research
Area & Chief
Scientific Officer
North America,
Sanofi US

8.30 Advancing Dermatology Therapies with Biologics

- Addressing the flourishing of biologic therapies targeting dermatological conditions such as psoriasis and atopic dermatitis
- Dupilumab – analyzing the innovative mechanistic aspects and new pathways against type II inflammation
- Analyzing the current new chapter in the understanding and targeting of immune-mediated diseases in the dermatology space



Marie Bernasconi,
Senior Director &
Head of Dermatology
Therapeutic Area
R&D, **Almirall**

9.00 Psoriasis: The Shift in Treatment Paradigm in the Last 25 Years

- Analyzing innovative approaches to the treatment of psoriasis: New biologics, new pathways, biosimilar space
- Is there still an unmet medical need? – addressing the need for new oral or topical treatment and what the R&D effort to develop them looks like
- What are the patients' expectations?



Anne Parneix, VP &
Senior Global
Program Head,
Dermatology
Novartis

9.30 Beyond the Hype – Exploring the Application of Biologic Therapies to Tackle Unmet Needs in Dermatology

- Discussing how biologics hold great promise for other indications other than psoriasis and atopic dermatitis
- Addressing rare diseases – developing Ilaris (canakinumab)
- Exploring therapeutic approaches against Hidradenitis suppurativa

10.00 Morning Refreshments & Networking



Ernst Kriehuber,
**Novartis Institutes
for Biomedical
Research**



Frank Nestle,
Sanofi US

10.45 Panel Discussion: Pioneering Biological Therapies in Dermatology

- Analyzing the explosion in new programs – the promise of more and more efficient therapies vs. the hurdles of a crowded development space
- Differentiating MOA that translate into actual benefit to the patient – is good efficacy enough?
- The growing investment – demonstrating value and understanding market share in advance

Enhancing the Clinical Development of Dermatology Therapeutics



Gregory P. Licholai,
President & Chief
Scientific Officer,
**Castle Creek
Pharmaceuticals**

11.30 New Horizons in Dermatology – Rare & Orphan Disease Drug Development Opportunities & Challenges

- Analyzing the recent expansion of interest in rare, orphan and ultra-orphan diseases and how dermatology represents an important therapeutic area that has recently been a focus for rare and orphan drug development
- Outlining external stakeholder perspectives on drug development for orphan diseases – discussing how sponsors and investors accurately perceive orphan diseases as tremendous unmet medical needs that can generate value as well as create strong patient impact, how activist organizations have pressured regulators, and how many physicians welcome the chance to provide treatments to previously untreatable patients
- Exploring the landscape of unique challenges and opportunities in dermatology drug development in rare and orphan diseases – discussing clinical and regulatory strategies, trial design, patient selection and enrolment, and endpoint selection
- Presenting reflections on recent experiences and future challenges

12.00 Lunch & Networking



Mayte Suarez-Farinas, Associate Professor, Biostatistics, **Icahn School of Medicine at Mount Sinai**

1.00 Can Molecular & Machine Learning Bring Efficiency to Clinical Trials in Dermatology?

- Discussing the “assessment gap” between the moment a patient’s response to treatment is biologically determined and when a response can actually be determined clinically
- Addressing statistical models that estimate disease improvement at the molecular level, showing smaller placebo effect and superiority of the treatment groups as early as one month of treatment
- Building precision medicine algorithms that use gene expression or blood protein biomarkers from the first month of treatment, to evaluate the long term treatment response
- Exploring how the highly promising and encouraging results we obtained with our prediction tool in psoriasis emphasize the potential of molecular profiling coupled with machine learning and statistical techniques to accelerate and optimize the conduction of clinical trials



Monica Luchi, former Chief Medical Officer & VP, **Immune Pharmaceuticals**

1.30 Challenges with Dermatology Clinical Study Endpoints

- Understanding what is a meaningful clinical change
- Getting regulatory consensus on endpoints in rare diseases
- Accounting for inter-observer differences and subjectivity (mitigation strategies include BSA and PGA values)
- Addressing how comparing between trials can be difficult due to variability in assessments
- Considering differences in aggressive vs. more cautious tendencies in medication administration/tapering



Tomoko Maeda-Chubachi, Senior Medical Director, Dermatology, **GlaxoSmithKline**

2.00 Collaborative Efforts to Harmonize the Endpoints & Outcome Measures in Dermatological Diseases

- Delving into dermatology specific issues in clinical trials
- Understanding difficulties in meta-analysis
- Underlying the necessity of international harmonization

The Evolution of the Regulatory Environment in Dermatology Drug Development



Gavin Corcoran, **Allergan**



Marie Bernasconi, **Almirall**

2.30 Panel Discussion: Dermatology Drug Development – A Regulatory Paradigm Shift

- Discussing the regulatory perspective on the changing landscape in the dermatology space – new delivery mechanisms, new therapeutic approaches and new targets
- Are regulatory guidelines in tune with current developments?
- Aligning regulation worldwide

3.15 Afternoon Refreshments & Networking

Commercial Decision-Making in Dermatology



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

3.45 How to Win in the Competitive Market Place?

- Overviewing the changing dynamics in the global dermatology market
- Analyzing the evolving payer environment for biologic treatments
- Raising awareness for unmet needs and importance of disease impact on patients’ lives
- Winning over key stakeholders through right value proposition
- Evolving towards more patient centric marketing



Dogan Fidan, **Galderma**



Gavin Corcoran, **Allergan**



Greg P. Licholai, **Castle Creek Pharmaceuticals**

4.15 Panel Discussion: Addressing the Overall Concern of Rising Treatment Costs in Dermatology

- Evaluating the need for better tools to describe why prescribing biological treatments is valuable – patient reported outcome tools that effectively show the improved outcomes with treatment
- Is the cost worth it? The need for raising awareness among stakeholders
- Defining better market access strategies in dermatology



Monica Luchi, **Immune Pharmaceuticals**

5.00 Chairman’s Closing Remarks

PRE-CONFERENCE WORKSHOP

Tuesday, October 10, 2017

Innovating Drug Delivery & Formulation of Dermatological Drugs

1.00pm – 4.00pm

Ensure that your drug delivery platforms and formulation approaches are a step ahead. This is your opportunity to gain in-depth insights from a veteran in the field, with plenty of actionable case studies to learn from.

Key topics to be discussed:

- Normal and Diseased Skin – a moving target
- There is no placebo in dermatology, only vehicles
- *In Vitro* models of drug release and drug distribution
 - *How predictable are they?*
 - *Drug physical parameters - Is there a set for optimal skin penetration?*
 - *How to determine Drug Strength?*
- The influence of vehicles
 - *Potency*
 - *Patient compliance*
- Analyzing manufacturing
 - *Influence of scale-up from bench to pilot to plant on formulation*
- Exploring novel formulation approaches
 - *Encapsulation*
 - *Challenges for delivery of peptides and oligonucleotides*
 - *Driving innovation in dermatology delivery and formulation*

Join this interactive and comprehensive session that will allow you to streamline and boost innovative delivery and formulation approaches that match the potential of your drug candidates.



Workshop Leader

Braham Shroot, Dermatology Drug Development Independent Consultant

Dr Shroot has over 35 years hands-on experience in Drug Research and Development specializing in Skin disorders including Acne, Rosacea, Psoriasis, Atopic Dermatitis, Fungal Infections, Chronic Ulcers and novel Aesthetic Biologic Products.

Dr Shroot currently is an R&D consultant to Health Care Companies, with a focus on a wide range of acute and chronic skin disorders including rare diseases.

Braham Shroot is the former CEO of Signum BioSciences/ Argyle Therapeutics, a private biotechnology company dedicated to developing small molecule therapeutics for dermatological applications. Previously, he served as CSO at Barrier Therapeutics, Inc, which was acquired by Stiefel Laboratories Inc., in August 2008. Dr. Shroot was also CSO and VP of R&D for DFB Pharmaceuticals, Inc., a fully integrated private specialty pharmaceutical company with a focus on the skin, wound care, and surgical markets. In addition Dr Shroot had scientific responsibility for another DFB company, DPT Laboratories a contract research and manufacturing company with a focus on semi-solid topical formulations. Before DFB, Dr. Shroot was employed by L'Oreal where he was Group Leader and eventually Vice General Manager of a newly created Galderma Research entity, which he helped to establish.

Dr Shroot earned his B.Sc. in Chemistry and Ph.D. in Organic Chemistry at Glasgow University, Scotland, UK. After three years of Postdoctoral Research in the Laboratory of Professor R.B Woodward he embarked on his career in the Industry.

PARTNERSHIP OPPORTUNITIES



Expertise Partner

EnDev Laboratories™, is a full service R&D provider for topical and dermal pharmaceutical development. EnDev has complete formulation and skin biology capabilities including IVRT, extensive analytical resources and stability programs. We can determine mechanisms of action, design proof-of-concept studies, product development de-risking strategies and more, to give you a fact-based foundation for moving forward. EnDev bridges the gap between what is possible and what gets done. EnDev is a division of Ei, A Pharmaceutical SolutionWorks™.

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Industry Partner

Novan, Inc. is a pharmaceutical company focused on redefining the standard of care in dermatology through the development and commercialization of innovative therapies using the Company's nitric oxide platform. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate differentiated, first-in-class product candidates. We are rapidly advancing programs in five dermatological conditions with significant unmet medical need.

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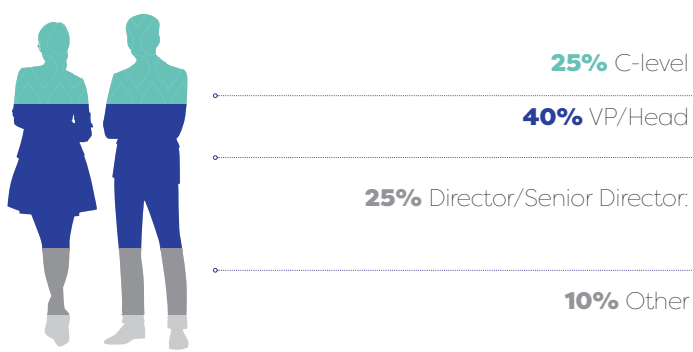


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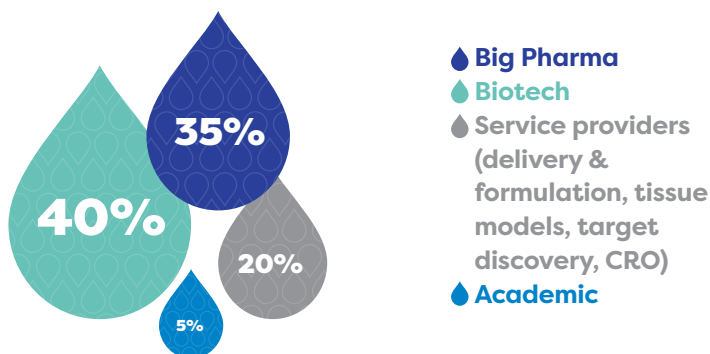
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- 1** Accelerate the development of innovative dermatological therapies
- 2** Be in tune with growing excitement in the dermatology drug development space
- 3** Hear from KOLs how to tackle the challenges to bring better dermatology drugs to market

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.

SECURE YOUR PLACE

Package Details	Register & Pay before Friday September 1, 2017	Standard Prices
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Workshop		\$699

*Academics are entitled to a 40% discount off the Industry Pricing using the code 'ACA'
(Please note: Discounts cannot be combined with any other offer)

💧 A huge success for everyone who attended. The participants were top notch. I learned a lot and made some good contacts. The content was extremely strong overall 💧

Pfizer, Past Attendee, Hanson Wade Event



VENUE

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