ALOPECIA AREATA RESEARCH SUMMIT
Forging the Future

PRELIMINARY PROGRAM

Tuesday, December 4—Wednesday, December 5

Alfred Lerner Hall, Columbia University
Roone Arledge Auditorium (1st Floor W)
2920 Broadway (115th Street)
New York City, New York 10027 USA

Summit Co-Chairs

Jerry Shapiro, MD
NYU School of Medicine

Natasha A. Mesinkovska, MD, PhD
UC Irvine School of Medicine

Angela M. Christiano, PhD | Honorary
Columbia University Medical Center

Hosted By

National Alopecia Areata Foundation
ALOPECIA AREATA Treatment Development Program
### TUESDAY, DECEMBER 4

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<th>Time</th>
<th>Event</th>
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<tr>
<td>8:00 AM–8:30 AM</td>
<td>Breakfast</td>
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<tr>
<td>8:30 AM–9:05 AM</td>
<td>Opening Session</td>
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<td>Moderator: Angela M. Christiano, PhD</td>
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<td></td>
<td>Welcome Address</td>
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<td>NAAF President and CEO, Dory Kranz will welcome participants and Summit Co-Chairs, Drs. Jerry Shapiro, Natasha Mesinkovska and Angela Christiano will summarize meeting objectives.</td>
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<td>Opening Keynote—Coping with Stress: Stem Cells in Injury and Inflammation</td>
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<td>Elaine Fuchs, PhD</td>
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<td>Understanding how stem cells remain quiescent during times of minimal wear and tear, how these cells become mobilized during the cyclical bouts of hair growth and wound-repair, and how the normal process of stem cell activation goes awry in inflammatory disorders such as alopecia areata.</td>
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<td>9:05 AM–10:35 AM</td>
<td>Session 1—Setting the Stage</td>
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<td>Moderator: David Norris, MD</td>
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<td>Summary of Preceding Alopecia Areata Research Summits</td>
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<td>Natasha A. Mesinkovska, MD, PhD</td>
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<td>Summary of outcomes resulting from past research summits and overview of the current state of alopecia areata research.</td>
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<td>Genetics and Immunology of Alopecia Areata</td>
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<td>Angela M. Christiano, PhD</td>
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<td>An update on genetic and immunological studies in alopecia areata since GWAS evidence, in conjunction with gene expression profiling, pointed to key members of the interferon-gamma pathway regulated in part by Janus kinases (JAKS), which led to early clinical trials with existing JAK inhibitors.</td>
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<td>Current Treatment of Alopecia Areata</td>
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<td>Maria Hordinsky, MD</td>
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<td>Overview of options available to treat pediatric and adult alopecia areata, including the risks and benefits of current and evolving off-label treatment options with the understanding that there is currently no treatment approved by the FDA for this disease.</td>
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<td>Alopecia Areata: Autoimmune Disease or Hair Follicle Response Pattern to Immunological Damage?</td>
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<td>Ralf Paus, MD, FRSB</td>
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<td>Discussion of the immune privilege collapse model of alopecia areata pathogenesis, available evidence to support this hypothetical scenario, and promising avenues for future investigation.</td>
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<td>Pre-Clinical Research in Vivo: Pros and Cons of the C3H/HeJ versus the Humanized Mouse Model</td>
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<td>Amos Gilhar, MD</td>
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<td>In order to probe the efficacy of new immune-intervention strategies in alopecia areata, the field can now choose from two mutually complementary mouse models.</td>
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<td>10:35 AM–10:45 AM</td>
<td>Break</td>
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**Session 2: Alopecia Areata Clinical Research—Investigator Insights**

**Moderator:** Jerry Shapiro, MD | NYU School of Medicine, New York, NY, USA

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<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Institution</th>
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<tr>
<td>JAK Inhibitors for the Treatment of Alopecia Areata in the Pediatric Population</td>
<td>Brittany Craiglow, MD</td>
<td>Yale School of Medicine, Dermatology Physicians of Connecticut, Fairfield, CT, USA</td>
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<td>Review of the available data regarding the use of JAK inhibitors for alopecia areata in children.</td>
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<td>Responsiveness of Eyebrows and Eyelashes to Tofacitinib in Patients with Severe Alopecia Areata</td>
<td>Brett King, MD, PhD</td>
<td>Yale School of Medicine, New Haven, CT, USA</td>
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<td>While JAK inhibitors have emerged as treatment of alopecia areata, studies have focused on scalp hair growth. In this study, we evaluated the response of eyebrows and eyelashes to tofacitinib.</td>
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<td>Long-Term Treatment for Severe Alopecia Areata with Oral Tofacitinib Citrate</td>
<td>Melissa Peck Piliang, MD</td>
<td>Cleveland Clinic Lerner College of Medicine, Cleveland, OH, USA</td>
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<td>Results from Cleveland Clinic’s retrospective study indicate tofacitinib to be a safe and viable treatment option for patients with severe alopecia areata.</td>
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<td>Platelet-Rich Plasma in the Treatment of Alopecia Areata</td>
<td>Hind Almohanna, MD</td>
<td>University of Miami Miller School of Medicine, Miami, FL USA</td>
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<td>A comprehensive review of data on efficacy, safety and mechanism of action of platelet-rich plasma (PRP) injections in treating alopecia areata.</td>
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<td>In Vivo Imaging in Alopecia Areata Patients Using Multiphoton Microscopy</td>
<td>Jessica Lin, BSc Biology</td>
<td>University of California, Irvine, Orange, CA, USA</td>
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<td>Exploring the utility of multiphoton microscopy (MPM) as an adjunct to histological studies and a diagnostic tool for alopecia areata.</td>
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<td>Cytokine Targeted Treatments for Alopecia Areata</td>
<td>Emma Guttman-Yassky, MD, PhD</td>
<td>Icahn School of Medicine at Mount Sinai Medical Center, New York, NY, USA</td>
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<td>A short overview of potential pathogenic cytokines and targeted therapeutic clinical trials for alopecia areata patients that have been recently performed or are ongoing.</td>
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<td>Alopecia Areata: Lessons from Other Inflammatory Skin Diseases</td>
<td>Mark Lebwohl, MD</td>
<td>Icahn School of Medicine at Mt. Sinai, New York, NY, USA</td>
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<td>By identifying key cells and cytokines that play roles in the development of diseases like psoriasis and atopic dermatitis, we have been able to target very specific parts of the immune system and thereby treat these diseases more effectively and more safely. Following the same methodology, we hope to identify key targets that allow us to do the same for alopecia areata.</td>
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**DISCUSSION**

**Lunch and Keynote**

**Alopecia Areata: A Patient’s Perspective**

Dustin Lee, BS | NAAF Health & Research Ambassador, New York, NY, USA

A viewpoint of alopecia areata from a patient, researcher in the immunology field, and advocate for the alopecia areata patient community.

**DISCUSSION**
This panel is designed as an open exchange between panel experts, patient advocates, and audience members. The objective is to learn how all stakeholders can work together to implement and advance patient involvement across the entire clinical development continuum.

**PANELISTS**

**David Gordon, MB, ChB**  
Chief Medical Officer, Aclaris Therapeutics, Wayne, PA, USA  
David Gordon joined Aclaris as Chief Medical Officer in May 2018 and has responsibilities ranging from drug discovery, through clinical development to medical affairs. He was previously Senior Vice President and Head of Dermatology Research and Development at GlaxoSmithKline (GSK). During 18 years at GSK he served as Clinical Vice President and Medicine Development Leader in the Immuno-Inflammation and Biopharmaceutical groups and led teams in all stages of research. His British medical degree was awarded from Aberdeen University. He is accredited as a specialist in Pharmaceutical Medicine by the Faculty of Pharmaceutical Medicine in London.

**Paul Frohna, MD, PhD, PharmD**  
Chief Medical Officer, Bioniz Therapeutics Inc., Irvine, CA, USA  
Paul Frohna is Chief Medical Officer of Bioniz Therapeutics where he oversees clinical and regulatory strategy and operations for the company’s platform of multi-cytokine inhibitors that are in development for alopecia areata, cutaneous T cell lymphoma, and a variety of other autoimmune diseases. Previously, Dr. Frohna was Vice President of Clinical Development and Translational Medicine at Receptos, Inc. where he was responsible for programs in multiple sclerosis, irritable bowel disease, and eosinophilic esophagitis. Dr. Frohna received his medical degree from Georgetown University with residency training in Internal Medicine, his PhD in Pharmacology from the University of Pennsylvania, and his Pharmacy Degree from the University of Texas at Austin.

**James V. Cassella, PhD**  
Chief Development Officer, Concert Pharmaceuticals Inc., Lexington, MA, USA  
James Cassella is a biopharmaceutical research and development executive with over 25 years of experience working in science-driven drug discovery and product development companies. Since February 2015, he has been the Chief Development Officer at Concert Pharmaceuticals, leading the Company’s drug development efforts. Previously, Dr. Cassella served as the Chief Scientific Officer and Executive Vice President of Research & Development at Alexza Pharmaceuticals and Senior Vice President of Clinical Research & Development at Neurogen Corporation. Dr. Cassella received a PhD in Neuroscience from Dartmouth College and completed a Postdoctoral fellowship in the Department of Psychiatry at the Yale University School of Medicine.

**Kathleen Wyrwich, PhD**  
Senior Research Leader, Patient-Focused Outcomes Center of Expertise, Eli Lilly & Company, Indianapolis, IN, USA  
Kathy Wyrwich is the Senior Research Advisor for the Patient-Focused Outcomes Center of Expertise at Eli Lilly and Company. With over two decades of experience conducting research studies in the development, validation, and interpretation of change over time of clinical outcome assessments (COAs), she recently led the development of several new alopecia areata COA measures at Lilly. Kathy earned her PhD in Health Services Research from Saint Louis University, and served as Vice President of Research at Evidera before joining Lilly in 2017. She frequently publishes on COA research endeavors with over 10,000 citations from this work.

**Saad Harti, MBA**  
Chief Executive Officer, Legacy HealthCare, Epalinges (Lausanne), Switzerland  
Saad Harti is a healthcare entrepreneur who was born in Morocco, educated in France and is currently living in Switzerland. He founded Legacy Healthcare with the purpose of develop botanical drugs, a new class of drugs regulated by US Food and Drug Administration (FDA) and European Medicines Agency (EMA). They are made from botanical extracts, have a much better safety profile than synthetic drugs and therefore, better suited for the treatment of chronic diseases. The most advanced candidates of Legacy Healthcare are topical solutions for the treatment of Pediatric Alopecia Areata, Androgenetic Alopecia and Chemotherapy Induced Alopecia.
### Michael L. Sierra, PhD
Vice President, LEO Science & Tech Hub, Cambridge, MA, USA

Michael Sierra is currently Vice President of LEO Science & Tech Hub. Prior to this position, he held the positions of Director of Medicinal Chemistry, Director of Chemical Research, Director of External Discovery and Executive Director of Translational Research at LEO Pharma. Before that, Michael worked 10 years at GlaxoSmithKline’s Research Center in France and the biotech, CareX, as Head of Chemistry. He received his BS in chemistry from Ohio Northern University, his PhD in chemistry at Wayne State University and held a 2 year post-doctoral position at Ecole Polytechnique in France. He has 26 years of drug discovery experience in the therapeutic areas of cardiovascular and metabolic diseases as well as inflammation and dermatology with the identification of 18 clinical candidates.

### Robert Wolk, MD, PhD, DSc
Executive Director, Global Clinical Lead, Global Product Development, Pfizer, Groton, CT, USA

Robert Wolk is the Global Clinical Lead for alopecia areata at Pfizer. Initially he worked in the Cardiovascular, Metabolic and Endocrine Diseases group and subsequently joined the Xeljanz team to lead the Phase 3 psoriasis program and the New Drug Application submission. Later, Dr. Wolk worked in biosimilars as a Clinical Submissions Expert and Global Clinical Lead across Pfizer’s global biosimilars portfolio. Dr. Wolk earned his medical degree from Warsaw Medical School and continued his training at the University of Strathclyde, Glasgow Royal Infirmary, University of Pittsburgh, and Mayo Clinic College of Medicine where he held the position of Associate Professor of Medicine.

### DISCUSSION

#### 2:45 PM–4:35 PM
**Session 4—Clinical Outcome Assessments**

**Moderator:** Natasha A. Mesinkovska, MD, PhD | NAAF, UC Irvine School of Medicine, Irvine, CA, USA

**Objective Outcome Measures: Collecting Meaningful Data on Alopecia Areata**

Elise A. Olsen, MD | Duke University Medical Center, Durham, NC, USA

*Overview of assessment methods for alopecia areata including the SALT and ALODEX scoring systems, response criteria and potential global score.*

**Importance of Addressing Eyebrows in Alopecia Areata**

Justin M. Ko, MD, MBA | Stanford University School of Medicine, Stanford, CA, USA

*Alopecia areata affects scalp hair and eyebrows. Satisfaction with treatment of alopecia areata doesn’t increase linearly with overall hair growth and can only be achieved with significant growth. Eyebrows are just as important as scalp hair to AA patients and should be included as a patient-centered outcome in clinical trials.*

**Alopecia Areata Patient-Reported Outcome Consortium**

Dory Kranz, MBA | National Alopecia Areata Foundation, San Rafael, CA, USA

*Report on the progress of NAAF’s the Patient-Reported Outcome (PRO) Consortium to develop a single, consensus-defined PRO instrument that can be shared across industry partners and other ongoing initiatives to incorporate the voice of the patient in alopecia areata research.*

**Lessons from the International Dermatology Outcome Measures**

Alice Gottlieb, MD, PhD | New York Medical College at Metropolitan Hospital, New York, NY, USA

*IDEOM's achievements in establishing domains for clinical research in both psoriasis and hidradenitis suppurativa, including collaborations with the AAD to establish simple outcome measures for clinical practice and registries, will be discussed.*

**Understanding Health Economics from the Payers Perspective**

Julia A. Gaebler, PhD | Health Advances LLC, Weston, MA, USA

### DISCUSSION

#### 3:30 PM–5:00 PM
**Poster Hang**

Low Memorial Library
Faculty Room (1st Floor)
Please join us at the Low Memorial Library building on the Columbia University Campus for a wonderful reception to mix and mingle with colleagues in a casual, fun, and beautiful setting. Scientific posters will be on display for informal presentations and discussion. Cocktails and hors d’oeuvres will be served.

01 Monitoring Response to Platelet Rich Plasma in Alopecia Areata Patients with Optical Coherence Tomography: A Case Series
Chloe Ekelem, MD, MPH | UC Irvine School of Medicine, Irvine, CA, USA

02 Prevalence of Infectious Disease History in Patients with Alopecia Areata
Dina Hagigeorges, BS | Massachusetts General Hospital, Boston, MA, USA

03 Quality of Life Predictors Among Individuals Living with Alopecia Areata
Garrett E. Huck, PhD | Penn State University, Hazleton, PA, USA

04 The Prevalence of Allergies in Patients with Alopecia Areata
Athena J. Manatis-Lornell, BA | Massachusetts General Hospital, Boston, MA, USA

05 Microneedling for the Treatment of Recalcitrant Alopecia Areata: A Systematic Review
Dustin H. Marks, BS | Massachusetts General Hospital, Boston, MA, USA

06 A Phase 2a Randomized, Placebo-controlled Study to Evaluate Efficacy and Safety of Janus Kinase Inhibitors PF-06651600 and PF-06700841 in Alopecia Areata
Elena Peeva, MD | Pfizer, Cambridge, MA, USA

07 A Series of Scalp Allergic Contact Dermatitis Cases Secondary to Nickel-Containing Products in Patients with Alopecia Areata
Christine Pham, BS | UC Irvine School of Medicine, Irvine, CA, USA

08 The Relationship between Physical Activity Levels, Quality of Life and Symptoms of Depression, Anxiety and Stress in Individuals with Alopecia Areata
Yamuna Rajoo, PhD Candidate | RMIT University, Melbourne, Australia

09 The Role of Patients in the Development of the Alopecia Areata Investigator Global Assessment (AA-IGA™), a Clinician-Reported Measure Evaluating Clinically Meaningful Success in Clinical Trials
Kathleen W. Wyrwich, PhD | Eli Lilly & Company, Indianapolis, IN, USA

10 Integrated Behavioral Health in Alopecia Areata Dermatology Care: Pilot Study Purpose and Methodology
Kristina Gorbatenko-Roth, PhD, LP | University of Wisconsin-Stout, Hudson, WI, USA
WEDNESDAY, DECEMBER 5

7:30 AM–8:00 AM  Breakfast and Opening Session

Introduction and Review of Day One Discussion
David Norris, MD | University of Colorado School of Medicine, Aurora, CO, USA

A review of key topics discussed on the first day.

8:00 AM–8:55 AM  Session 5–Late Breaking Abstracts

Moderator: Jerry Shapiro, MD | NYU School of Medicine, New York, NY, USA

01 Monitoring Response to Platelet Rich Plasma in Alopecia Areata Patients with Optical Coherence Tomography: A Case Series
Chloe Ekelem, MD, MPH | UC Irvine School of Medicine, Irvine, CA, USA

06 A Phase 2a Randomized, Placebo-controlled Study to Evaluate Efficacy and Safety of Janus Kinase Inhibitors PF-06651600 and PF-06700841 in Alopecia Areata
Elena Peeva, MD | Pfizer, Cambridge, MA, USA

08 The Relationship between Physical Activity Levels, Quality of Life and Symptoms of Depression, Anxiety and Stress in Individuals with Alopecia Areata
Yamuna Rajoo, PhD Candidate | RMIT University, Melbourne, Australia

09 The Role of Patients in the Development of the Alopecia Areata Investigator Global Assessment (AA-IGA™), a Clinician-Reported Measure Evaluating Clinically Meaningful Success in Clinical Trials
Kathleen W. Wyrwich, PhD | Eli Lilly & Company, Indianapolis, IN, USA

DISCUSSION

8:55 AM–10:10 AM  Session 6: The Basics–New Frontiers

Moderator: Angela M. Christiano, PhD | Columbia University Medical Center, New York, NY, USA

Mechanism of Hair Growth Pattern Formation
Maksim Plikus, PhD | University of California, Irvine, Irvine, CA, USA

A description of how all hair follicles on the body coordinate their regenerative activities to achieve efficient hair renewal.

The Role of Regulatory T cells in Alopecia Areata
Michael D. Rosenblum, MD, PhD | University of California San Francisco, San Francisco, CA, USA

Exploring our current understanding of the role of regulatory T cells (Tregs) in the pathogenesis of alopecia areata and the therapeutic potential of Treg augmentation for this disease.

SSEA-Positive Myeloid are Involved in Hair Loss in the AA Mouse Model
Aziz Ghahary, PhD | ICORD, University of British Columbia, Vancouver, BC, Canada

Novel induction of alopecia areata in C3H/HeJ mice shows a potential role of previously unrecognized endogenous SSEA-positive myeloid cells in driving inflammatory cascade and hair loss mechanisms.

Rare Genetic Mutations Contribute to Alopecia Areata Etiology
Lynn Petukhova, PhD | Columbia University, New York, NY, USA

While genome-wide association studies of common genetic variants in alopecia areata have highlighted etiological contributions from specific immune cells and pathways, exome studies of rare variants in patients and family members are implicating components of the hair follicle extracellular matrix, suggesting a crucial point of communication between the hair follicle and the immune system.

DISCUSSION
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<th>Time</th>
<th>Session 7: Epidemiology and Burden of Disease</th>
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<td>10:10 AM – 10:25 AM</td>
<td>Break</td>
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<td>10:25 AM – 12:00 PM</td>
<td>Moderator: Natasha A. Mesinkovska, MD, PhD</td>
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### Using Big Data to Unravel Uncommon Diseases
Amit Garg, MD | Donald and Barbara Zucker School of Medicine, New Hyde Park, NY, USA

*Observations in uncommon diseases are limited by small cohorts and selected samples which restrict the ability to make important observations on disease burden, disease course, co-morbid associations, disease outcomes, and treatment outcomes. The purpose of this talk is to describe the application of big data in overcoming such limitations.*

### Prevalence of AA in the US: Results from a Cross-Sectional Survey Study
Arash Mostaghimi, MD, MPA, MPH | Brigham & Women’s Hospital, Boston, MA, USA

*The epidemiology of alopecia areata in the United States is not currently known. This cross-sectional study of 45,000 patients establishes the current point prevalence of alopecia areata among the general population.*

### Willingness to Pay and Quality of Life in Alopecia Areata
Jean-Phillip Okhovat, MD, MPH | Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

*Measuring willingness to pay in patients with alopecia areata to gauge their willingness to pay out of pocket for a cure or control of their condition.*

### Broadening Diversity in Alopecia Areata Clinical Trial Participants
Amy McMichael, MD | Wake Forest Baptist Medical Center, Winston Salem, NC, USA

*The FDA plans to prioritize improvements in the quality of demographics subgroup data collection, reporting and analysis, encourages greater participation of diverse patients, and supports the transparency of subgroup data. To this end, ways to recruit, engage, educate, and study those of diverse backgrounds to alopecia areata trials will be discussed.*

### The NAAF Patient Registry: Driving Towards a New Understanding of Alopecia Areata
Mark Collins, PhD | Helomics Corp, Pittsburgh, PA, USA

*Through its partners, NAAF is establishing a new advanced bio-repository capability for its patient registry that will enable researchers to access high quality annotated specimens for research. New specimen storage, processing and analysis coupled to state-of-the-art information systems and analytics will be used to help researchers gain a deeper understanding of alopecia areata.*

### DISCUSSION

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<td>12:00 PM – 12:45 PM</td>
<td>CTP-543: Highlights from the Phase 2a Trial Interim Analysis</td>
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<td>James V. Cassella, PhD</td>
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*CTP-543 is an oral JAK1/JAK2 inhibitor currently in a Phase 2 trial in patients with moderate-to-severe alopecia areata. An interim analysis assessing the effects of 4 mg BID and 8 mg BID compared to placebo following 24 weeks of treatment was recently completed. Treatment with 8 mg of CTP-543 significantly improved hair regrowth in patients with alopecia areata with an acceptable safety profile.*

### DISCUSSION
Session 8: Group Breakouts

Participants will choose to join one of the four breakout groups below based on their own knowledge and expertise. The goal of these breakout groups is to discuss the following key questions within the research area:

- What has been done, where is it going and how is it related?
- What questions need to be answered and which will have the most impact?
- What resources are needed?
- What could/should NAAF do to facilitate progress?

Group leaders will facilitate dialogue and give a 10 minute report on key points of discussion in the next session.

1: Clinical Outcome Assessments  
Group Leader: Elise A. Olsen, MD | Duke University Medical Center

2: Health Economics and Burden of Disease  
Group Leader: Arash Mostaghimi, MD, MPA, MPH | Brigham & Women’s Hospital

3: Genetics, Immunology and Therapeutic Targets  
Group Leader: Angela M. Christiano, PhD | Columbia University Medical Center

4: Perspectives on Patient-Industry Engagement  
Group Leader: Dory Kranz, MBA | National Alopecia Areata Foundation

1:45 PM–2:00 PM  
Break

2:00 PM–3:00 PM  
Session 9: Breakout Reports  
Roone Arledge Auditorium (1st Floor W)

1: Clinical Outcome Assessments  
Group Leader: Elise A. Olsen, MD | Duke University Medical Center

2: Health Economics and Burden of Disease  
Group Leader: Arash Mostaghimi, MD, MPA, MPH | Brigham & Women’s Hospital

3: Genetics, Immunology and Therapeutic Targets  
Group Leader: Angela M. Christiano, PhD | Columbia University Medical Center

4: Perspectives on Patient-Industry Engagement  
Group Leader: Dory Kranz, MBA | National Alopecia Areata Foundation

DISCUSSION

3:00 PM–4:00 PM  
Closing Session

NIAMS Funding Opportunities  
Ricardo Cibotti, PhD | Division of Skin and Rheumatic Diseases, NIAMS/NIH, Bethesda, MD, USA

A comprehensive review of current NIAMS funding opportunities to support clinical and basic research in alopecia areata.

Meeting Summary, Outcomes and Action Plan  
Summit Co-Chairs: Jerry Shapiro, Natasha Mesinkovska and Angela Christiano

4:00 PM  
Close Summit
INDUSTRY PARTNERS

We gratefully acknowledge the following industry partners for their support of the 2018 Alopecia Areata Research Summit.

**Silver—$50,000 & Up**

CoNCERT Pharmaceuticals Inc.

LEOSCIENCE & TECHHUB

Lilly

**Bronze—$25,000 & Up**

ACLARIS THERAPEUTICS

BIONIZ THERAPEUTICS

Pfizer

legacy HEALTHCARE

**Other Support**

This conference was supported (in part) by the National Institute Of Arthritis And Musculoskeletal And Skin Diseases under Award Number R13AR074890. The content is solely the responsibility of the organizers and does not necessarily represent the official views of the National Institutes of Health.