TIDES: Oligonucleotide & Peptide Therapeutics

Event Guide

May 7-10, 2018
Hynes Convention Center
Boston, MA

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Event Partner: Avecia

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General Information

Admission
Admission is limited to persons actively engaged in oligonucleotide and peptide R&D and manufacturing. KNect365 has taken every effort to prohibit admissions to persons not engaged in this area. Children under 18 are not permitted in the Exhibit Hall under any circumstances. Badges and badge holders must be worn at all times while attending the event. Conference badges are non-transferable and lost badges will not be replaced without payment of the full conference registration fee. No exceptions.

Registration Desk Open
Monday, May 7 7:00 AM - 5:00 PM
Tuesday, May 8 7:00 AM - 5:30 PM
Wednesday, May 9 7:00 AM - 5:45 PM
Thursday, May 10, 8:00 AM - 3:30 PM

Exhibit Hall & Poster Viewing Hours
Tuesday, May 8 2:45 pm - 7:00 pm
Wednesday, May 9 10:00 am - 6:45 pm
Thursday, May 10 10:00 am - 2:00 pm

Video/Photo Consent Policy
This conference is being filmed. When you enter this event, you may be in areas that are being filmed by video or photography. By entering the event premises, you consent to the filming, display, release, publication, exhibition or reproduction of your image and anything spoken by you to be used for news, Web casts, promotional purposes, telecasts, advertising, inclusion on Web sites, or any other purposes by KNect365 Life Sciences. You release KNect365 Life Sciences and its respective affiliates, employees and representatives, and each and all persons involved from any liability connected with such filming. You have been fully informed of your consent and release.

Program Changes
KNect365 does everything in its power to ensure there are no changes to the published program but sometimes circumstances that are beyond our control (i.e. speaker cancellations, speaker changes, etc.) do arise. In the event this does occur, every effort is made to find a suitable replacement. Please Note: The listings and contents of this book are proprietary and cannot be reproduced in part or in whole without permission. Every effort has been made to ensure the accuracy of this Guide. However, KNect365 Life Sciences cannot be held responsible for errors or omissions. Product names may be trademarks or registered trademarks of their companies.

TIDES Networking App
All registered attendees have access to the TIDES Networking App, our digital tool that allows you to view the full attendee list, send meeting requests, access speaker slides and create a custom agenda. If you need assistance with the app, please visit the registration desk or contact howard.choi@knect365.com.

Assistance and Special Needs
Organizers of the TIDES Conference fully support the Americans with Disabilities Act. If you require assistance of any kind, please inquire at Attendee Registration.

Lost and Found
Items found can be dropped off at Attendee Registration. Items not claimed by the conclusion of the conference will be turned over to building security.

Coat Check
A complimentary coat check will be available Monday through Thursday for all TIDES attendees on Level 3 – Room 305.

Passport Contest
All registered attendees receive access to the TIDES app, which allows you to view the full attendee list, schedule meetings, win prizes in the passport contest and more. Download the app on your iOS/Android mobile device by searching for ‘KNect365’ in the app store. All attendees were emailed their log in details before the event. Please visit our team at the registration desk if you need assistance.

Have Your Silhouette Cut!
See our silhouette artist in the exhibit hall Tuesday through Wednesday

WiFi
WiFi Network: Hynes
Follow us on Twitter @TIDES365 and tweet using hash tag #TIDES365
Join KNect365 Life Sciences’ LinkedIn group and becoming a member of our LinkedIn groups: Oligonucleotide and Peptide Development Professionals

Health and Safety Guidelines
The fire alarm sound in this building is a siren
If you discover a fire raise the main alarm at the security desk or at any pull station located throughout the venue.
Do not stop to collect your belongings or use elevators
Do not obstruct any exits or gangways
There is a no smoking policy at this event
The assembly point for this event is located at Trader Joe’s at 899 Boylston Street - outside the Boylston Street exit across the street.
Should you require special assistance please tell a member of KNect365 staff
Please be responsible when plugging laptop and mobile chargers into sockets
## Agenda At-A-Glance

**MONDAY, MAY 7, 2018 • Pre-Conference Workshops**

<table>
<thead>
<tr>
<th>Time</th>
<th>Workshop #1: Mass Spectrometry for Peptides and Oligonucleotides (Room 202)</th>
<th>Workshop #2: An Introduction to messenger RNA (mRNA) Therapeutics (Room 208)</th>
<th>Workshop #3: Risk-Based Approaches to CMC Development of Therapeutic Oligonucleotides (Room 207)</th>
<th>Workshop #4: Novel Technologies for Manufacturing Peptides (Room 203)</th>
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**TUESDAY, MAY 8, 2018 • Main Conference**

**KEYNOTE SESSION:** Dr. Robert Langer, Massachusetts Institute of Technology, Jesper Lau, Ph.D., Novo Nordisk A/S, Denmark, John Maraganore, Ph.D., Alnylam Pharmaceuticals, Stéphane Bancel, Moderna Therapeutics

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<td>TIDES Brewery Event Co-Sponsored by Thermo Fisher Scientific and KNect365</td>
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<td>8:00 am</td>
<td>Breakfast (Boynton Hallway - Prefunction Area)</td>
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<tr>
<td>8:25 am</td>
<td>Spotlight Lunch &amp; Poster Viewing Sessions Sponsore by GAP Peptides (Room 210), Nagase (Room 208), Trilink (Room 207)</td>
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<tr>
<td>9:00 am</td>
<td>Plenary Session (Room 302/304/306)</td>
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<td>Spotlight Luncheon Presentations Sponsored by GAP Peptides (Room 210), Nagase (Room 208), Trilink (Room 207)</td>
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<tr>
<td>9:30 am</td>
<td>Networking Reception in Poster and Exhibit Hall Sponsored by Ajinomoto and Ribibio</td>
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<tr>
<td>9:45 am</td>
<td>Workshop Lunch (Room 210)</td>
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<tr>
<td>9:45 am</td>
<td>Networking Lunch &amp; Poster Viewing Sessions Sponsore by BioSpring GmbH (Room 304), Ajinomoto Co. Inc. (Room 302), USP (Room 306)</td>
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**WEDNESDAY, MAY 9, 2018 • Main Conference**

**Breakfast Spotlight Presentations** Sponsored by ST Pharm (Room 302), Polymun Scientific (Room 306)

**KEYNOTE SESSION:** Dr. Robert Langer, Massachusetts Institute of Technology, Jesper Lau, Ph.D., Novo Nordisk A/S, Denmark, John Maraganore, Ph.D., Alnylam Pharmaceuticals, Stéphane Bancel, Moderna Therapeutics

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<tr>
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<td>Networking Lunch &amp; Poster Viewing Sessions Sponsore by BioSpring GmbH (Room 304), Ajinomoto Co. Inc. (Room 302), USP (Room 306)</td>
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**THURSDAY, MAY 10, 2018 • Main Conference**

**Breakfast Spotlight Presentations** Sponsored by CordenPharma (Room 306), Intertek (Room 302), Sumitomo Chemical (Room 304)

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<td>Networking Reception in Poster and Exhibit Hall Sponsored by Bachem</td>
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<td>Networking Lunch &amp; Poster Viewing Sessions Sponsore by BioSpring GmbH (Room 304), Ajinomoto Co. Inc. (Room 302), USP (Room 306)</td>
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# Thank You to Our Sponsors

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<td>Wednesday Night Reception Sponsor:</td>
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<td>Spotlight Presentation Sponsors:</td>
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<td>Lanyard Sponsor:</td>
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TIDES PASSPORT CONTEST – PARTICIPATE AND WIN PRIZES!

Don’t miss out on this fun and interactive tour through the Exhibit Hall. Stop by booths marked with a Passport stop around the Exhibit Hall and use the App to scan their QR code. Visit all participating booths up until 1:30 pm on Thursday, to not only walk away with innovative ideas but to have a chance of winning some fabulous prizes. Prizes will be drawn at 1:45 pm on Thursday.

1. Visit each booth in the Exhibit Hall listed in your passport. Each booth will be labeled as a “Passport Stop”.

2. Download the ‘KNect365’ app on your smartphone and log in using your TIDES networking app login. Go to the ‘Passport Prize Program’ tab and use your phone’s QR scanner and scan each participating exhibitor. Please visit the registration desk if you need your app log in details.

3. Attendees are to have scanned ALL participating exhibitors by 1:30 pm on Thursday. The winners will be announced at 1:45 at Booth #140 at the back of the Exhibit Hall. You MUST be present to win.

Thanks to our exhibitors for donating the following prizes:

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<th>Prize</th>
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Check the App for an updated list

TIDES Europe

• EuroTIDES
• EuroPEPTIDES

6-9 November 2018
Postillion Convention Centre
Amsterdam

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MONDAY, MAY 7, 2018 • PRE-CONFERENCE WORKSHOPS

7:00 Registration & Breakfast (Prefunction Hall D)

Workshop #1: MASS SPECTROMETRY FOR PEPTIDES AND OLIGONUCLEOTIDES
Morning Half-Day Workshop • 8:00am-12:00pm

Room 202
8:00 Workshop Leader’s Welcome and Opening Remarks
Fanyu Meng, Ph.D., Principal Scientist, Analytical Research and Development, Merck Research Labs, Merck & Co., Inc., Switzerland
8:15 Contribution of High Resolution Mass Spectrometry in Synthetic Peptides: Importance of Detailed Impurity Characterization for Better Manufacturing
David Cosquer, Mass Spectrometry Specialist, Analytical Development, PolyPeptide, Belgium
8:45 LC/MS Oligonucleotide Mass Fingerprinting Enables Rapid Characterization of Critical Quality Attributes in Therapeutic mRNA
Serenus Hua, Ph.D., Senior Scientist, Moderna Therapeutics, Belgium
9:15 Assessment of Peptide Metabolism at the Subcutaneous Injection Site by Liquid Chromatography-high Resolution Mass Spectrometry
Simone Esposito, Ph.D., DMF Research Scientist, Chemistry - Preclinical Research Unit, IRBM Science Park, Italy
9:45 Networking Refreshment Break
10:15 Oligonucleotide Characterization: Applications and Uses of Mass Spectrometry
Gangani Silva, Ph.D., Senior Scientist, Analytical Development, Nitto Avecia
10:45 LC Peak Purity Assessment Using a Novel LC-MS Data Processing Approach
Patrik Plattner, Ph.D., Group Leader Mass Spectrometry Service, Bachem AG, Switzerland
11:15 Mass Spectrometry Methodologies for Analytical Control of Synthetic Oligonucleotides
Fanyu Meng, Ph.D., Principal Scientist, Analytical Research and Development, Merck Research Labs, Merck & Co., Inc.
11:45 Concluding Remarks and Discussion
12:00 Close of workshop - lunch in Rm. 210

Workshop #2: AN INTRODUCTION TO messenger RNA (mRNA) THERAPEUTICS
Morning Half-Day Workshop • 8:00am-12:00pm

Room 208
8:00 Workshop Leader’s Welcome and Opening Remarks
Jim Thompson, Ph.D., Head CMC Project Management, Moderna Therapeutics
8:15 Introduction to mRNA Therapeutics
Jim Thompson, Ph.D., Head CMC Project Management, Moderna Therapeutics
9:00 Design and Manufacturing of Chemically Modified Messenger RNA Therapeutics
Anton McCaffrey, Ph.D., Senior Director of Research and Development, Biology, TriLink BioTechnologies, Inc.
10:00 Networking Refreshment Break
10:30 Delivery Strategies for mRNAs
Luis Brito, Ph.D., Director, Formulation Design, Moderna Therapeutics
11:00 Applications of mRNA Therapeutics
Patrick Baumhof, Ph.D., Vice President, Formulation and Delivery, Curevac, Germany
11:30 Panel Discussion and Q&A
12:00 Close of workshop - lunch in Rm. 210

Workshop #3: RISK-BASED APPROACHES TO CMC DEVELOPMENT OF THERAPEUTIC OLIGONUCLEOTIDES
Morning Half-Day Workshop • 8:00am-12:00pm

Room 207
There is a growing trend in the pharmaceutical industry towards accelerated development of therapeutics to address unmet medical needs. The shorter timelines coupled with increasing complexity of the development candidates and/or delivery systems presents extraordinary challenges for managing the chemistry, manufacturing and controls activities. Key to regulatory and operational success is a risk based approach to management of manufacturing, product quality and supply chain. This workshop will address important concepts for balancing and mitigating a variety of risks (safety, economic or regulatory, etc.) towards successful clinical development, regulatory approval and commercialization of therapeutic oligonucleotides.
8:00 Workshop Co-Leaders’ Welcome and Opening Remarks
G. Susan Srivatsa, Ph.D., President, ElxinPharma
Trishul Shah, Director, Business Development, North America, PolyPeptide
8:20 Selection and Justification of Regulatory Starting Materials
Paul McCormac, Ph.D., Executive Director, Pfizer Bio-therapeutic Pharmaceutical Sciences
8:45 Impurities in Oligonucleotide Drug Substances and Drug Products: Safety Considerations
Tom Zanardi, Ph.D., Director, Toxicology, Ionis Pharmaceuticals
9:10 Networking Refreshment Break
10:10 Planning for Oligonucleotide Supply: Personalized Medicine to Large Scale Markets
Hans Kistemaker, Ph.D., Senior Scientist, Chemistry & Manufacturing, ProQR Therapeutics, The Netherlands
10:50 Case Study: Evolution of the Rent, Buy or DIY Strategy
Lubomir Nechev, Ph.D., Vice President, Process Sciences, Alnylam Pharmaceuticals
11:30 Panel Discussion
12:00 Close of workshop - lunch in Rm. 210

Workshop #4: NOVEL TECHNOLOGIES FOR MANUFACTURING PEPTIDES
Morning Half-Day Workshop • 8:00am-12:00pm

Room 203
8:00 Workshop Leader’s Welcome and Opening Remarks
Trishul Shah, Director, Business Development, North America, PolyPeptide
8:15 Chemo-enzymatic Synthesis (CEPS) of Exenatide: Laboratory Scale Development
Timo Nuijens, Ph.D., Lead Scientist, EnzyPep BV, The Netherlands
8:45 Cost Efficient Peptide Purification via ZEOsphere DRP Mixed-Mode Chromatography
Jürgen Machielse, Business Development Director Spherical Gels, Zeochem, Switzerland
9:00 Towards Commercial Manufacturing of Therapeutic Peptides Using Chemo-enzymatic Peptide Synthesis (CEPS)
Jan Pawlas, Ph.D., Scientist, PolyPeptide Group, Sweden
9:30 Bringing Continuous Manufacturing into Peptide Manufacturing
Andreas Segenroos, CEO, Swedish Biomimetics 3000®
10:00 Networking Refreshment Break
10:30 Group-Assisted Purification (GAP) Technology and Its Future Potential for Peptide Synthesis
Cale Seffert, Ph.D., Chief Scientific Officer, GAP Peptides, LLC
11:00 Unlocking the Potential for the Future of SPPS
Jon Holbech Rasmussen, Ph.D., Director, Global Development, PolyPeptide Group, Sweden
11:30 Panel Discussion
12:00 Close of workshop - lunch in Rm. 210
Agilent Technologies has acquired a 20 acre plot in Frederick, Colorado. Construction of the new pharmaceutical facility will be completed this year and cGMP operations will commence in 2019.

The expansion will enable the company to more than double its commercial manufacturing capacity for nucleic acid based therapeutics.

Visit us at Booth 315 to learn more.

www.agilent.com/chem/nucleicacid

pdl-boulderinfo@agilent.com
Workshop #5: PEPTIDE AGGREGATION CHALLENGES FROM API TO DRUG PRODUCT
Afternoon Half-Day Workshop • 1:00pm-5:00pm

Room 202
1:00 Workshop Leader's Welcome and Opening Remarks
Trishul Shah, Director, Business Development, North America, PolyPeptide
1:15 Peptide Aggregation
Juerg Tschopp, Ph.D., Chief Executive Officer & President, Stratum Medical Corporation
2:00 Assessment of Deamidation and Aggregation of Peptide Variants
Mohammad Al-Sayah, Ph.D., Senior Scientist, Genentech, Inc.
2:45 Networking Refreshment Break
3:15 The Effect of Peptide Aggregation on Downstream Purification: A DISASTER
Imre Sallay, Ph.D., Manager, Technical Sales, DAISOGEI Group, Osaka Soda, Co., Ltd., Japan
4:00 Solid-State NMR Investigation of Insoluble Aggregation of Peptide Drugs
Yongchao Su, Ph.D., Associate Principal Scientist, Merck & Co.
4:30 Panel Discussion
5:00 Close of Workshop

Workshop #7: LESSONS FROM THE PEPTIDE FIELD THAT CAN BE APPLIED TO Oligonucleotides
Afternoon Half-Day Workshop • 1:00pm-5:00pm

Room 203
1:00 Workshop Leader's Welcome and Opening Remarks
Gary Musso, Ph.D., President, Musso and Associates LLC
1:10 Introductory Presentation on Peptide Chemistry
Michael Verlander, President, Proactive Quality Compliance, Inc.
1:35 Synergy between Synthesis of Oligonucleotide and Peptide: From Concepts to Practical Applications
Yogesh S. Sanghvi, Ph.D., President, Rasayan, Inc.
2:00 A Triple Contemplation – Regulatory Considerations on Recombinant Proteins, Synthetic Peptides and Oligonucleotides
René Thürmer, Ph.D., Deputy Head, Unit Pharmaceutical Biotechnology, BfArM Federal Institute for Drugs and Medical Devices, Germany
2:45 Networking Refreshment Break
3:15 An Engineer's Perspective on Oligonucleotide Manufacturing and Applications from the Peptide Field
Christina Nacos, Associate Director, Oligonucleotides, Corden Pharma Colorado
3:40 Peptide and Oligonucleotide Therapeutics: Bioanalytical Challenges and Lessons Learned
Rafiq Islam, Senior Director Bioanalytical Services, Celerion
4:05 Alternative Manufacturing Strategies and Concepts Used on Peptides; Considerations for Use in Oligonucleotides
Gary Musso, Ph.D., President, Musso and Associates LLC
4:30 Panel Discussion
5:00 Close of Workshop

Workshop #6: AN INTRODUCTION TO CRISPR AND GENOME EDITING APPLICATIONS
Afternoon Half-Day Workshop • 1:00pm-5:00pm

Room 208
1:00 Workshop Leader's Welcome and Opening Remarks
Cecilia Fernández, Ph.D., Senior Director, Platform Strategy and Operations, Editas Medicine
1:15 CRISPR's Road to the Clinic
TJ Cradick, Ph.D., Head of Genome Editing, CRISPR Therapeutics
1:45 Development of High Quality CRISPR/CAS9 Agents
Terence Ta, Ph.D., Scientist II, Editas Medicine
2:15 Genome instability and Cas9 Specificity
Tom Barnes, Ph.D., Senior Vice President, Innovative Sciences, Intellia Therapeutics
2:45 Networking Refreshment Break
3:15 Peptide Technology to Deliver CRISPR Ribonucleoprotein in Cells
David Guay, Ph.D., Research Director, Feldan Therapeutics, Canada
3:45 Delivery of CRISPR/Cas RNP Using Polymer Nanoparticle System
Kunwoo Lee, Ph.D., Chief Executive Officer, GenEdit
4:15 Panel Discussion
4:45 Close of Workshop

Workshop #8: THE PATH TO A SUCCESSFUL Oligonucleotide IND/IMPD SUBMISSION: REGULATORY, NONCLINICAL AND CMC PERSPECTIVES
Afternoon Half-Day Workshop • 1:00pm-5:00pm

Room 207
1:00 Workshop Leader's Welcome and Opening Remarks
Jennifer Lockridge, SVP, Program Development, Dicerna Pharmaceuticals, Inc.
1:15 Regulatory Perspectives and Points to Consider in Making Successful Oligonucleotide IND/CTA Submissions
Paul Manley, President and Principal Consultant, Orvieto Consulting
2:00 CMC Perspectives on Oligonucleotides
Vidhya Gopalakrishnan, Ph.D., Senior Vice President, Pharmaceutical Development, Quark Pharmaceuticals, Inc.
2:45 Networking Refreshment Break
3:15 Considerations for the Early Preclinical Development of Oligonucleotide-based Therapeutics
Sarah Voytek, Ph.D., Associate Director, Preclinical Development, Bluebird Bio
4:00 Case Study: Lessons Learned from IND/IMPD Submissions for DCR-PH1, A Synthetic siRNA in a Lipid Nanoparticle Formulation
Jennifer Lockridge, SVP, Program Development, Dicerna Pharmaceuticals, Inc.
4:30 Panel Discussion
5:00 Close of Workshop

TIDES BREWERY EVENT
May 7 from 5:30pm-8:30pm

See what’s brewing at Harpoon! Join us at this exclusive TIDES event at the Harpoon Brewery & Beer Hall, located in Boston's Seaport District. Harpoon offers a full selection of Harpoon beers straight from the source along with delicious pretzels to pair with your pint. Cap off your evening by taking a guided tour of the brewery or challenge a coworker to a game of giant Jenga! This is the perfect place to enjoy beer with TIDES attendees and our sponsor Thermo Fisher Scientific. Please note that space is limited and subject to availability. Please visit the registration desk to inquire about availability. Buses will depart at 5:30pm from the Boylston Street entrance.

See what’s brewing at Harpoon! Join us at this exclusive TIDES event at the Harpoon Brewery & Beer Hall, located in Boston's Seaport District. Harpoon offers a full selection of Harpoon beers straight from the source along with delicious pretzels to pair with your pint. Cap off your evening by taking a guided tour of the brewery or challenge a coworker to a game of giant Jenga! This is the perfect place to enjoy beer with TIDES attendees and our sponsor Thermo Fisher Scientific. Please note that space is limited and subject to availability. Please visit the registration desk to inquire about availability. Buses will depart at 5:30pm from the Boylston Street entrance.

*Schedule subject to change
Visit AIC at Booth 305

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7:00 Registration and Breakfast

8:00 Chairperson’s Remarks
Muthiah (Mano) Manoharan, Ph.D., Senior Vice President of Drug Discovery, Alnylam Pharmaceuticals

8:10 Advances in Drug Carriers of Medicine
Dr. Robert Langer
David H. Koch Institute Professor, Koch Institute of Integrative Cancer Research, Massachusetts Institute of Technology

8:55 Keynote Q&A

9:00 RNAi Therapeutics Delivered: Patisiran and Beyond
John Maraganore, Ph.D.
Chief Executive Officer, Alnylam Pharmaceuticals

9:45 Networking Refreshment Break

10:15 The Discovery of Semaglutide – A Journey from Ala Scan to Structural Design of GLP-1 Analogues
Jesper Lau, Ph.D.
Vice President, Protein & Peptide Chemistry, Novo Nordisk A/S, Denmark

11:00 Thoughts on Building a Biotech Company Enabled by New Science
Stéphane Bancel
Chief Executive Officer, Moderna Therapeutics

11:45-12:55 SPOTLIGHT PRESENTATION LUNCHEONS

**Room 208**
Solution-phase Synthesis of Oligonucleotides via Segmental Approach
Mamoru Hyodo, Ph.D., Chief Researcher, R&D Unit, Shikoku Nucleic Acid Chemistry (S-NAC), Japan

**Room 207**
Advantages of in vivo DNA Barcoding in Nanoparticle Selection and Therapeutic Gene Editing at the Target Site with CRISPR/CAS9 for β-thalassemia
James Dahlman, Ph.D., Assistant Professor, Biomedical Engineering, Georgia Institute of Technology and Emory Medical School
Mike Houston, Ph.D., Chief Scientific Officer, TriLink BioTechnologies
TJ Cradick, Ph.D., Head of Genome Editing, CRISPR Therapeutics

*Schedule subject to change*
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12:55 Chairperson’s Remarks
Cecilia Fernández, Ph.D., Senior Director, Platform Strategy and Operations, Editas Medicine

1:00 Fireside Chat: The Emergence of CRISPR Therapeutics
Bill Lundberg, M.D., Chief Scientific Officer, CRISPR Therapeutics
Vic Myer, Ph.D., Chief Technology Officer, Editas Medicine
Tom Barnes, Ph.D., Senior Vice President, Innovative Sciences, Intellia Therapeutics

1:45 MC4R Pathway Defects: Treatment of Rare Monogenic Forms of Obesity
Lex Van der Ploeg, Ph.D., Chief Scientific Officer, Rhythm Pharmaceuticals

2:15 Launching Clinical Antisense Oligonucleotide Manufacturing Capability in a Biologics Company
Sheron Branham, Associate Director, ASO Process Engineering and Manufacturing, Drug Product Facility, Biogen

2:45 Grand Opening of Poster and Exhibit Hall and Networking Refreshment Break

CMC for Oligonucleotides and Peptides: Current Regulatory Trends

3:25 Chairperson’s Remarks
G. Susan Srivatsa, Ph.D., President, ElixinPharma

3:30 CMC Regulatory Considerations for Oligonucleotides and Peptides: What Are the Common Questions and Challenges Faced by Both Oligo and Peptide Developers
René Thürmer, Ph.D., Deputy Head, Unit Pharmaceutical Biotechnology, BfArM Federal Institute for Drugs and Medical Devices, Germany

4:00 CMC Regulatory Perspectives and Strategies: Integrating Experiences from Different Product Modalities to Accelerate Development of New Molecules
Allison Wolf, Principal Research Scientist, Global Regulatory Affairs CMC, Eli Lilly

4:30 SPINRAZA® (nusinersen) Approval: CMC Strategies and Lessons Learned
Firoz D. Antia, Ph.D., Director, Antisense Oligonucleotide Process Development and Manufacturing, Biogen

5:00 CMC Regulatory Panel Discussion
Moderator:
G. Susan Srivatsa, Ph.D., President, ElixinPharma
Panelists:
René Thürmer, Ph.D., Deputy Head, Unit Pharmaceutical Biotechnology, BfArM Federal Institute for Drugs and Medical Devices, Germany
Allison Wolf, Principal Research Scientist, Global Regulatory Affairs CMC, Eli Lilly
Firoz D. Antia, Ph.D., Director, Antisense Oligonucleotide Process Development and Manufacturing, Biogen

5:30pm-7:00pm
Networking Reception in Poster and Exhibit Hall
Join fellow attendees and speakers for the TIDES opening night networking reception. Enjoy drinks and appetizers to live rock and roll with colleagues while viewing the exhibits and scientific poster sessions.
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NAGASE Booth 630
Nagase introduces unique technologies for peptide and nucleotide area. One is Liquid-Phase Oligonucleotide Synthesis by Segment Condensation and another is Maruoka Catalyst® which can create UNAA (Unnatural amino acid). LPOSSC brings high output and less purification loss. See you on Day 3 at Breakfast Presentation by Mr. Kataoka.
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BIOSPRING The Oligo Company Booth 342
Since 1997, the BioSpring team has provided oligonucleotides of highest quality at all scales for various applications. Since 2007, BioSpring is cGMP certified for manufacturing therapeutic oligonucleotides. Our customers from all over the world rely on BioSpring’s individually tailored production and analytical services.
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<tr>
<th>Time</th>
<th>Session Title</th>
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<tr>
<td>7:30</td>
<td>Registration and Coffee (Boylston Hallway - Prefunction Area)</td>
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<tr>
<td>7:45</td>
<td><strong>Breakfast Spotlight Presentation</strong></td>
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<td>8:25</td>
<td><strong>Room 304</strong></td>
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<tr>
<td>8:30</td>
<td>Chairperson’s Welcome and Opening Remarks</td>
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<tr>
<td>8:35</td>
<td>Develop Antisense Therapies for Genetic Diseases</td>
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<td>9:00</td>
<td>From Discovery to the Clinic: Translational Strategies for Oligonucleotides</td>
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<td>9:30</td>
<td>mRNA Therapies for Acute Regenerative and Chronic Approaches</td>
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<td>10:00</td>
<td>Networking Refreshment Break in Poster and Exhibit Hall</td>
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<td>Development of RNAI-based Modulation of sFLT1 as a Novel Approach for Treatment of Preeclampsia</td>
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<td>11:15</td>
<td>Stereocellular Control of Antisense Oligonucleotides Enhances Target Efficacy</td>
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<td>Sustained Suppression of Huntingtin mRNA and Protein through the Central Nervous System after Intrathecal Administration of Antisense Oligonucleotides</td>
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*Schedule subject to change*
### Track 1: Oligonucleotide Discovery, Preclinical and Clinical

**Room 302/304**

**1:55** Chairperson’s Remarks
Cindy Berman, Ph.D., Toxicology Consultant

**2:00** Introduction of the Oligonucleotide Safety Working Group (OSWG)
Jeffrey Foy, Ph.D., Director, Nonclinical Writing & Documentation, Celgene

**2:30** From Excitement to Despair to Exhilaration in 13 Months – The Story of Arrowhead’s Move from DPCs to the TRiM™ Platform
Thomas Schluep, Vice President, Program Management, Arrowhead Pharmaceuticals

**3:00** Improved Specificity of Conjugate siRNAs through Chemical Modifications
Mark K. Schlegel, Ph.D., Senior Scientist, RNAi Discovery, Alnylam Pharmaceuticals

**3:30** Networking Reception Break in Poster and Exhibit Hall

### Track 2: Oligonucleotide Chemistry, Manufacturing and Controls

**Room 306**

**1:55** Chairperson’s Remarks
Ved Srivastava, Ph.D., Vice President, Chemistry, Intarcia Therapeutics

**2:00** Engineering “Smartness” into Insulin: Glycosylated Insulins with Responsivity to Physiological Levels of Glucose
Songjian Lin, Ph.D., Director, Chemistry Modalities, Merck Research Laboratories

**2:30** Clinical Development of Oral Calcitonin for Osteoporosis
Nazer Mehta, Ph.D., Principal, Peptide Technologies LLC

**3:00** Designing Peptides for the Medicin Drug Delivery System™
Andrew A. Young, M.D., Ph.D., Chief Scientific Officer, Intarcia Therapeutics, Inc.

**3:30** Networking Refreshment Break in Poster and Exhibit Hall

### Track 3: Peptide Discovery, Preclinical and Clinical

**Room 309**

**1:55** Chairperson’s Remarks
Marian Gindy, Ph.D., Executive Director, Pharmaceutical Sciences, Merck Research Laboratories

**2:00** Overcoming Endosomal Entrapment in Drug Delivery with Cyclic Cell-Penetrating Peptides
Dehua Pei, Ph.D., Professor, Department of Chemistry and Biochemistry, Ohio State University

**2:30** Targeted Delivery of Antisense Oligonucleotides to Pancreatic B-cells
Shalini Andersson, Ph.D., Senior Director Drug Metabolism & Pharmacokinetics, CVMD Innovative Medicines, AstraZeneca, Sweden

**3:00** Design and Development of Lipid Nanoparticles for mRNA Vaccines
Marian Gindy, Ph.D., Executive Director, Pharmaceutical Sciences, Merck Research Laboratories

### Track 4: Peptide Chemistry, Manufacturing and Controls

**Room 313**

**1:55** Chairperson’s Remarks
Andrew Kuhn, Ph.D., Vice President RNA Biochemistry & Manufacturing, BioNTech RNA, Germany Pharmaceuticals GmbH

**2:00** mRNA Therapeutics: Ex-vivo and In-vivo Modification of Antigen Presenting Cells
Kris Thielemans, M.D., Ph.D., Professor, Vrije Universiteit Brussel and Chief Scientific Officer, eTheRNA immunotherapies NV, Belgium

**2:30** mRNA-based Cancer Immunotherapeutics
Robert Jabulowsky, Ph.D., Deputy Head of Project Management, BioNTech AG, Germany

**3:00** VEGF mRNA in Cardiovascular Disease
Anna Collen, Ph.D., Project Leader VEGF Project, AstraZeneca, Sweden

### Track 5: mRNA, CRISPR and Hot Topics in Oligonucleotides

**Room 313**

**1:55** Chairperson’s Remarks
Peter Lutwyche, Ph.D., CTO & Vancouver Site Head, Genevant Sciences Corporation, Canada

**2:00** Essential Quality Attributes of mRNA-containing Lipid Nanoparticles
Mark Neben, Ph.D., Senior Director, Regulytx Therapeutics

**2:30** Quality Control of mRNA for Preclinical and Clinical Studies
Kristian Link, Ph.D., Associate Director, Analytical Development, Moderna Therapeutics

### Track 6: Delivery of Macromolecular Therapeutics

**Room 309**

**1:55** Chairperson’s Remarks
Robert Jabulowsky, Ph.D., Deputy Head of Project Management, BioNTech AG, Germany

**2:00** Robust In Vivo Gene Editing with Systemic Lipid Nanoparticle Delivery of CRISPR/Cas9 RNA Components
Amy Rhoden Smith, Ph.D., Principal Scientist, Intellia Therapeutics

**2:30** Quality Control of mRNA for Preclinical and Clinical Studies
Andreas Kuhn, Ph.D., Vice President RNA Biochemistry & Manufacturing, BioNTech RNA Pharmaceuticals GmbH, Germany

### Track 7: mRNA CMC and Manufacturing

**Room 313**

**1:55** Chairperson’s Remarks
Marian Gindy, Ph.D., Executive Director, Pharmaceutical Sciences, Merck Research Laboratories

**2:00** Essential Quality Attributes of mRNA-containing Lipid Nanoparticles
Peter Lutwyche, Ph.D., CTO & Vancouver Site Head, Genevant Sciences Corporation, Canada

**2:30** Quality Control of mRNA for Preclinical and Clinical Studies
Andreas Kuhn, Ph.D., Vice President RNA Biochemistry & Manufacturing, BioNTech RNA Pharmaceuticals GmbH, Germany

### Nonclinical Development of Oligonucleotides

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Cindy Berman, Ph.D., Toxicology Consultant

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Jeffrey Foy, Ph.D., Director, Nonclinical Writing & Documentation, Celgene

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Thomas Schluep, Vice President, Program Management, Arrowhead Pharmaceuticals

**3:00** Improved Specificity of Conjugate siRNAs through Chemical Modifications
Mark K. Schlegel, Ph.D., Senior Scientist, RNAi Discovery, Alnylam Pharmaceuticals

### Peptide Preclinical and Clinical

**Room 306**

**1:55** Chairperson’s Remarks
Ved Srivastava, Ph.D., Vice President, Chemistry, Intarcia Therapeutics

**2:00** Engineering “Smartness” into Insulin: Glycosylated Insulins with Responsivity to Physiological Levels of Glucose
Songjian Lin, Ph.D., Director, Chemistry Modalities, Merck Research Laboratories

**2:30** Clinical Development of Oral Calcitonin for Osteoporosis
Nazer Mehta, Ph.D., Principal, Peptide Technologies LLC

**3:00** Designing Peptides for the Medicin Drug Delivery System™
Andrew A. Young, M.D., Ph.D., Chief Scientific Officer, Intarcia Therapeutics, Inc.

### Delivery: Cross-Fertilizing Ideas from Oligonucleotides, Peptides, mRNA and CRISPR

**Room 309**

**1:55** Chairperson’s Remarks
Marian Gindy, Ph.D., Executive Director, Pharmaceutical Sciences, Merck Research Laboratories

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Dehua Pei, Ph.D., Professor, Department of Chemistry and Biochemistry, Ohio State University

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Shalini Andersson, Ph.D., Senior Director Drug Metabolism & Pharmacokinetics, CVMD Innovative Medicines, AstraZeneca, Sweden

**3:00** Design and Development of Lipid Nanoparticles for mRNA Vaccines
Marian Gindy, Ph.D., Executive Director, Pharmaceutical Sciences, Merck Research Laboratories

### Transcriptomic Analysis

**Room 313**

**1:55** Chairperson’s Remarks
Andrew Kuhn, Ph.D., Vice President RNA Biochemistry & Manufacturing, BioNTech RNA, Germany Pharmaceuticals GmbH

**2:00** Essential Quality Attributes of mRNA-containing Lipid Nanoparticles
Peter Lutwyche, Ph.D., CTO & Vancouver Site Head, Genevant Sciences Corporation, Canada

**2:30** Quality Control of mRNA for Preclinical and Clinical Studies
Andreas Kuhn, Ph.D., Vice President RNA Biochemistry & Manufacturing, BioNTech RNA Pharmaceuticals GmbH, Germany

### Networking Reception in Poster and Exhibit Hall

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<tr>
<th>Time</th>
<th>Track 1: Oligonucleotide Discovery, Preclinical and Clinical</th>
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<td>Paul Metz, Principal Consultant, Metz Biotechnology Consulting, LLC</td>
<td>Claus Rentel, Ph.D., Executive Director, Ionis Pharmaceuticals</td>
<td>Trishul Shah, Director, Business Development, North America, Polypeptide Therapeutics</td>
<td>Arthur A. Levin, EVP Research and Development, Avidity Biosciences</td>
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<td>8:30</td>
<td>HEPLISAV-B Path to Approval</td>
<td>Transfer of Analytical Methods for DNA and MOE Phosphoramidites from LC-LC TOF Mass Spectrometry</td>
<td>Registration of Generic Peptide Drug Substances, Where Are the Challenges and How Should These Be Approached?</td>
<td>Development of Cellular Therapies Using CRISPR</td>
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<td>HEPLISAV-B Path to Approval</td>
<td>Kyeong Eun Jung, Ph.D., Senior VP, Head of Oligo and R&amp;D Division, ST Phann. Co. Ltd., South Korea</td>
<td>Peter Larsson, Global Director Regulatory Affairs, PolyPeptide Group, Sweden</td>
<td>Vic Myer, Ph.D., Chief Technology Officer, Editas Medicine</td>
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<td>9:00</td>
<td>Temporary Inhibition of P53 for Tissue Protection: From Therapeutic Concept to Prevention of Acute Kidney Injury in Humans following Kidney Transplantation and Cardiac Surgery</td>
<td>Analytics for Oligonucleotides</td>
<td>(9:30) Opportunities and Challenges of the FDA Draft Guidance ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin</td>
<td>Enhancing the Versatility of CRISPR Genome Editing</td>
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<td>Elena Feinstein, M.D., Ph.D., Chief Scientific Officer, Quark Pharmaceuticals, Israel</td>
<td>Development of a Platform Impurity Characterization Method for RNAi Therapeutics</td>
<td>Gerhard Haas, Ph.D., Vice President, Quality Assurance and Regulatory Affairs, Bachem AG, Switzerland</td>
<td>Benjamin Kleinstein, Ph.D., Pathology Instructor, Massachusetts General Hospital</td>
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<td>9:30</td>
<td>Novel Chemical Modifications for Improving Pharmacological Function of siRNAs</td>
<td>Assay Determination by Mass Spectrometry for Oligonucleotide Therapeutics</td>
<td>Panel Discussion</td>
<td>Heavily Modified Guides for Spycas9-mediated Genome Editing</td>
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<td>Muthiah (Mano) Manoharan, Ph.D., Senior Vice President of Drug Discovery, Ionis Pharmaceuticals</td>
<td>Mark Madsen, Ph.D., Associate Director, Analytical Development, Ionis Pharmaceuticals</td>
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<td>Jonathan K. Watts, Ph.D., Associate Professor, RNA Therapeutics Institute, University of Massachusetts Medical School</td>
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<td>Networking Refreshment Break in Poster and Exhibit Hall</td>
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<td>10:45</td>
<td>Advanced GalNAc-siRNA Platform and Its Therapeutic Applications</td>
<td>Improving Specificity of Reverse-Phase Analytical Purity Methods for Oligonucleotides</td>
<td>Bachem's Experience with the Registration of Peptide APIs in Japan</td>
<td>RNA Activation in NASH, Liver Failure and Hepatocellular Carcinoma</td>
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<td>Torsten Hoffmann, Ph.D., Chief Scientific Officer, Silence Therapeutics, Germany</td>
<td>Jonathan Neidigh, Ph.D., Analytical Development Group Leader, Nitto Avecia</td>
<td>Valeska Kreibich, Ph.D., Specialist Regulatory Affairs, Bachem AG, Switzerland</td>
<td>Nagy Habib, M.D., Head of R&amp;D, Mina Therapeutics Ltd., United Kingdom</td>
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<td>Troels Koch, Ph.D., VP &amp; Head of Research, RNA Therapeutics, Roche, Roche Innovation Center Copenhagen, Denmark</td>
<td>Claus Rentel, Ph.D., Executive Director, Ionis Pharmaceuticals</td>
<td>Bradley L. Pentelute, Ph.D., Professor, Chemistry, Massachusetts Institute of Technology</td>
<td>Huw M. Nash, Ph.D., COO and CBO, Stoke Therapeutics</td>
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<tr>
<td>11:45</td>
<td>Inhibition of Difficult to Drug Tumor Cell and Immuno-Oncology Targets with Next Generation Antisense</td>
<td>Development of a Robust Analytical Control Strategy for the Manufacture of Liquid Oligonucleotide Products</td>
<td>Considerations in the Development and Implementation of Analytical Methods for Understanding and Controlling the Chemical and Physical Stability of Formulated Synthetic Peptides and Oligonucleotides</td>
<td>Axiomer® Technology: Therapeutic Oligonucleotides for Directing Site-specific A-to-I Editing by Endogenous ADAR Enzymes</td>
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<td>A. Robert MacLeod, Ph.D., Vice President, Oncology and Exploratory Discovery, Ionis Pharmaceuticals</td>
<td>Jessica Stolee, Ph.D., Senior Scientist, Biogen</td>
<td>Paul L. Walsh, Ph.D., Principal Scientist, Merck Research Labs</td>
<td>Antti Aalto, Ph.D., Senior Scientist, ProQR Therapeutics NV, The Netherlands</td>
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### Concurrent Spotlight Presentations

**Oligonucleotide Downstream Optimization for Large Scale Manufacturing** *(Room 306)*  
Amanda Lewis, Senior Chemist, Oligonucleotide Division, Corden Pharma

**SUMITOMO CHEMICAL**  
Sumitomo’s Approach for Large-Scale Synthesis of Long RNA Oligos *(Room 304)*  
Akihiro Sakata, Senior Research Scientist, Sumitomo Chemical Co., Ltd., Japan

**Analytical Challenges in the Characterization of Therapeutic Oligonucleotides** *(Room 302)*  
Jordi Trafach, Characterisation Manager, Intertek Pharmaceutical Services

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**Track 1: Oligonucleotide Discovery, Preclinical and Clinical**  
Room 304

**Track 2: Oligonucleotide Chemistry, Manufacturing and Controls**  
Room 302

**Track 3: Peptide Discovery, Preclinical and Clinical**  
Room 306

**Track 4: Peptide Delivery**  
Room 301

**Track 5: mRNA, CRISPR and Hot Topics in Oligonucleotides**  
Room 313

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#### 12:20

**Concurrent Spotlight Presentations**

- **Oligonucleotide Downstream Optimization for Large Scale Manufacturing** *(Room 306)*  
Amanda Lewis, Senior Chemist, Oligonucleotide Division, Corden Pharma

- **SUMITOMO CHEMICAL**  
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Akihiro Sakata, Senior Research Scientist, Sumitomo Chemical Co., Ltd., Japan

- **Analytical Challenges in the Characterization of Therapeutic Oligonucleotides** *(Room 302)*  
Jordi Trafach, Characterisation Manager, Intertek Pharmaceutical Services

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#### 12:50

Networking Luncheon in Poster and Exhibit Hall

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#### 1:55

Chairperson’s Remarks
- **Paul Metz**, Principal Consultant, Metz Biotechnology Consulting, LLC
- **Mimoun Ayoub**, Ph.D., Director and Head of North American and Emerging Markets, CordenPharma International, Switzerland
- **Bruce Morimoto**, Ph.D., Vice President, Scientific Affairs, Celerion, Inc.
- **Stephen Spagnol**, Ph.D., Senior Scientist, Sterile Formulation Sciences, Merck Research Laboratories

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#### 2:00

**Effects on Lp(a), Oxidized Phospholipids and Monocyte Inflammation by Antisense Oligonucleotides Targeting Apolipoprotein(a)**  
Nicholas Viney, Executive Director, Clinical Development, Ionis Pharmaceuticals

**Microbial Aspects of Oligonucleotide Solutions**  
Julie Ma, Ph.D., Associate Director, Pharmaceutical Development, Ionis Pharmaceuticals

**Design and Development of a Novel Peptide-centric Drug Delivery System**  
Sheauyu Teddy Hsu, Ph.D., Managing Director, Adepthera

**Development of New Lipid Nanoparticles for mRNA-based Therapeutics**  
Kerry Benenato, Ph.D., Director, Chemistry, Moderna Therapeutics

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#### 2:30

**Antibody-Oligonucleotide Conjugates (AOC): Exploiting Cell Surface Receptors for Directed Delivery and Uptake of siRNA**  
Arthur A. Levin, EVP Research and Development, Avidity Biosciences

**Combining Peptides and Oligonucleotides in a Nanoparticle Drug Product**  
Marc Lemaire, Ph.D., Principal, ML Consult and Chief Operating Officer, Sinaomics, Inc.

**PASylation: the Biological Alternative to PEGylation**  
Lars Friedrich, Scientist, XL-protein GmbH, Germany

**Progress in the Delivery of mRNA Therapeutics**  
Kim Askew, Ph.D., Director, Pharmacology, Translate Bio

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#### 3:00

**Some Chemical Insights of Delivery Utilizing GalNAc-siRNA Conjugates**  
Kallanthottathil G. Rajeev, Ph.D., Senior Director, Chemistry, Alnylam Pharmaceuticals

**Statistical Models for Predicting the Long-Term Storage of Peptide Drug Products Using Accelerated Stability**  
Jameson Bothe, Ph.D., Associate Principal Scientist, Analytical Sciences – MRL, Merck & Co.

**Design and Development of a Glucose-Responsive Insulin Formulation**  
Christopher A. Rhodes, Ph.D., Chief Technology Officer, Sensulin LLC and President & CEO, Drug Delivery Experts

**Optimizing mRNA Therapeutics**  
Patrick Baumhof, Ph.D., Vice President Formulation & Delivery, CureVac AG, Germany

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#### 3:30

Close of Conference

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Exhibit & Poster Hall Viewing Hours
Tuesday, May 8: 2:45 pm-7:00 pm
Wednesday, May 9: 10:00 am-6:45 pm
Thursday, May 10: 10:00 am-2:00 pm

Dedicated Poster Viewing Hours
Even-Numbered Posters (ending in 2,4,6)
Tuesday, May 8: 6:00-7:00 pm
Odd-Numbered Posters (ending in 1,3,5)
Wednesday, May 9: 5:45-6:45 pm

Poster presentations will be on display at all times during Exhibit Hall viewing hours. Poster presenters may stand by their posters at any time, but to ensure that attendees are able to meet poster presenters at specific times during the conference, we have designated the following days/times as “Dedicated Poster Viewing” Hours. We ask all poster presenters to stand by their posters during the dedicated hours listed above to make it easy for attendees to "find" you. We will be promoting these dedicated poster viewing hours during the conference to facilitate better attendee and poster presenter interactions and discussions.

BIOANALYTICAL STRATEGIES AND TECHNOLOGIES

B1 Multiplex Screening for Cystine-Dense Peptides (CDP) Therapeutics Proteins by HPLC-MS/MS Chad Christianson Alturas Analytics, Inc.
B3 An Enhanced Workflow for Characterization and Impurity Profiling of Synthetic Peptide Drugs by UPLC-HRMS Nilini Ranbaduge Waters Corporation
B4 Rapid, High Throughput and Sensitive Method for the Quantitation of the Exendin 9-39 in Dog Plasma by Using LC/MS/MS Stephanie Pasas-Farmer NanoMedical Systems

CRISPR THERAPEUTICS - DEVELOPMENT STRATEGIES AND CASE STUDIES

C1 Chemical Synthesis of Long RNA Enables Highly Efficient CRISPR Editing Kevin Holden Synthego

CROSS-PLATFORM DRUG DELIVERY TECHNOLOGIES FOR OLIGOS, PEPTIDES AND OTHER MOLECULES

CR1 Illuminating the Challenges of Drug Delivery: Leveraging in vivo Imaging to Characterize Bioperformance and Drive Design Stephan Spagnol Merck Research Laboratories
CR2 Polymer Based Delivery Technology Platform of Therapeutic mRNA Sojin Lee Samyang Biopharmaceuticals
CR3 Kristian Link, Ph.D., Associate Director, Analytical Development, Moderna Therapeutics Vincent J. Lebot Polypeptide Therapeutic Solutions S.L.

MESSENGER RNA (mRNA) THERAPEUTICS - DEVELOPMENT STRATEGIES AND CASE STUDIES

M1 Strategies to Minimize Innate Immune Stimulation to Maximize Messenger RNA Bioavailability Craig Dobbs TriLink BioTechnologies
M2 Key Critical Quality Attributes for the cGMP Production of Therapeutic Messenger RNA Jessica Madigan TriLink BioTechnologies
M3 AmpTec as Manufacturer of High Quality Synthetic mRNA Supports Scientific and Clinical Progress Guido Krupp AmpTec GmbH

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Anion Exchange HPLC of 25 mer (200 μm) DNA phosphorothioate, synthesized on CPG using POS. Oligo has 30% A; 40% G; 26% T and 4% C.
### Poster Presentations (continued)

#### OLIGONUCLEOTIDE DISCOVERY TECHNOLOGIES AND DESIGN STRATEGIES

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<td>Annabelle Biscans</td>
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<td>OD3</td>
<td>Cellular Uptake Mediated by Epidermal Growth Factor Receptor Facilitates the Intracellular Activity of Phosphorothioate-Modified Antisense Oligonucleotides</td>
<td>Shiyu Wang</td>
<td>Ionis Pharmaceuticals</td>
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<td>OD4</td>
<td>Development of Innovative Hepatocyte-Targeted siRNA Conjugates for the Treatment of Liver-Related Disorders</td>
<td>Marie Wikstrom Lindholm</td>
<td>Silence Therapeutics</td>
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<td>OD5</td>
<td>PNA/DNA mixed-backbones oligonucleotides: design and efficiency.</td>
<td>Alexandre Debacker</td>
<td>UMASS Medical School</td>
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#### OLIGONUCLEOTIDE MANUFACTURING, CMC AND ANALYTICAL CASE STUDIES & TECHNOLOGIES

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<td>Characterization and Control of GalNAc Starting Material Related Impurity in GalNAc Conjugated Oligonucleotide</td>
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<td>Large-Scale Syntheses of Long RNA Oligonucleotides</td>
<td>Yuki Tanaka</td>
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<td>Eric Yau</td>
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<td>Andrew Livingston</td>
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<td>Harumi Okumura</td>
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<td>Samyang Biopharmaceuticals Corporation</td>
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<td>OM13</td>
<td>Application of Failure Sequence Analysis for Sequencing a 58 Residue Synthetic Oligonucleotide</td>
<td>Gangani Silva</td>
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OM14 Effects of Elution Conditions in the Purification of Oligonucleotides by Agarose-Based Anion Exchange Chromatography
Cecilia Unoson Bio-works

OM15 Implementation and Validation of a UV Melting Temperature™ Test Method for Antisense Oligonucleotide Drug Substance and Drug Product Identity Determination
Brian Laing Biogen

OM16 GaINac Solid Support Starting Material Comparability for Oligonucleotide Synthesis
Alexander Rudolph Alnylam Pharmaceuticals

OM17 Analytical Characterization of Oligonucleotides and Their Delivery Vehicles to Enable Formulation Development and Specification Setting
Cory Bottone Merck and Co.

OT1 2′-O-(2-Methoxyethyl) Nucleosides are Not Phosphorylated or Incorporated Into the Genome of Human Lymphoblastoid TK6 Cells
Amer Saleh AstraZeneca

OT2 Novel Cluster And Monomer-Based GaINac Structures Induce Effective Uptake of siRNAs in vitro and in vivo
Vivek Sharma University of Massachusetts Medical School

OT3 Efficiency and Expansion of the Branched DNA Methodology from the Non-Clinical to Clinical Space
Jessica St. Charles Tiffany Palmer MPI Research Moderna Therapeutics

OT4 Defined Multimeric Oligonucleotides for Enhanced Therapeutic Effect.
Jonathan Miles Brown MPEGLA LLC

OT5 Pulmonary Delivery of Spherical Nucleic Acids (SNAs) for Lung Diseases
Richard Kang Exicure Inc.

OT6 TLR9-targeted Spherical Nucleic Acid, AST-008: In vitro and in vivo Immunostimulatory Activity and Preclinical Studies in Combination with IDO-1 inhibitor in a Tumor Model and as a Vaccine Adjuvant with HBsAg
SubbaRao Nallagatla Exicure, Inc.

OT7 RGL54326 inhibits miR-17 and Confers Efficacy in Preclinical Models of Autosomal Dominant Polycystic Kidney Disease (ADPKD)
Edmund Lee Regulus Therapeutics

OT8 Pharmacokinetics and Pharmacodynamics of RG-101, a Novel Hepatocyte Targeted Inhibitor of MicroRNA-122, in Cynomolgus Monkeys
Graham Jang REGulus

OT9 Development of in vivo Evaluation Systems for Novel Non-Coding RNA, SINEUP, to Enhance Translation Level of Target Genes as a Nucleic Acid Medicine
Kazuhiro Nitta RIKEN Center for Life Science Technologies (CLST)

OT10 Fluorescently Labeled siRNA Nanoparticles as Cancer Theranostics
Stephen Kozuch Seton Hall University

OT11 Delivering therapeutic mRNA with Lipid Nanoparticles (LNP) for Clinical Application
Paulo Lin Acuitas Therapeutics

OT12 Lipid Nanoparticles for Delivery of Nucleic Acid Vaccines
Jessica Cohen GSK Vaccines

OT13 Rapide development and seamless Scale-Up of Genetic Nanomedicines
Andrea Armstead Precision NanoSystems Inc.
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PD1 Predicting Protein Protein Binding Sites and Epitope Mapping
Al Ajamian Chemical Computing Group

PD2 High Density Peptide Microarrays to Discover TNF Inhibitors
Chris Diehnelt Associate Research Professor

PD3 UV Dependent Immobilization of Peptides on Diverse Surfaces
Courtney Brand IBBR/NIST

PD4 Bridging the Gap Between Small Molecule and Biologics Editing: Drawing, Viewing and Sharing Complex Biomolecules
Aurora Costache ChemAxon LLC

PD5 Parallel Automated Solid Phase Synthesis: Efficient High-Throughput Optimization for Therapeutic Discovery and Development
Cyr Ramos-Colon Gyros Protein Technologies

PEPTIDE MANUFACTURING, CMC AND ANALYTICAL CASE STUDIES & TECHNOLOGIES

PM1 TamiSolve™ NxG as a Suitable Solvent for Cost-Efficient Green SPPS
Jan Pawlas PolyPeptide Group

PM2 Development of Efficient LPPS with Simple Protecting Group and Condition. The Application to Exenatide
Shohei Yamamoto KANEKA corporation

PM3 Synthetic Peptide Impurity Analysis by Reversed-Phase Chromatography
Hua Yang Waters Corporation

PM4 Life Science – Validity of 100 Å RP Silica Gel in Peptide Purification Process
Tetsuyuki Saika DAISO Fine Chem USA, Inc.

PM5 DualPore Silica Beads: Advanced Chromatographic Media for TIDES Purification
Riichi Miyamoto Kyoto University

PM6 Mass-Directed Purification of Peptides Using UPLC with Small Scale Fraction Collection
Asish Chakraborty Waters Corporation

PM7 Strategies in the Synthesis and Optimization of Complex Peptides Using Parallel SPPS
James Cain Gyros Protein Technologies

PM8 Innovative Synthesis Technology for the Substances of Peptide Therapeutics
Toko Sakuta Jitsubo Co., Ltd.

PM9 Analytical Method Development for Quantification of Lipid- Peptide Conjugate in a Liposomal Drug Product
Ying Gao Pharmaceutical Companies of Johnson and Johnson

PM10 Purification of Peptides by Twin-Column Countercurrent Chromatography
Thomas Müller-Späth ETH Zurich

PM11 Stationary Phases for the Process Scale Purification of Peptides and Insulin Analog
Marc Jacob Phenomenex

PEPTIDE THERAPEUTICS: PRECLINICAL AND CLINICAL DEVELOPMENT

PT1 Novel Cell-Penetrating Drug Delivery System for siRNA
Xuan Zhao JenKem Technology Co. Ltd.

PT2 Novel Peptide-Targeted Delivery Of Imaging And Therapeutic Compounds Into Acute Brain Injuries
Sazid Hussain AivoCode Inc

PT3 Probing the Role of MC1 Receptor Agonists in Diverse Immunological Diseases
John Dodd Palatin Technologies, Inc.
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