

TIDES: Oligonucleotide & Peptide Therapeutics

May 20-23, 2019
Manchester Grand Hyatt
San Diego, CA

THE LARGEST MEETING TO ACCELERATE OLIGONUCLEOTIDE AND PEPTIDE PRODUCTS FROM EARLY DISCOVERY TO LATE-STAGE DEVELOPMENT & COMMERCIALIZATION

Featuring Industry Experts to Help You Fast-Track Product Development

Rare Diseases and RNA-Targeted Medicines



Sarah Boyce
President,
Akcea Therapeutics

RNAi Therapeutics: Onpattro and Beyond



Kevin Fitzgerald, Ph.D.
Senior Vice President and Head of
Research, Alnylam Pharmaceuticals

Antisense Technology: Today and Tomorrow



Stanley Crooke, M.D., Ph.D.
Chairman of the Board and Chief Executive Officer,
Ionis Pharmaceuticals

A Platform for In-solution Enrichment from Large Libraries to Identify Peptide Inhibitors of Protein-Protein Interactions



Bradley Pentelute, Ph.D.
Professor, Chemistry, Massachusetts Institute of
Technology

Diamond
Sponsor: **Nitto** **Avecia**

Event
Partner:  **Agilent** | Trusted Answers

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SCIENCE

Accelerate your pipeline of oligonucleotide and peptide therapeutics to market by applying best practices and lessons learned from 125+ case studies and new data presentations from global industry leaders working across the entire spectrum of development and production.

"TIDES is the premier venue to actually network with the peptide community. It attracts the research community up to the clinical community – it covers the entire spectrum of peptide science."

– Dr. Alex Fässler, Bachem AG



TECHNOLOGY

Bring your product to market by meeting 90+ leading product and service providers showcasing live technology demonstrations in our exhibit hall.

"TIDES is a 'must-go' conference for scientists working in the peptide/oligonucleotide area"

– George Wang, Analytical Chemist, Bristol-Myers Squibb



NETWORKING

Connect with 1000+ scientists and executives from 30 countries focused in oligonucleotide and peptide development and production during luncheons, cocktail receptions and networking breaks. Networking has never been easier with the included TIDES app that allows you to view the attendee list and schedule meetings before, during and after the event.

"Definitely the best meeting in the US for companies developing peptide therapeutics"

– Rodney Lax, Ph.D., Senior Director, PolyPeptide Group

AGENDA AT-A-GLANCE

MONDAY, MAY 20, 2019 • Pre-Conference Workshops

8:00 am - 12:00 pm	Workshop #1: The State of the Art in mRNA Delivery	Workshop #2: Oligonucleotide Drug Development at Warp Speed: Managing CMC Operations to Support Accelerated Clinical Development	Workshop #3: Potential Green Chemistry Solutions for Peptide Manufacturing	Workshop #4: Accelerating Peptides to IND: Moving to the Clinic, CMC and Beyond
1:00 pm - 5:00 pm	Workshop #5: Peptide Aggregation – Challenges, Effects, and Solutions	Workshop #6: The Path to A Successful Oligonucleotide IND/IMP Submission: Regulatory, Nonclinical and CMC Perspectives	Workshop #7: Evolving Regulatory CMC Requirements for Peptides	Workshop #8: Analytical and Bioanalytical Strategies for Oligonucleotide Therapeutics

TUESDAY, MAY 21, 2019 • Main Conference

Exhibit Hall & Poster Viewing Hours: 3:00 pm-6:45 pm

8:20 am - 12:15 pm	KEYNOTE SESSION: Stanley Crooke, M.D., Ph.D., Chairman of the Board and Chief Executive Officer, Ionis Pharmaceuticals Bradley Pentelute, Ph.D., Professor, Chemistry, Massachusetts Institute of Technology				Kevin Fitzgerald, Ph.D., Senior Vice President and Head of Research, Alnylam Pharmaceuticals Sarah Boyce, President, Akcea Therapeutics
12:15 am - 1:25	Spotlight Luncheon Presentations <i>Sponsored by</i> Ajinomoto, Avanti Polar Lipids, TriLink, Ribobio, BioSpring				
1:25 pm - 3:00 pm	Plenary Session				
3:00 pm - 3:45 pm	Grand Opening of Poster and Exhibit Hall and Networking Refreshment Break				
3:45 pm - 5:15 pm	Plenary Session				
5:15 pm - 6:45 pm	Networking Reception in Poster and Exhibit Hall				

WEDNESDAY, MAY 22, 2019 • Main Conference

Exhibit Hall & Poster Viewing Hours: 10:00 am – 6:45 pm

7:45 am - 8:15 am	Breakfast Spotlight Presentation Sponsored by Polymun, AxoLabs, Zeechem					
	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Peptide Chemistry Manufacturing and Controls		
8:25 am - 10:00 am	Preclinical Discovery of Oligonucleotides	Oligonucleotide CMC Manufacturing	Peptide Discovery Strategies	Peptide CMC, Quality and Manufacturing		
	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Chemistry Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	mRNA Therapeutics and CRISPR Therapeutics	
10:45 am - 12:15 pm	Preclinical Discovery of Oligonucleotides	Oligonucleotide CMC Manufacturing	Peptide Discovery Strategies	Peptide CMC, Quality and Manufacturing	CRISPR Therapeutics	
12:20 pm - 12:50 pm	Spotlight Presentations Sponsored by Nagase, ST Pharm, ThermoFisher Scientific, Hongene					
12:50 pm - 1:55 pm	Networking Luncheon in Poster and Exhibit Hall					
	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Peptide Chemistry Manufacturing and Controls	mRNA Therapeutics and CRISPR Therapeutics	Drug Delivery Innovations and Strategies
1:55 pm - 3:30 pm	Novel Chemistries (1:50-3:35 pm)	CMC QC Analytics for Oligonucleotides	Peptide Discovery Strategies	Innovations in Peptide Synthesis and Manufacturing	CRISPR Therapeutics	Novel Technologies for the Delivery of Macromolecular Therapeutics
4:15 pm - 5:45 pm	Oligonucleotide Discovery and Development (4:10-5:50 pm)		New Frontiers in Peptide Drug Development			
5:45 pm - 6:45 pm	Networking Reception in Poster and Exhibit Hall					

THURSDAY, MAY 23, 2019 • Main Conference

Exhibit Hall & Poster Viewing Hours: 10:00 am-2:00 pm

	Oligonucleotide Discovery, Preclinical and Clinical	Drug Delivery Innovations and Strategies	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Peptide Chemistry Manufacturing and Controls	mRNA Therapeutics and CRISPR Therapeutics
8:25 am - 12:15 pm	Extra-Hepatic Delivery of Oligonucleotides		Regulatory Perspective Innovations in Oligonucleotide CMC	Individualized Neo-Antigens		mRNA Discovery and Development (7:55am-12:15pm)
12:20 pm - 12:50 pm	Spotlight Presentations Sponsored by Intertek, Sumitomo Chemical					
12:50 pm - 1:55 pm	Networking Luncheon in Poster and Exhibit Hall					
	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	mRNA Therapeutics and CRISPR Therapeutics	Peptide Chemistry Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Drug Delivery Innovations and Strategies
1:55 pm - 3:30 pm	Oligonucleotides in the Clinic	mRNA CMC and Manufacturing		Peptide Purification and Downstream Processing	Innovations in Peptide Delivery	

**Workshop #1:
The State of the Art in mRNA Delivery**
Morning Half-Day Workshop • 8:00am-12:00pm

- 8:00 **Workshop Moderator's Opening Remarks**
Örn Almarsson, Ph.D., Head of Formulations, Moderna Therapeutics
- 8:15 **LUNAR®: Enabling mRNA Therapeutics and Vaccines**
Pad Chivukula, Ph.D., CSO and COO, Arcturus Therapeutics
- 8:45 **Safe Delivery of Nucleic Acid Cargoes Using Anionic Carriers**
Steffen Panzner, Ph.D., CEO, Germany
- 9:15 **Chemical Design of Synthetic Carriers for CRISPR/Cas Gene Editing and mRNA-mediated Protein Replacement Therapy**
Daniel Siegwart, Ph.D., Associate Professor, Department of Biochemistry, UT Southwestern Medical Center
- 9:45 **Networking Refreshment Break**
- 10:15 **Design and Application of Complexes for mRNA Delivery**
Frank DeRosa, Ph.D., Senior Vice President, R&D, Translate Bio
- 10:45 **Development of Nucleic Acid Delivery Platforms; a pan-RNA approach**
James Heyes, Ph.D., SVP, Technology Development, Genevant Sciences, Canada
- 11:15 **Delivering mRNA Products from Discovery through Development - Opportunities and Challenges**
Hari Pujar, Head of Technical Development, Moderna Therapeutics
- 11:45 **Concluding Remarks and Discussion**
- 12:00 **Close of Workshop**

**Workshop #2: Oligonucleotide Drug Development at Warp Speed:
Managing CMC Operations to Support Accelerated Clinical Development**
Morning Half-Day Workshop • 8:00am-12:00pm

Workshop Co-Moderators:
G. Susan Srivatsa, Ph.D., President, ElixinPharma
Fran Wincott, Ph.D., Wincott & Associates, LLC

Workshop Description:

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. This workshop will present strategic and operational approaches for successful clinical development, regulatory approval and commercialization of therapeutic oligonucleotides within the framework of accelerated development.

Confirmed Speakers:

From Target to Patient; Options for Oligonucleotides as Personalized Medicines
Chantal Reed, Ph.D., Vice President, Brain HZ Consulting, Inc.

Presentation Title TBA

Paul Manley, President and Principal Consultant, Orvieto Consulting

Use of Prior Knowledge to Establish Flexible Enhanced Model-based Control Strategies
Zhijie Sui, Ph.D., Senior Scientist, Biogen

Additional Speakers to Be Confirmed

**Workshop #4:
Accelerating Peptides to IND: Moving to the Clinic, CMC and Beyond**
Morning Half-Day Workshop • 8:00am-12:00pm

- 8:00 **Workshop Moderator's Opening Remarks**
Bruce Morimoto, Ph.D., Vice President, Drug Development-Operations, Alkahest
- 8:15 **Analytical Methods, Pre-formulation, and Formulation for Early Phase Development**
Christopher Rhodes, Ph.D., President and CEO, Drug Delivery Experts
- 9:00 **IND-enabling, Nonclinical Safety Studies for Peptides: Pharmacokinetics, Bioanalysis and Toxicology**
Bruce Morimoto, Ph.D., Vice President, Drug Development-Operations, Alkahest
- 9:45 **Networking Refreshment Break**
- 10:15 **Peptide CMC Approaches for a Fast and Successful IND Filing**
Mimoun Ayoub, Ph.D., Director and Head of North American and Emerging Markets, CordenPharma International, Switzerland
- 11:00 **Regulatory Issues during Early Development of Peptide Product from R&D to IND**
Duu-Gong Wu, Ph.D., Senior Director, Regulatory Consulting, PPD (and Former Deputy Division Director of Division of New Drug Chemistry, CDER, FDA)
- 11:45 **Concluding Remarks and Discussion**
- 12:00 **Close of Workshop**

**Workshop #3:
Potential Green Chemistry Solutions for Peptide Manufacturing**
Morning Half-Day Workshop • 8:00am-12:00pm

- 8:00 **Workshop Moderator's Opening Remarks**
Trishul Shah, Director, Business Development, North America, PolyPeptide
- 8:15 **Solid-Phase Peptide Synthesis: Being Greener, Being Better**
Fernando Albericio, Ph.D., Professor, Organic Chemistry, University of Barcelona
- 9:00 **Evolved Enzymes for Commercial Chemical Synthesis Pathways**
Christina Boville, Ph.D., Resnick Prize Postdoctoral Scholar, Frances Arnold Lab, California Institute of Technology
- 9:45 **Networking Refreshment Break**
- 10:15 **Convergent Peptide Synthesis in Flow: Preferred Regulatory Strategies for Commercial Peptide Manufacture**
Michael Kopach, Ph.D., Senior Research Advisor, Eli Lilly and Company
- 11:00 **Perspectives on Green Chemistry**
Jon Holbech Rasmussen, Ph.D., Director, Global Development, PolyPeptide Group, Sweden
- 11:45 **Concluding Remarks and Discussion**
- 12:00 **Close of Workshop**

12:00-1:00 **Spotlight Presentation Luncheons**

Workshop #5: Peptide Aggregation – Challenges, Effects, and Solutions

Afternoon Half-Day Workshop • 1:00pm-5:00pm

- 1:00 **Workshop Moderator's Opening Remarks**
Christopher Rhodes, Ph.D., President and CEO, Drug Delivery Experts
Ved Srivastava, Ph.D., Vice President, Chemistry, Intarcia Therapeutics
- 1:05 **Introduction to Peptide Aggregation, Gelation, and Injection Site Precipitation, and the Consequences**
Christopher Rhodes, Ph.D., President and CEO, Drug Delivery Experts
- 1:35 **Non-aqueous Approaches to Peptide Aggregation**
Steven Prestrelski, Ph.D., Chief Scientific Officer, Xeris Pharmaceuticals, Inc.
- 2:05 **In Vitro and in Vivo Models for Injection Site Precipitation and Formulation Solutions**
Laxma G. Reddy, Ph.D., Fellow, Formulation and Product Development, Drug Delivery Experts
- 2:35 **Characterization of Gelation – The Importance of Reversibility**
Ved Srivastava, Ph.D., Vice President, Chemistry, Intarcia Therapeutics
- 3:05 **Networking Refreshment Break**
- 3:30 **Protein Aggregation in Consequence of Siliconization and Preservation: Challenges during Formulation Development**
Kathrin Spielberger, Ph.D., Senior Scientist, Product and Process Development, R&D, Sanofi, Germany
- 4:00 **Charge Variant Analysis of Therapeutic Peptides**
Anuja Rane, Ph.D., Associate Scientist, Teva Pharmaceuticals
- 4:30 **Non-Arrhenius Behavior of Peptide Fibril Formation in the Presence of Stabilizing Excipients and Its Impact on Formulation Development**
Katelyn Smith, Ph.D., Senior Scientist, Merck & Co., Inc.
- 5:00 **Close of Workshop**

NEW DATA

Workshop #7:

Evolving Regulatory CMC Requirements for Peptides

Afternoon Half-Day Workshop • 1:00pm-5:00pm

Workshop Description:

This workshop will provide an overview of CMC requirements for peptides including discussions on a wide variety of topics including 1) Risk assessments 2) Genotoxic impurities and justification 3) Related substance impurities and qualification justification 4) Report results vs a defined specification 5) Compendial Tests – Ph Eur vs USP vs Harmonized or not harmonized 6) Regulatory starting materials 7) Method Validation requirements at Phase 2- US vs EU and more.

- 1:00 **Workshop Moderator's Opening Remarks**
Gary Musso, Ph.D., President, Musso and Associates LLC
- 1:15 **Regulatory Recommendations in Development – EU vs USA Differences**
Gary Musso, Ph.D., President, Musso and Associates LLC
- 2:00 **European Regulatory Update on CMC Requirements for Synthetic Peptides**
René Thürmer, Ph.D., Deputy Head, Unit Pharmaceutical Biotechnology, BfArM Federal Institute for Drugs and Medical Devices, Germany
- 2:30 **Networking Refreshment Break**
- 3:00 **Of Peptides and PANDAS: Innovative Preclinical Assessment Tools for Safety and Efficacy of Protein and Peptide Therapeutics**
Annie De Groot, M.D., Professor (Research) and Director, Institute for Immunology and Informatics, University of Rhode Island and Founder, CEO and CSO, EpiVax, Inc., USA
- 3:45 **Quantification of Impurities in Synthetic Peptides Using Proteolytic Sample Preparation and RP Chromatography**
Michael Berger, Director, Bachem AG, Switzerland
- 4:30 **Genotoxicity Assessment of Impurities in Peptide/Protein-containing Biotherapeutics**
Zhanna Sobol, Ph.D., Genetic Toxicology Head, Drug Safety Research and Development, Pfizer, Inc.
- 5:00 **Close of Workshop**

Workshop #6: The Path to A Successful Oligonucleotide IND/IMPD Submission: Regulatory, Nonclinical and CMC Perspectives

Afternoon Half-Day Workshop • 1:00pm-5:00pm

- 1:00 **Workshop Moderator's Opening Remarks**
Jennifer Lockridge, Ph.D., 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**
Speaker TBA.
- 2:45 **Networking Refreshment Break**
- 3:15 **Getting Your ASO in Top Shape for IND/IMPD Submission: How to Successfully and Efficiently Identify A Solid Development Candidate**
Sebastien Burel, Ph.D., Executive Director, Nonclinical Development, Ionis Pharmaceuticals
- 4:00 **Case Study: DCR-PHXC, An siRNA Therapeutic Being Developed for the Treatment of Primary Hyperoxaluria**
Jennifer Lockridge, SVP, Program Development, Dicerna Pharmaceuticals, Inc.
- 4:45 **Concluding Remarks and Discussion**
- 5:00 **Close of Workshop**

Workshop #8:

Analytical and Bioanalytical Strategies and Techniques for the Discovery and Development of Oligonucleotide Therapeutics

Afternoon Half-Day Workshop • 1:00pm-5:00pm

- 1:00 **Workshop Moderator's Opening Remarks**
Klaus Charisse, Ph.D., Director, Analytical R&D, Alnylam Pharmaceuticals
- 1:15 **Presentation Title TBA**
Matthias Kretschmer, Ph.D., Senior Director Analytical Sciences, Alnylam Pharmaceuticals
- 1:45 **Presentation Title TBA**
Hans Gaus, Ph.D., Director of Structural Biology, Ionis Pharmaceuticals, Inc.
- 2:15 **Strategies for Chiral Thioates**
Pallavi Lonkar, Ph.D., Principal Scientist, WAVE Life Sciences
- 2:45 **Networking Refreshment Break**
- 3:15 **Presentation Title TBA (Invited)**
Ingo Roehl, Ph.D., Director, Analytical Chemistry, LGC Axolabs, Germany
- 3:45 **Presentation Title TBA (Invited)**
Marjie Hard, Ph.D., Executive Director of Clinical Pharmacology & DMPK, Moderna Therapeutics
- 4:15 **Panel Discussion with Workshop Speakers**
- 5:00 **Close of Workshop**

7:30 *Registration and Coffee*

8:20 **Chairperson's Remarks**



8:30 **Antisense Technology: Today and Tomorrow**
Stanley Crooke, M.D., Ph.D.

Chairman of the Board and Chief Executive Officer,
Ionis Pharmaceuticals



9:30 **RNAi Therapeutics: Onpattro and Beyond**
Kevin Fitzgerald, Ph.D.

Senior Vice President and Head of Research,
Alnylam Pharmaceuticals

10:15 *Networking Refreshment Break*



10:45 **A Platform for In-solution Enrichment from Large Libraries to Identify Peptide Inhibitors of Protein-Protein Interactions**
Bradley Pentelute, Ph.D.

Professor, Chemistry, Massachusetts Institute of Technology



11:15 **Rare Diseases and RNA-Targeted Medicines**
Sarah Boyce

President, Akcea Therapeutics



11:45 **Late Breaking Keynote Presentation**

12:15-1:25

SPOTLIGHT PRESENTATION LUNCHEONS

AJINOMOTO®

Track Record of Oligonucleotide Manufacturing in Large Scale by Solution Phase Approach AJIPHASE®

Daisuke Takahashi, Ph.D., Senior Principal Researcher, Research Institute for Bioscience Products & Fine Chemicals, Ajinomoto Co. Inc., Japan



Lipid Nanoparticles – From Benchtop to Clinic: A CDMO Perspective

Di L. Bush, Ph.D., Formulations Director, Avanti Polar Lipids

RIBOBIO

Selecting an Asian CMO Partner for Therapeutic Oligonucleotide Manufacturing

J.O. Adams, Head of Research, Ribo Biologics Co. Ltd., China



Presentation Title TBA

Mario Jauker, Ph.D., Head of Process Characterization, BioSpring, Germany



Development of Synthetic Self-Replicating RNA Platforms for Oncology Vaccines and Therapeutics

Nathaniel Wang, Ph.D., Head of R&D, RNA Medicines, Synthetic Genomics, Inc.

Anton McCaffrey, Ph.D., Senior Director of Emerging Science and Innovation, TriLink BioTechnologies

The Road to Personalized Medicines and Individualized Therapies

1:25 **Chairperson's Remarks**

1:30 **Using Artificial Intelligence to Accelerate Drug Development and Precision Medicine**

Brendan Frey, Ph.D., Founder and CEO, Deep Genomics

2:00 **Parameters for Accelerated Development of Antisense Oligonucleotides as Personalized Medicine**

Timothy Yu, M.D., Ph.D., Attending Physician, Division of Genetics and Genomics, Boston Children's Hospital and Assistant Professor in Pediatrics, Harvard Medical School

NEW
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2:30 **Development of Neoantigen-Based Personalized Cancer Vaccine, NEO-PV-01**

Jesse Z. Dong, Ph.D., Vice President, Peptide Chemistry, Neon Therapeutics

3:00 *Grand Opening of Poster and Exhibit Hall and Networking Refreshment Break*

3:45 **mRNA as a Platform Technology Ideally Suited for Individualized Therapeutics**

Andreas Kuhn, Ph.D., Vice President RNA Biochemistry & Manufacturing, BioNTech RNA Pharmaceuticals GmbH, Germany

4:15 **Manufacturing NeoAntigen Peptides: Requirements and Pragmatism**

Trishul Shah, Director, Business Development, North America, PolyPeptide

4:45 **PANEL DISCUSSION WITH SESSION SPEAKERS: Personalized Medicine and Individualized Therapies**

5:15-6:45

Networking Reception in the Poster and Exhibit Hall



WEDNESDAY, MAY 22, 2019

7:30	Registration and Coffee				
	Breakfast Spotlight Presentations				
7:45-8:15	 Cost Efficient Peptide Purification via ZEOsphere DRP Mixed-Mode Chromatography Jürgen Machielse, Business Development Director Spherical Gels, ZEOchem, Switzerland	 Lessons Learned from Liposomal Products and Processes – Chemistry, Manufacturing and Controls Charalampos Koutsoulas, Ph.D., Head of Liposome R&D, Polymun Scientific GmbH, Austria	  Preclinical and Clinical Development of Oligonucleotide Therapeutics: Covering the Value Chain from Lead ID to Phase 1 Supply Hans-Peter Vornlocher, Ph.D., Managing Director Research, LGC Axolabs Juergen Mueller, Ph.D., Commercial and Strategic Development Director, LGC Axolabs		
	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Peptide Chemistry Manufacturing and Controls	
	Preclinical Discovery of Oligonucleotides	Oligonucleotide CMC Manufacturing	Peptide Discovery Strategies	Peptide CMC, Quality and Manufacturing	
8:25	Chairwoman's Remarks Shuling Guo, Ph.D., Vice President, Antisense Drug Discovery, Ionis Pharmaceuticals	Chairman's Remarks Doug Brooks, Ph.D., Consultant, Matapalo Pharma Consulting Services	Chairman's Remarks	Chairman's Remarks Alex Fässler, Ph.D., Bachem Holding AG, Switzerland	
8:30	Human Genetics Moves from Clinic to Bench and Back: Develop Antisense Therapies for Inherited Diseases Shuling Guo, Ph.D., Vice President, Antisense Drug Discovery, Ionis Pharmaceuticals	Industrial Scale Manufacture of 2-cyanoethyl-N,N,N',N'-tetraisopropylphosphorodiamidite (Phos reagent) Gary Woodward, Ph.D., Senior Research Fellow, Technology Solutions GBU, Solvay Solutions, United Kingdom	Genetically Encoded Selection of Novel Cyclic and Bicyclic Architectures Ratmir Derda, Ph.D., Associate Professor, Department of Chemistry, University of Alberta, Canada	CMC Development Concept for Synthetic Peptides Tanja Huth, Ph.D., Group Leader QA/RA Project Management, Bachem AG, Switzerland	NEW DATA
9:00	Targeted Delivery of Oligonucleotides to Muscle with Antibody Oligo Conjugates. Arthur A. Levin, EVP, Research and Development, Avidity Biosciences	Increasing Yields and Reducing Waste in Oligonucleotide Manufacture Anna Watson, Senior Scientist (Process Engineer), Pharmaceutical Technology and Development, AstraZeneca, United Kingdom	Chemoenzymatic Synthesis of Macrocycles David Craik, Ph.D., Professor of Biomolecular Structure, Institute for Molecular Bioscience, University of Queensland, Australia	Supply Chain and CMC Considerations during Development of Lumicell's Cleavable PEGylated Peptide-dye Conjugate for Fluorescence Guided Surgery Daniel Harris, Ph.D., Director of Drug Manufacturing, Lumicell	NEW DATA
9:30	Development of microRNA Therapeutics Aimee L. Jackson, Ph.D., Director of Target Development, miRagen Therapeutics	Development of A Novel Method for Manufacturing A Single-stranded Long-chain RNA Oligomer, Which Is An Active Pharmaceutical Ingredient of TRK-250 Hideaki Inada, Senior Research Associate, Pharmaceutical Research Laboratories, Toray Industries, Inc., Japan	The Power of Isoacyl Chemistry: Its Application to Insulin and Glucagon Fa Liu, Ph.D., Director of Discovery Chemistry, Novo Nordisk Research Center Seattle	APL-2 Drug Substance: Strategic Dual-sourcing of a PEG-ylated Peptide during Late Stage Clinical Development Najib Maslough, Vice President of Manufacturing and Technical Operations, Apellis Pharmaceuticals	NEW DATA
10:00	Networking Refreshment Break in Poster and Exhibit Hall				
	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Peptide Chemistry Manufacturing and Controls	mRNA Therapeutics and CRISPR Therapeutics
10:45	Overcoming the Hurdle of Subcutaneous Delivery of mRNA in LNP to Enable Treatment of Chronic Diseases Shalini Andersson, Ph.D., Senior Director and Head of New Therapeutic Modalities, AstraZeneca, Sweden	Enzyme Catalysed Assembly of Oligonucleotides David Tew, Project Leader and GSK Senior Fellow, Advanced Manufacturing Technology, GlaxoSmithKline, United Kingdom	An Appropriate Screening Funnel at An Early Stage of Peptide Discovery is Key to Success: An Overview Stefania Colarusso, Senior Research Scientist, Peptide Chemistry, IRBM Science Park SPA, Italy	Introducing Green and Sustainable Chemistry in Liquid Phase Peptide Manufacturing Processes El Djouhar Rekaï, Ph.D., Head of Development & Manufacturing Process, PolyPeptide Group, Belgium	CRISPR Therapeutics Co-Chairwomens' Remarks Cecilia Fernández, Ph.D., Senior Director, Platform Strategy and Operations, Editas Medicine; Rubina Parmar, Ph.D., Director, Chemistry, Intellia Therapeutics (10:50) CRISPR/Cas Lipid Nanoparticle Formulations Optimized for Delivery and In Vivo Gene Editing Christopher Cheng, Ph.D., Associate Director Formulation Technology Development, Casebia Therapeutics
11:15	Small Activating RNAs – An Innovative Platform for Gene Activation David Blakey, Ph.D., Chief Scientific Officer, MiNA Therapeutics, United Kingdom	Applications of Hydrophilic Interaction Chromatography (HILIC) to Oligonucleotides Zach Parsons, Ph.D., Research Scientist II, Avecia Therapeutics, United Kingdom	Epitope Targeted Protein Catalyzed Capture Agents Heather Agnew, Ph.D., Vice President R&D Operations, Indi Molecular	Late Breaking Presentation	PANEL DISCUSSION: Optimizing Lipid Nanoparticles (LNPs) for Liver Delivery of CRISPR/Cas9 Panel Discussion Moderator: Manmohan Singh, Ph.D., Vice President, Pharmaceutical Sciences and Delivery Technologies, Beam Therapeutics
11:45	Recent Progress in the Use of Targeted-Augmentation of Nuclear Gene Output (TANGO) for the Treatment of Genetic Diseases Charles R. Allerson, Ph.D., Vice President of Chemistry, Stoke Therapeutics	Purge-based Risk Assessment for Solvent and Small Molecule Impurities Generated during Oligonucleotide Synthesis Jessica Stolee, Ph.D., Associate Director, Pharma and ASO Analytical Development, Biogen	Late Breaking Presentation	Late Breaking Presentation	
12:15	Transition to Spotlight Presentation Rooms				
	Concurrent Spotlight Presentations				
12:20	 Manufacturing of Oligonucleotide API Using Nucleotide Blockmers Masanori Kataoka, Ph.D., Chief Technical Officer, Shikoku Nucleic Acid Chemistry (S-NAC), Japan	 Comparison of Purification Strategy in Oligonucleotide API Manufacture: Chromatography and Desalting Processes Kyeong Eun Jung, Ph.D., Senior Vice President, Head of Oligo and R&D Division, ST Pharm. Co. Ltd., South Korea			
12:50	Networking Luncheon in Poster and Exhibit Hall				

	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Peptide Chemistry Manufacturing and Controls	mRNA Therapeutics and CRISPR Therapeutics	Drug Delivery Innovations and Strategies
	Novel Chemistries	CMC QC Analytics for Oligonucleotides	Peptide Discovery Strategies	Innovations in Peptide Synthesis and Manufacturing	CRISPR Therapeutics	Novel Technologies for the Delivery of Macromolecular Therapeutics
1:55	(1:50) Chairman's Remarks	Chairman's Remarks Claus Rentel, Ph.D., Executive Director, Analytical Development/QC, Ionis Pharmaceuticals	Chairman's Remarks	Chairman's Remarks	Chairman's Remarks	Chairman's Remarks Stephen T. Spagnol, Ph.D., Associate Principal Scientist, Sterile Formulation Sciences, Pharmaceutical Sciences, Merck Research Labs, Merck & Co., Inc.
2:00	(1:55) Reinventing Oligonucleotide Synthesis Phil Baran, Ph.D., Professor, Department of Chemistry, The Scripps Research Institute	High Resolution Mass Spectrometry Enabled Sensitive Impurity Profiling and Structural Characterization of Oligonucleotides Kui Yang, Ph.D., Chemist, Division of Pharmaceutical Analysis, CDER, US FDA	Peptide Drug Products: Formulation Development and Process Characterization to Inform Control Strategies Suzanne D'Addio, Ph.D., Associate Principal Scientist, Discovery Pharmaceutical Sciences, Merck & Co.	New Engineering Tools for Peptide Synthesis: Prediction, Control and Automation to Boost Process Performances Olivier Ludemann-Hombourger, Ph.D., Global Director Innovation and Strategy, PolyPeptide Group, France	Successful Millimole gRNA Production & Highly Resolving Purity Test Methods Joe Guiles, Ph.D., Head of Development, Nucleic Acid Solutions Division, Agilent Technologies, Inc.	Polymeric Architecture Affects Cellular and in vivo Delivery of Nucleic Acids and Genome Editing Theresa M. Reineke, Department of Chemistry, University of Minnesota
	(2:20) Biomimetic Chemistry of RNAi Therapeutics Muthiah (Mano) Manoharan, Ph.D., Senior Vice President of Drug Discovery, Alnylam Pharmaceuticals					
2:30	(2:45) Enhancing Therapeutic Profile of ASOs Using Gap-modifications Punit Seth, Ph.D., Vice President, Medicinal Chemistry, Ionis Pharmaceuticals	An Ion-Pair HPLC-UV-MS Methodology for Quality Control Analysis of Oligonucleotide Therapeutics Carolyn Mazzitelli, Ph.D., Associate Director, Ionis Pharmaceuticals	Late Breaking Presentation	Commercial Manufacturing of Disulfide-Rich Peptides Michael Pennington, Ph.D., Chief Scientific Officer, AmbioPharm, Inc.	High Fidelity Chemically Synthesized Guide RNA for CRISPR Applications: Synthesis, Processing and Purity Analysis John A. Walker II, Ph.D., Director of Chemistry Research, Synthego	Characterizing Lipid Nanoparticle Function to Inform on mRNA Vaccine Design Marian Gindy, Ph.D., Executive Director, Pharmaceutical Sciences, Merck Research Laboratories
3:00	(3:10-3:35) From Stereopurity to Precision Medicine: Optimizing the Properties of Antisense Nucleic Acid Therapeutics Chandra Vargeese, Ph.D., Senior Vice President, Head of Drug Discovery, WAVE Life Sciences	Selectivity in Ion-pairing Reversed Phase Liquid Chromatography of Oligonucleotides Brian Trammell, Ph.D., Principal Scientist, Analytical Development, Avecia	Long-Acting Human Growth Hormone Analogue Somapacitan by non-Covalent Albumin Binding Henrik Sune Ramirez-Andersen, Scientific Director, Novo Nordisk A/S, Denmark	Presentation Title TBA Speaker TBA, Corden Pharma	Evaluating Genome Editing Specificity with CRISPR/CAS9 and CPF1 Eugenio Marco, Ph.D., Senior Scientist, Computational Biology, Editas Medicine	Optimization of Novel Polymeric Delivery Vehicles by Chemical Evolution Ernst Wagner, Ph.D., Chair, Professor and Chair, Pharmaceutical Biotechnology, Department of Pharmacy, Ludwig Maximilians University, Germany
3:30	Networking Refreshment Break in Poster and Exhibit Hall					
	Oligonucleotide Discovery and Development	CMC QC Analytics for Oligonucleotides	New Frontiers in Peptide Drug Development		CRISPR Therapeutics	Novel Technologies for the Delivery of Macromolecular Therapeutics
4:15	(4:10) From Rectal Solution to Oral Capsule: Life Cycle Management of Cobitolimod, a Novel Immunomodulatory Oligonucleotide for Local Treatment of Active Ulcerative Colitis Christine Dieterich Johansson, Ph.D., Senior Project Manager CMC and Pre-clinical, InDex Pharmaceuticals, Sweden	Control of Impurities for siRNA Therapeutics Matthias Kretschmer, Ph.D., Senior Director Analytical Sciences, Alnylam Pharmaceuticals	Reimagining Drug Discovery: How Artificial Intelligence Can Balance the Return on Research Investment and Fuel New Peptide Discoveries Nora Khaldi, Ph.D., Founder and Chief Scientific Officer, Nuritas Ltd., Ireland		Novel Cas12a Mutants with Improved Activity and Expanded PAM Recognition Domains Mark Behlke M.D., Ph.D., Chief Scientific Officer, Integrated DNA Technologies	mRNA Vaccination with Charge-altering Releasable Transporters Elicits Human T cell Responses and Cures Established Tumors in Mice Robert Waymouth, Ph.D., Robert Eckles Swain Professor of Chemistry, Stanford University
4:45	(4:35) Preclinical and Clinical Development of AST-008, A Toll-like Receptor Agonist 9 Spherical Nucleic Acid for Immuno-oncology Applications Weston Daniel, Ph.D., Senior Director of Program Management, Exicure, Inc.	Experiences as Commercial Release Lab for Oligonucleotides Susann Rosmus, Ph.D., Head of Quality Management, BioSpring GmbH, Germany	The Orally Available Clinical Stage All-D-enantiomeric Peptide PRI-002 Reverses Cognition Deficits and Decelerates the Neurodegeneration Phenotype in Transgenic Alzheimer's Disease Mouse Models Dieter Willbold, Ph.D., Director, ICS-6 Structural Biochemistry, Forschungszentrum Jülich, Germany		sgRNA Plate-Based Synthesis For In Vitro CRISPR Screening Michelle Young, Ph.D., Senior Scientist, Intellia Therapeutics	Rapidly Identifying Nanoparticles for Non-hepatocyte RNA Delivery by Testing Thousands in vivo Using DNA Barcodes James Dahlman, Ph.D., Assistant Professor, Biomedical Engineering, Georgia Institute of Technology
5:00	Intrathecal Delivery of siRNA Conjugates Leads to Robust and Durable Silencing in the Central Nervous System Stuart Milstein, Ph.D., Associate Director, Alnylam Pharmaceuticals	Late Breaking Presentation	Progress in the Development of Peptide Therapeutics for Unmet Medical Needs Mark Smythe, Ph.D., Founder and Vice President, Protagonist Therapeutic, Australia		Synthesis and Characterization of High Purity gRNAs for CRISPR-based Therapeutics Stacy Capehart, Ph.D., Scientist II, Editas Medicine	Characterizing the Therapeutic Application of messenger RNA-lipid Nanoparticles Ying Tam, Ph.D., Chief Scientific Officer, Acuitas Therapeutics
	(5:25-5:50) DTx Pharma: Leveraging Fatty Acids as Targeting Ligands to Enable Delivery of RNA Medicines Beyond the Liver Arthur Suckow, Ph.D., CEO and CSO, DTx Pharma					
5:45-6:45	Networking Reception in Poster and Exhibit Hall					

7:30	Registration and Coffee					
	Oligonucleotide Discovery, Preclinical and Clinical	Drug Delivery Innovations and Strategies	Oligonucleotide Chemistry, Manufacturing and Controls	Peptide Discovery, Preclinical and Clinical	Peptide Chemistry Manufacturing and Controls	mRNA Therapeutics and CRISPR Therapeutics
	Extra-Hepatic Delivery of Oligonucleotides		Regulatory Perspectives	Individualized Neo-Antigens		mRNA Discovery and Development
						(8:20) Chairman's Remarks
8:25	Chairman's Remarks Muthiah (Mano) Manoharan, Ph.D., Senior Vice President of Drug Discovery, Alnylam Pharmaceuticals		Chairman's Remarks	Chairman's Remarks Trishul Shah, Director, Business Development, North America, PolyPeptide		(8:25) Inhibition and Degradation of Drug Targets Using bioPROTAC mRNAs – A Novel Approach with Broad Therapeutic Potential Anthony Partridge, Ph.D., Principal Scientist, Early Discovery Pharmacology, Translational Medicine Research Centre, Merck Sharp & Dohme, Singapore
8:30	RNAi Delivery: Overcoming a Billion Years of Evolutionary Defenses Steven Dowdy, Ph.D., Professor, Cellular and Molecular Medicine, UCSD School of Medicine		Regulatory Agency Questions and Learnings from Recent Commercial Submissions Jennifer Franklin, Director, CMC Regulatory Affairs, Ionis Pharmaceuticals	A New Source of Frameshift Neoantigens for Vaccines and Diagnostics Stephen Albert Johnston, Ph.D., Chief Executive Officer, Calviri, Inc.		(8:50) Evaluation of Modified Interferon alpha mRNA Constructs for the Treatment of Non-melanoma Skin Cancer Markus Mandler, Ph.D., Chief Scientist Officer, Accanis, Austria
9:00	Moving Antibody-Oligonucleotide Conjugates (AOCs) into Development Andy Geall, Ph.D., Vice President of Formulations, Analytics and Chemistry, Avidity Biosciences		Quality Development in European Early Access Approaches (PRIME) René Thürmer, Ph.D., Deputy Head, Unit Pharmaceutical Biotechnology, BfArM Federal Institute for Drugs and Medical Devices, Germany	Improving Formulation Consistency of Individualized, Peptide-based Therapies Using Self-assembling Nanoparticles Geoffrey Lynn, M.D., Ph.D., CEO, Avidia Technologies		(9:15) Messenger RNA Therapeutics for Bone Regeneration and for Pulmonary Diseases Christian Plank, Ph.D., Chief Technology Officer, Ethris GmbH, Germany
9:30	Ocular Delivery of siRNA Conjugates: Efficient and Durable Gene Silencing of TTR after Single Intravitreal Administration of siRNA Conjugates Jayaprakash Nair, Ph.D., Associate Director, Research, Alnylam Pharmaceuticals		Spinraza Regulatory CMC Experiences Mia Kiistala, Associate Director Regulatory Affairs, Biogen	Pioneering NeoAntigen Immunotherapies: via ATLAS & Rethinking Peptide NeoAntigens Daniel DeOliveira, Ph.D., Director of Pharmaceutical Sciences & Manufacturing, Genocoe Biosciences		(9:40-10:05) Novel mRNA Immunotherapies Robert Jabulowsky, Ph.D., Deputy Head of Project Management, BioNTech AG, Germany
10:00	Networking Refreshment Break in Poster and Exhibit Hall					
10:45	Targeting RNA with Antisense Oligonucleotides to Treat Diseases of the CNS Frank Rigo, Ph.D., Executive Director, Neuroscience Drug Discovery, Ionis Pharmaceuticals		Innovations in Oligonucleotide CMC Saving GalNAc: Improvements on Solution-Phase Conjugation of Oligonucleotides Simon Breitler, Ph.D., Process Chemist, Roche, Switzerland	FlowVax: A Synthetic, Adjuvanted Microsphere Peptide Vaccine Platform Reid Rubsamen, M.D., Founder, CEO and Director, Flow Pharma		Nucleoside-modified mRNA Immunization against Infectious Diseases Norbert Pardi, Ph.D., Research Assistant Professor of Medicine, University of Pennsylvania
11:15	Extrahepatic Targeting and the Future of Oligonucleotide Therapeutics David Rozema, Ph.D., Head of Therapeutic Chemistry, Empirico Therapeutics		Control of Oligonucleotide Drugs: Product Quality Attribute Assessment to Ascertain Criticality Robert Duff, Ph.D., Principal Scientist, Attribute Sciences, Amgen	Late Breaking Presentation		mRNA Based Vaccines Expressing RSV are Immunogenic and Protective in Preclinical Models of Respiratory Syncytial Virus Infection Andrew Bett, Ph.D., Senior Principal Scientist, Infectious Diseases and Vaccine Research, Merck Research Laboratories
11:45	Inhibition of Glutathione S-Transferase P (GSTP) for the Treatment of KRAS-Driven NSCLC using a Novel siRNA Lipid Nanoparticle Roger Adami, Ph.D., Senior Director Pharmaceutical Sciences, Nitto BioPharma, Inc.		Delivering Answers Through Innovation Brian Carothers, Vice President and General Manager, Nucleic Acid Solutions Division, Agilent Technologies, Inc.	Late Breaking Presentation		Program on Self-amplifying RNAs for Prophylactic Vaccination Dong Yu, Ph.D., Director & Function Head, Antigen Identification & Molecular Biology, GSK Vaccines
12:15	Transition to Spotlight Presentation Rooms					
	Concurrent Spotlight Presentations					
12:20-12:50	SUMITOMO CHEMICAL Sumitomo's Approach for Large-Scale Synthesis of Long RNA Oligos with High Purity Yuki Tanaka, Researcher, Health & Crop Science Research Laboratory, Sumitomo Chemical Co. Ltd., Japan		intertek Total Quality. Assured.			
12:50	Networking Luncheon in Poster and Exhibit Hall					

	Oligonucleotide Discovery, Preclinical and Clinical	Oligonucleotide Chemistry, Manufacturing and Controls	mRNA Therapeutics and CRISPR Therapeutics	Peptide Discovery, Preclinical and Clinical	Drug Delivery Innovations and Strategies	Peptide Chemistry Manufacturing and Controls
	Oligonucleotides in the Clinic	mRNA CMC and Manufacturing		Innovations in Peptide Delivery		Peptide Purification and Downstream Processing
1:55	Chairman's Remarks	Chairman's Remarks		Chairman's Remarks Christopher Rhodes, Ph.D., President and CEO, Drug Delivery Experts		Chairman's Remarks Marc Jacob, Business Development Manager, Purification Technologies - North America, Phenomenex
2:00	Update on the DCR-PHXC and DCR-HBV Clinical Programs and Other Pipeline Progress Bob Brown, Ph.D., CSO and SVP, Research, Dicerna Pharmaceuticals	Characterization of Critical Quality Attributes of mRNA Pengao Duan, Ph.D., Senior Scientist, Moderna Therapeutics		Adhesive Dermally Applied Microarray (ADAM): Experience in Osteoporosis, Diabetes and Migraine Mahmoud Ameri, Ph.D., Vice President, Research and Development, Zosano Pharma		Industrial Peptide Purification – Challenges and Concepts Ralf Eisenhuth, Ph.D., Process Manager Technology Transfer and Chromatography, Bachem AG, <i>Switzerland</i>
2:30	The Oligonucleotide Agent BC 007 Neutralizes Agonistic Autoantibodies Directed Against β1-Adrenoceptors - Data of Clinical Phase 1 Trial Annekathrin Haberland, Ph.D., Director Regulatory Affairs, Berlin Cures GmbH, <i>Germany</i>	Defining Critical Quality Attributes for RNA Nanoparticle Manufacturing from Extended Characterization Heinrich Haas, Ph.D., Vice President, RNA Formulation & Drug Delivery, BioNTech AG, <i>Germany</i>		Engineered Amphiphilic Peptides Enable Delivery of Protein and CRISPR Cargoes to Cells David Guay, Ph.D., Research Director, Feldan Therapeutics, <i>Canada</i>		Aggregation of Peptides in Preparative Chromatography Anthony Zidell, Analytical Chemist, Corden Pharma Colorado
3:00	Anti-FGF2 Aptamer RBM-007 in Phase I/IIa Trials for Wet AMD Yusuf Ali, Ph.D., CEO, RIBOMIC USA	Late Breaking Presentation		Exploiting a Novel Cell Death Mechanism for Selective Killing of Cancer Cells Upregulating Homologous Recombination Maria Soloveychik, Ph.D., CEO, SyntheX, Inc.		High-Throughput Approaches to Column Screening for the Preparative Purification of Peptides Steven McIntyre, Peptide Process Development Department Manager, Almac Group, <i>United Kingdom</i>
3:30	Close of Conference					

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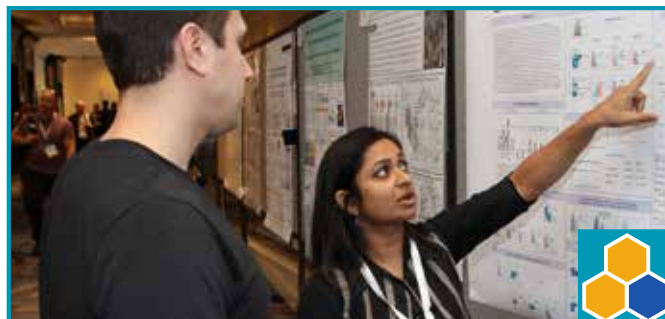
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