

February 28 – March 1, 2012 • Sheraton Miyako Hotel • Tokyo, Japan

**Pre-Conference Tutorials****Tuesday, February 28, 2012**

8:30 Conference Registration Begins

**Tutorial #1:****Technical and Regulatory Aspects of Peptide Specifications and Characterization: From Preclinical through to Market Application****Saga East Room***Tutorial Leaders:*

Robert Hagopian, Director, Business Development, PolyPeptide Laboratories, USA  
 Christopher P. Holmes, Ph.D., Executive Director, Chemistry, Affymax, Inc., USA  
 Bruce Morimoto, Ph.D., Vice President, Drug Development, Allon Therapeutics, Inc., Canada

9:00 **Introduction to the Tutorial: Scientific and Regulatory Framework for Peptide Characterization and Analytical Release Testing**

Bruce Morimoto, Ph.D., Vice President, Drug Development, Allon Therapeutics, Inc., Canada

9:30 **Analytical Requirements and Related Specifications Based on Various Phases of Clinical Trials (Drug Substance)**

Robert Hagopian, Director, Business Development, PolyPeptide Laboratories, USA

10:15 **What to Avoid and Include in your Filing: Common Deficiencies in Chemistry and Analytical Development in Preclinical and Early Clinical Phases (Drug Substance and Drug Product)**

Dr. René Thürmer, Deputy Head Unit Pharmaceutical Biotechnology, BfArM - Federal Institute for Drugs and Medical Devices, Germany

11:00 *Networking Refreshment Break*

11:30 **Regulatory Considerations on Setting Impurity Specification for Peptide Drug Products**

Duu-Gong Wu, Ph.D., Executive Director, Consulting Division, Pharmanet, USA

12:15 **Characterization of Hematide**

Christopher P. Holmes, Ph.D., Executive Director, Chemistry, Affymax, Inc., USA

1:00 *Close of Tutorial*

**Tutorial #2:****Strategies and Approaches for *in vivo* Delivery of Oligonucleotides: How to Achieve Acceptable Therapeutic Indexes in Various Organs and Tissues Using Therapeutically Relevant Administration Routes****Daigo East Room***Tutorial Leader:*

Dmitry Samarsky, Ph.D., Executive Vice President, Technology Development, RiboBio, China

9:00 **Introduction to the Tutorial**

9:30 **UNPUBLISHED DATA Fundamentals of Developing Successful Oligonucleotide Delivery Systems**

Sujit K. Basu, Ph.D., Senior Director, Formulation, Dicerna Pharmaceuticals, Inc., USA

10:15 **Development of Lipid-Based Systems for Delivery of siRNA to the Liver**

James J. Cunningham, Ph.D., Associate Director, Pharmaceutical Sciences and Clinical Supplies, Merck Research Laboratories, USA

11:00 *Networking Refreshment Break*

11:30 **Transition of Systemic siRNA Delivery Systems into the Clinic: Practical Considerations**

Peter Lutwyche, Ph.D., Senior Vice President, Pharmaceutical Development, Tekmira Pharmaceuticals Corporation, Canada

12:15 **UNPUBLISHED DATA Evaluation of Antisense Pharmacology in Multiple Tissues by In-situ Hybridization**

A. Robert MacLeod, Ph.D., Executive Director, Discovery Biology, Isis Pharmaceuticals, Inc., USA

1:00 *Close of Tutorial*

*Lunch will be served for tutorial attendees.*

1:00 *Registration for Main Conference Begins*

**Main Conference • Plenary Keynote Presentations****Tuesday, February 28, 2012****Daigo East Room**

1:55 **Chairperson's Remarks**

Laura Sepp-Lorenzino, Ph.D., Senior Director, RNA Therapeutics, Merck & Co., Inc., USA

2:00 **UNPUBLISHED DATA Oligonucleotide and Delivery Platform Optimization Strategies for siRNA Drug Development**

Laura Sepp-Lorenzino, Ph.D., Senior Director, RNA Therapeutics, Merck & Co., Inc., USA

2:40 **Overview of Peptide Therapeutics and Vaccines in Development**

Yuji Heike, M.D., Ph.D., Chief of Medical Staff, Department of Medical Oncology, National Cancer Center Hospital, Japan

3:20 **Evolution and Development of GLP-1 Based Therapeutics**

Andrew A. Young, M.D., Ph.D., Vice President, Head, Enterendocrine Biology, GlaxoSmithKline, USA

4:00 *Networking Refreshment Break and Business Card Exchange*

4:30 **Recent Advances in Routes of Delivery for Peptide Pharmaceuticals**

Nozer Mehta, Ph.D., Vice President, R&D, Unigene Laboratories, Inc., USA

5:10 **Clinical Development of Mipomersen, an Antisense Second-Generation Oligonucleotide Targeting Apolipoprotein B**

Tejdeep Singh, M.D., Medical Director, Global Patient Safety and Risk Management, Genzyme Corporation, USA

5:50 *Close of AsiaTIDES Day One*

6:30 **Networking Dinner**

*Join fellow attendees, speakers and exhibitors for a pleasant networking dinner this evening at a venue near the hotel. A few spaces are still available. Please check at registration desk at your earliest convenience if you wish to attend the dinner.*

## Updates on Oligonucleotide-Based Therapeutics in Preclinical and Clinical Development

### Updates on Oligonucleotide-Based Therapeutics in Preclinical Development

#### Daigo East Room

Session Sponsor:  Avecia

- 8:30 **Chairperson's Remarks**  
William S. Marshall, Ph.D., *President and Chief Executive Officer, miRagen Therapeutics, Inc.*

#### Keynote Presentation

- 8:35 **A Pivotal Year for Oligonucleotide Therapeutics**  
Arthur A. Levin, Ph.D., *Chief Development Officer, Santaris Pharma A/S, USA and Denmark*
- 9:15 **Discovery and Development of Novel Cardiovascular Drug Candidates Based on microRNA Targeting**  
William S. Marshall, Ph.D., *President and Chief Executive Officer, miRagen Therapeutics, Inc., USA*
- 9:45 **UNPUBLISHED DATA Therapeutic Applications of Tumor Suppressor miRNAs**  
David Brown, Ph.D., *Director of Research, Mirna Therapeutics, Inc., USA*
- 10:15 *Grand Opening of Exhibit and Poster Hall with Networking Refreshment Break*
- 11:00 **Dicer Substrate siRNA Preclinical Development: Tumor Delivery and Efficacy Using LNPs**  
Bob D. Brown, Ph.D., *Senior Vice President, Research, Dicerna Pharmaceuticals, USA*
- 11:30 **CASE STUDY UNPUBLISHED DATA A Novel Antithrombotic Strategy by Targeting Intrinsic Coagulation Pathway Factor XI Using Antisense Oligonucleotide**  
Tae-Won Kim, Ph.D., *Executive Director, Toxicology, Isis Pharmaceuticals, Inc., USA*
- 12:00 **A New Trial of miRNA Therapeutics Targeting on the Tumor Initiating Cells of Osteosarcoma**  
Tomohiro Fujiwara, M.D., *Division of Molecular and Cellular Medicine, National Cancer Center Research Institute, Japan*
- 12:30 *Luncheon in Exhibit and Poster Hall*

### Updates on Oligonucleotide-Based Therapeutics in Clinical Development

Session Sponsor:  Agilent Technologies

- 1:30 **Chairperson's Remarks**  
James D. Thompson, Ph.D., *Vice President, Pharmaceutical Development, Quark Pharmaceuticals, Inc., USA*
- 1:35 **CASE STUDY UNPUBLISHED DATA siDNA – A New Strategy Interfering with Tumor Cell's DNA Repair Signaling to Overcome Tumor's Resistance to Cancer Therapies: From Concept to Clinic**  
Prof. Jian-Sheng Sun, Ph.D., *CEO, DNA Therapeutics SA, France*
- 2:05 **Update on Safety and Clinical Activity of Synthetic siRNAs for Ophthalmic and Renal Indications**  
James D. Thompson, Ph.D., *Vice President, Pharmaceutical Development, Quark Pharmaceuticals, Inc., USA*
- 2:35 **PRO-044 and Other Exons: A Rare Opportunity**  
Allison L. Morgan, *Vice President, Clinical Research and Development, Prosensa Therapeutics, The Netherlands*
- 3:05 *Networking Refreshment Break in Exhibit and Poster Hall*
- 3:50 **Local Delivery of Nucleic Acids: tkRNAi for FAP and tauRNAi for Bladder Cancer**  
Michael V. Templin, Ph.D., *DABT, Senior Vice President, Chief Technology Officer, Marina Biotech, USA*
- 4:20 **UNPUBLISHED DATA Identification and Characterization of STAT3RX: A Potent Generation 2.5 ASO for Cancer**  
A. Robert MacLeod, Ph.D., *Executive Director, Discovery Biology, Isis Pharmaceuticals, Inc., USA*

#### Featured Presentation

- 4:50 **Update on RNAi Therapeutics in the Clinic**  
Akin Akinc, Ph.D., *Associate Director, Research, Alnylam Pharmaceuticals, Inc., USA*

## Updates on Peptide-Based Therapeutics in Preclinical and Clinical Development

### Updates on Peptide-Based Therapeutics in Preclinical Development

#### Saga East Room

- 8:30 **Chairperson's Remarks**  
Jesper Lau, Ph.D., *Vice President, Diabetes Protein and Peptide Chemistry, Novo Nordisk, Denmark*

#### Keynote Presentation

- 8:35 **RaPID Selection of a New Class of Peptide Drug Leads against Various Therapeutic Targets**  
Hiroaki Suga, Ph.D., *Professor, Chemical Biology and Biotechnology Lab, The University of Tokyo, Japan*
- 9:15 **UNPUBLISHED DATA Albumin Binding PYY and Exendin-4 Synergistically Normalize Weight and Glucose in Obese and Diabetic Mice**  
Bruce J. Hamilton, Ph.D., *Investigator, Targeted Biopharm Discovery Unit, GlaxoSmithKline, United Kingdom*
- 9:45 **CASE STUDY UNPUBLISHED DATA SKL-18287: A Long-Acting GLP-1 Analog**  
Masayuki Okamoto, *Senior Researcher, Drug Discovery Laboratories, Sanwa Kagaku Kenkyusho CO., LTD, Japan*
- 10:15 *Grand Opening of Exhibit and Poster Hall with Networking Refreshment Break*
- 11:00 **CASE STUDY UNPUBLISHED DATA Dual- or Triple-Acting Peptide Agonists for Treatment of Diabetes and Obesity**  
Christian Gröndahl, D.V.M., Ph.D., M.D., *Executive Vice President and Chief Scientific Officer, Zealand Pharma, Denmark*
- 11:30 **Modification of a Novel Angiogenic Peptide, AG30, for the Development of Novel Therapeutic Agents**  
Hironori Nakagami, M.D., Ph.D., *Professor, Vascular Medicine and Epigenetics, Osaka University United Graduate School of Child Development, Japan*
- 12:00 **UNPUBLISHED DATA A Novel Peptide Inhibiting Binding between C1q and Immune Complex Suppresses Joint Destruction in Experimental Arthritis**  
Tetsuya Tomita, M.D., Ph.D., *Associate Professor, Orthopaedic Biomaterial Science, Graduate School of Medicine, Osaka University, Japan*
- 12:30 *Luncheon in Exhibit and Poster Hall*

### Updates on Peptide-Based Therapeutics in Clinical Development

- 1:30 **Chairperson's Remarks:**  
Jesse Z. Dong, Ph.D., *Vice President, IPSEN/Biomeasure, Incorporated, USA*
- 1:35 **Pharmaceutical Protein and Peptide Engineering**  
Jesper Lau, Ph.D., *Vice President, Diabetes Protein and Peptide Chemistry, Novo Nordisk, Denmark*
- 2:05 **CASE STUDY Design Considerations for DPX-Survivac, a Multi-Cancer Peptide-Based Vaccine**  
Marc Mansour, Ph.D., *COO and CSO, Immunovaccine Inc., Canada*
- 2:35 **UNPUBLISHED DATA Speeding up Peptide-Based Vaccine Research with VesiVax® Conjugatable Adjuvant Lipid Vesicles (CALV)**  
Gary Fujii, Ph.D., *President and CEO, Molecular Express, Inc., USA*
- 3:05 *Networking Refreshment Break in Exhibit and Poster Hall*
- 3:50 **UNPUBLISHED DATA Update on Clinical Development of CurePeptin**  
Takahiro Nakazawa, Ph.D., *Senior Director, Research and Development, Anges MG, Inc., Japan*
- 4:20 **The Effect of Davunetide on Clinical and Biomarker Endpoints in a Pilot Study of Schizophrenia**  
Bruce Morimoto, Ph.D., *Vice President, Drug Development, Allon Therapeutics, Inc., Canada*

#### Featured Presentation

##### Daigo East Room

- 4:50 **Update on RNAi Therapeutics in the Clinic**  
Akin Akinc, Ph.D., *Associate Director, Research, Alnylam Pharmaceuticals, Inc., USA*

## Manufacturing and Analytical Development for Peptides and Oligonucleotides

### Daigo East Room

- 8:00 **Chairperson's Remarks**  
Paula Lorence, *Vice President, Business Development, Avecia, USA*
- 8:10 **CASE STUDY UNPUBLISHED DATA** **Hydrophobic Tag-assisted Multi-step Solution Phase Peptide Synthesis for Advanced Modifications and Large Scale Production**  
Kazuhiro Chiba, Ph.D., *Professor, Applied Biological Science, Tokyo University of Agriculture and Technology, Japan*
- 8:35 **From R&D to Revolutionary Peptide Production**  
Didier Monnaie, Ph.D., *Analytical Development Group Leader, Lonza Braine SA, Belgium*
- 9:00 **CASE STUDY UNPUBLISHED DATA** **Synthetic Manufacturing of Icatibant (Firazyr®)**  
Thomas Meier, *Vice President, Production, Bachem AG, Switzerland*
- 9:25 **CASE STUDY UNPUBLISHED DATA** **Application of AjiPhase™ to Large Scale Peptide Manufacturing**  
Daisuke Takahashi, *Section Chief, Institute for Bioscience Products and Fine Chemicals, Ajinomoto Co., Inc., Japan*
- 9:50 **A Novel High Loading Polymer Support for Therapeutic Oligonucleotide Synthesis**  
Yi Jin, Ph.D., *Director of Biomedical Division, Nitto Denko Technical Corp., USA*
- 10:15 *Networking Refreshment Break in Exhibit and Poster Hall*
- 10:45 **Spotlight Presentation** *Sponsored by*  
**Impact of Phosphoramidite Impurities on the Impurity Profile of Oligonucleotides**  
Dr. Hüseyin Aygün, *CSO, Nucleic Acid Technologies, BioSpring GmbH, Germany*



### Panel Discussion

- 11:10 **Controls and Specifications for Raw Materials**  
*Moderator: Paula Lorence, Vice President, Business Development, Avecia, USA*  
*Panelists:*  
Dr. Hüseyin Aygün, *CSO, Nucleic Acid Technologies, BioSpring GmbH, Germany*  
Sujit K. Basu, Ph.D., *Senior Director, Formulation, Dicerna Pharmaceuticals, Inc., USA*  
Paul Metz, *Senior Director, Operations, Nucleic Acids Solutions Division, Agilent Technologies, Inc., USA*  
Ipsita Roymoulik, Ph.D., *Associate Director, Analytical Development, Avecia, USA*  
Dr. René Thürmer, *Deputy Head Unit Pharmaceutical Biotechnology, BfArM - Federal Institute for Drugs and Medical Devices, Germany*  
Mike Webb, *Head, API Chemistry and Analysis, UK, GlaxoSmithKline, United Kingdom*
- 11:40 **CASE STUDY UNPUBLISHED DATA** **Multi-Site Evaluation of a Validated HPLC Method for Phosphoramidites.**  
Paul Metz, *Senior Director, Operations, Nucleic Acids Solutions Division, Agilent Technologies, Inc., USA*
- 12:05 **Spotlight Presentation** *Sponsored by:*  
**Considerations for Design of a Large-Scale Oligonucleotide Manufacturing Facility**  
Thomas M. Rupp, *Technical Advisor, Oligonucleotide Manufacturing, Girindus, USA*
- 12:30 **Oligo Manufacturing – The Journey to Commercial Readiness**  
Kelly G. Behrendt, *Vice President, Operations, Avecia, USA*
- 12:55 *Networking Luncheon in Exhibit and Poster Hall*



## Main Conference • Plenary Session

### Business Considerations for Successful Development of Oligonucleotide- and Peptide-Based Therapeutics

#### Daigo East Room

- 1:55 **Chairperson's Remarks**  
Kathryn L. Ackley, Ph.D., *Vice President, Business Development and Project Management, Girindus, USA*
- 2:00 **Industrialising a Therapeutic Oligonucleotide Portfolio – A CMC Perspective**  
Mike L. Webb, Ph.D., *Head, API Chemistry and Analysis, UK, GlaxoSmithKline, United Kingdom*
- 2:25 **Developing siRNA Therapeutics for Clinical Studies in China**  
Patrick Y. Lu, Ph.D., *Founder, President and CEO, Sirnaomics, Inc., USA and China*
- 2:50 **Peptide Ingredients: Market Overview and Growing Areas of Application**  
Ann-Kathrin Stoller, Ph.D., *Vice President, Marketing and Sales, Bachem Holding AG, Switzerland*
- 3:15 *Networking Refreshment Break in Exhibit and Poster Hall and Final Chance to See Exhibits and Posters*

## Formulation and Delivery of Peptides and Oligonucleotides

### Saga East Room

- 8:30 **Chairperson's Remarks**  
Bob D. Brown, Ph.D., *Senior Vice President, Research, Dicerna Pharmaceuticals, USA*
- 8:35 **UNPUBLISHED DATA** **Combinatorial Development of Biomaterials and Synthetic siRNA Delivery Systems**  
Daniel G. Anderson, Ph.D., *Associate Professor, Chemical Engineering, Harvard-MIT Division of Health Sciences and Technology, David H. Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology, USA*
- 9:15 **Progress in the Development of Lipid Nanoparticle siRNA-Based Drugs**  
Ian MacLachlan, Ph.D., *Executive Vice President & Chief Scientific Officer, Tekmira Pharmaceuticals Corp., Canada*
- 9:45 **Strategies for the Delivery of RNAi Therapeutics**  
Akin Akinc, Ph.D., *Associate Director, Research, Alnylam Pharmaceuticals, Inc., USA*
- 10:15 *Networking Refreshment Break in Exhibit and Poster Hall*
- 11:00 **Therapeutic Gene Silencing in Liver by Enteral siRNA Delivery**  
Takanori Yokota, M.D., Ph.D., *Professor, Department of Neurology and Neurological Science, Tokyo Medical and Dental University, Japan*
- 11:30 **Novel Approaches to Address Therapeutic Oligonucleotide Delivery**  
Dmitry Samarsky, Ph.D., *Executive Vice President, Technology Development, RiboBio, China*
- 12:00 **Clinical Development of a Solid Dosage Oral Formulation for the 32 Amino Acid Peptide Salmon Calcitonin**  
Nozer Mehta, Ph.D., *Vice President, R&D, Unigene Laboratories, Inc., USA*
- 12:30 **Spotlight Presentation**  
1:00 *Networking Luncheon in Exhibit and Poster Hall*

## Conference Documentation

Speaker presentations, biographies and related materials received to date are available at the secure, password protected website listed below. New or updated presentations collected onsite at the conference will be added (upon speakers' approval) to the site after the conference has concluded.

• Website: <http://materials.IBCLifeSciences.com/R12225>

• To access the materials, enter the following unique password:  
**AveciaOLIGO2012** (*The password is case sensitive.*)

Please note: Some speakers have not provided their slides for distribution to the delegates due to company external disclosure policies or academic restrictions against distributing unpublished materials. IBC has made every effort to obtain presentation materials from all speakers.

## Thursday, March 1, 2012 (continued)

### Regulatory Updates: Preclinical Safety Assessment of Oligonucleotides and Peptides

- 4:00 **Co-Chairpersons' Remarks**  
Arthur A. Levin, Ph.D., *Chief Development Officer, Santaris Pharma A/S, USA and Denmark*  
Kazuto Watanabe, Ph.D., *Principal Scientist, Safety Assessment Department, Chugai Pharmaceutical Co. Ltd., Topic Leader, ICH S6(R1) EWG, JPMA, Japan*
- 4:15 **Special Issues in Regulating Oligonucleotides (CMC)**  
Dr. René Thürmer, *Deputy Head Unit Pharmaceutical Biotechnology, BfArM - Federal Institute for Drugs and Medical Devices, Germany*
- 4:40 **Current Issues in Non-Clinical Safety Evaluation of Oligonucleotide Drugs in Japan**  
Kazuchika Takagaki, Ph.D., *Manager, Discovery Research Laboratories in Tsukuba, Nippon Shinyaku Co., Ltd., representing JPMA, Japan*
- 5:05 **Special Issues in Developing Oligonucleotide Therapeutics: Hybridization-Dependent Off-Target Events and Surrogate Drugs for Toxicity Testing**  
Arthur A. Levin, Ph.D., *Chief Development Officer, Santaris Pharma A/S, USA and Denmark*
- 5:30 **Background and Outcomes of Revision of ICH S6 Guideline**  
Kazuto Watanabe, Ph.D., *Principal Scientist, Safety Assessment Department, Chugai Pharmaceutical Co. Ltd.; Topic Leader, ICH S6(R1) EWG, JPMA, Japan*
- 5:55 *Close of AsiaTIDES*

## Poster Presentations

1	<b>A Novel Emulsion-Type Adjuvant Contains CpG Oligodeoxynucleotides Enhances CD8+ T Cell Immunity against Cervical Cancer</b>	Yin Chyi Song	National Institute of Infectious Diseases and Vaccinology Institution: National Health Research Institutes
2	<b>Oligonucleotide Affinity Measurements Using Electrokinetic Controlled Capillary Electrophoresis Microchip</b>	Turchaninov T.R	The Faculty of Bioengineering and Bioinformatics, Lomonosov Moscow State University
3	<b>Convenient &amp; High Yield Synthesis of High Purity Biologically Active long Chain RNA's</b>	Suresh Srivastava	ChemGenes Corp.
4	<b>A Novel Optimization Platform Technology to Improve Therapeutic Property of Lead Peptides</b>	Yusuke Kohno	Jitsubo Co.Ltd.
5	<b>Suppression of Autophagy by Estradiol Contributes to the Sex Difference in Ferrous Citrate-Induced Brain Injury</b>	Chin Hsu	Kaohsiung Medical University

## Thank you for attending AsiaTIDES

If you or your colleagues would like to join the 13th Annual **TIDES Summit** this May in Las Vegas, NV, here is a discount to save on your registration:

### Receive a 20% Discount to Attend:

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