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Part of the 12th annual RNA Therapeutic series of events

SMi Group Proudly Presents the Inaugural conference on...

Oligonucleotide Therapeutics and Delivery

On the way to maximising the potential of oligo-based medicine

HOLIDAY INN KENSINGTON FORUM, LONDON, UK

VIRTUAL ATTENDANCE OPTION AVAILABLE

WORKSHOP: 21ST
CONFERENCE: 22ND-23RD

SEPT 2021

HIGHLIGHTS FOR 2021:

- **Gain** first-hand insight into oligonucleotide therapy clinical success of the latest developments for novel agents
- **Listen** to case studies presenting the latest candidates undergoing pre-clinical and clinical research
- **Deepen** your understanding of crucial delivery methods and available platforms for non-hepatocytic delivery
- **Explore** the chemistry of oligonucleotide therapeutics and examine novel applications of antisense oligonucleotides in the AstraZeneca Deep Dive
- **Engage** in the latest innovations of oligonucleotide therapeutics with insights into immunochemotherapeutics, ocular indications and Duchenne Muscular Dystrophy

CHAIR FOR 2021:

- **Nagy Habib**, Professor of Surgery, Imperial College, Co-founder MiNA therapeutics, **Imperial College London**

FEATURED 2021 SPEAKERS INCLUDE:

- **David Evans**, Chief Scientific Officer, **Sirnaomics, Inc**
- **Stefan Vonhoff**, VP Chemistry & Manufacturing, **NOXXON Pharma AG**
- **Adrien Weingartner**, Principal Scientist, Group Leader Drug Delivery, **Silence Therapeutics AG**
- **Tom Baladi**, Postdoctoral Research Fellow, **AstraZeneca**
- **Maria Luisa Pineda**, CEO and Co-founder, **Envisagenics**
- **Ekkehard Leberer**, Senior Director, R&D Alliance Management, **Sanofi**
- **Michelle Lynn Hall**, Senior Director, Novel Therapeutic Modalities, **Eli Lilly and Company**
- **Arthur A Levin**, Chief Scientific Officer, **Avidity Biosciences Inc**
- **Meiling Li**, Senior Scientist, **F. Hoffmann-La Roche Ltd.**

...And Many More!

PLUS AN INTERACTIVE HALF DAY PRE-CONFERENCE WORKSHOP | TUESDAY 21ST SEPTEMBER 2021, HOLIDAY INN KENSINGTON FORUM, LONDON, UK | 13.00-17.00

Target Discovery for RNA Therapeutics

Workshop Leader: **Martin Akerman**, Chief Technology Officer, **Envisagenics**

Featured Guest Speakers From: **Envisagenics**, **Eli Lilly**, **InterNA Technologies**, **HAYA Therapeutics**, **Stoke Therapeutics** and **ARNAY Sciences**

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8.00 **Registration & Coffee**

9.00 **Chair's Opening Remarks**

Nagy Habib, Professor of Surgery, Imperial College, Co-founder MiNA therapeutics, **Imperial College London**

RECENT ADVANCES IN OLIGONUCLEOTIDE THERAPEUTICS

OPENING ADDRESS

9.10 **Evolution, challenges and potential of RNA Therapeutics**

- Background on RNA Therapeutics –what it encompasses, current status and pipeline
- Challenges surrounding development of RNA Therapeutics
- Promising future of RNA therapeutics

Michelle Lynn Hall, Senior Director, **Eli Lilly & Co - New Therapeutic Modalities**



CASE STUDY

9.45 **Automating the discovery and development of RNA therapeutics**

- Envisagenics' SpliceCore platform integrates proprietary machine learning algorithms, high performance computing, and RNA-splicing analytics to identify disease-specific isoforms that will function as therapeutic targets
- Proof-of-concept program in Triple Negative Breast Cancer (TNBC) – discovery of TNBC specific splicing isoforms
- Machine learning driven methodologies to designing and developing RNA therapeutics targeting TNBC specific splicing isoforms
- Streamlined experimental validations of SpliceCore designed RNA therapeutics

Maria Luisa Pineda, CEO and Co-founder, **Envisagenics**



10.20 **Morning Coffee**

10.50 **Oligonucleotides as a therapeutic option for Duchenne Muscular Dystrophy (DMD)**

- Background for the oligonucleotides PMOs / PPMOs and the MoA for RNA-exon skipping
- I.v. PMOs / PPMOs for RNA-exon skipping in DMD
- Clinical results for the PMOs / PPMOs from the Sarepta pipeline in DMD

Andre Muller-York, Senior Medical Affairs Director, **Sarepta Therapeutics Germany GmbH**

11.25 **Immunotherapeutic oligonucleotides for cancer treatment**

- Introducing the immunotherapeutic oligonucleotide approach
- Highlighting success in oncology mouse models to date
- Addressing challenges of delivery and maximising the EPR effect
- Vaccination with RNA
- Discussing next steps of the programs and evaluating potential delivery solutions

Steve Pascolo, Founder and CEO, **Miescher Pharma GmbH**

OPTIMISING OLIGONUCLEOTIDE DEVELOPMENT STRATEGIES

12.00 **Introduction of non-chiral phosphorodithioates into Locked Nucleic Acids**

- RNA therapeutics have clearly demonstrated their medical benefit.
- Phosphorodithioates have been extensively profiled and cover most of the clinically investigated entities. The complexity of diastereoisomers have resulted in the great challenges in understanding PK/PD of stereomixed oligonucleotides.
- Introduction of non-chiral phosphorodithioates dramatically reduces the diastereomeric complexity and can potentially improve PK/PD of oligonucleotides.
- Combinations of phosphorodithioates and stereodefined motifs will allow to rapidly identify highly potent one single phosphorothioate LNA isomer, which is supported by recent in vitro and in vivo data.

Meiling Li, Senior Scientist, **F. Hoffmann-La Roche Ltd.**

12.35 **Networking Lunch**

13.35 **The UK Nucleic Acid Therapy Accelerator (NATA)**

- A background and introduction to the aims of the NATA in supporting the development of synthetic RNA therapeutics
- The NATA Hub: a world leading research institute to support the RNA therapeutics community, providing dedicated capability in oligo synthesis and biological screening
- The NATA's upcoming funding calls to address barriers in the manufacture and the delivery of RNA therapeutics
- Opportunities to partner with the NATA Hub; Q&A session

Loic Roux, Head of Chemistry, **NATA**

14.10 **How to purify and analyse Oligonucleotide APIs**

- Introducing chromatographic approaches for purification and analysis
- Choosing appropriate strategies for different impurity classes
- Selected examples for the purification and analysis of therapeutic oligonucleotides

Patrick Endres, Junior Management Application Development, **Tosoh Bioscience GmbH**



TOSOH

14.50 **Formulation strategies for the development of injectable Spiegelmer drug product solutions**

- Introducing the Spiegelmer technology approach and NOXXON's clinical development program
- Defining a target product profile for injectable Spiegelmer drug product solutions
- Overcoming development challenges for Spiegelmers drug product solutions
- Establishing quality control methods for Spiegelmer drug product manufacturing and release in accordance with guidelines

Stefan Vonhoff, VP Chemistry & Manufacturing, **NOXXON Pharma AG**

15.25 **Afternoon Tea**

DEEP DIVE

15.55 **Fluorescent Base Analogs (FBAs) in Gapmer Technology: Stealth Labeling of Antisense**

- Outline of the design and assets of FBAs: modifying nucleobases to gain fluorescence properties without using external dyes
- Synthesis of FBA phosphoramidites and incorporation into ASOs
- Synthesis of FBA triphosphates and enzymatic incorporation into mRNA
- Assessment of structural, biological and photophysical properties of labelled constructs.

Tom Baladi, Postdoctoral Research Fellow, **AstraZeneca**



CLOSING KEYNOTE

16.30 **Treating diseases with antibody oligonucleotide conjugates: Combining the selectivity of antibodies with the specificity of oligonucleotide drugs**

- Antibody oligonucleotide conjugates utilize the selectivity of antibody delivery and the specificity of oligonucleotide therapeutics to treat diseases
- AOC1001 is designed to treat myotonic dystrophy type 1
- Other AOCs are in development to address muscle disease and other disorders

Arthur A Levin, Chief Scientific Officer, **Avidity Biosciences Inc**



17.05 **Chair's Closing Remarks and Close of Day One**

Nagy Habib, Professor of Surgery, Imperial College, Co-founder MiNA therapeutics, **Imperial College London**

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8.30 Registration & Coffee

9.00 Chair's Opening Remarks

Nagy Habib, Professor of Surgery, Imperial College, Co-founder MiNA therapeutics, **Imperial College London**

CLINICAL ADVANCES OF RNAI THERAPY

OPENING ADDRESS

9.10 Delivery of Novel siRNA constructs for treating cancer

- Creating siRNA payloads for cancer treatment
- Understanding the challenges of cell-specific delivery: how to get size and efficacy right?
- Choosing the appropriate delivery system
- Presenting success and future steps

David Evans, Chief Scientific Officer, **Sirnaomics, Inc**

9.45 Recent clinical progress with RNAi loaded KRAS-LODER for pancreatic tumour

- Introducing the RNAi loaded KRAS-LODER for targeting KRAS mutations
- Overviewing recent clinical success in phase II trials
- Presenting phase II clinical trials results including primary and secondary endpoints
- Outlining next steps of programme

Amotz Shemi, CEO, **Silenseed**

10.20 Morning Coffee

10.50 INT-1B3 (miR-193a-3p mimic): from bench-to-bedside

- Focus on microRNA R&D
- Success (bench-to-bedside) story for Oncology therapeutic intervention
- Preclinical to first in human study transition

Michel Janicot, CDO, **InterRNA Technologies BV**

EMERGING DELIVERY SOLUTIONS

KEYNOTE ADDRESS

11.25 Targeted Delivery of C/EBPa-saRNA by RNA Aptamers

- Understanding the principles of RNA activation and possibilities of therapeutic benefit
- Harnessing small activating RNAs for the treatment of Pancreatic ductal adenocarcinoma
- Evaluating aptamers and appropriate means of targeted delivery
- Looking at lessons learnt from using saRNA for oncological purposes

Nagy Habib, Professor of Surgery, Imperial College, Co-founder MiNA therapeutics, **Imperial College London**

12.00 Small activating RNAs — a novel therapeutic class of oligonucleotides

- Description of saRNA technology to upregulate transcription and broad applicability to a range of therapeutic targets
- Generation of a lead candidate saRNA to HNF4a for liver disease
- Update on MiNA's lead saRNA clinical agent MTL-CEBPA – Clinical PD and efficacy

Matthew Catley, Research Director, **MiNA Therapeutics Ltd**

12.35 Networking Lunch

DEEP DIVE

13.35 MicroRNA Therapeutics: Targeting the Pathways of Human Disease

- MicroRNAs are short non-coding RNAs that regulate biochemical pathways by RNA interference (RNAi). Dysregulation of microRNAs is associated with many diseases.
- MicroRNA-21 has been implicated with fibrotic diseases and cancer.
- The presentation shows the development of an anti-fibrotic antisense oligonucleotide (anti-miR-21) for the treatment of a genetic fibrotic kidney disease called Alport Syndrome, and summarizes the potential of anti-miR-21 as a drug to treat hepatocellular carcinoma.

Ekkehard Leberer, Senior Director, R&D Alliance Management, **Sanofi**

14.10 The tool-box approach to improve the performance of siRNA-platform technology

- Interplay of design and function
- Stability and duration of action
- Linker design and valency of ligands
- Is there room for additional improvements?

Adrien Weingartner, Principal Scientist, Group Leader Drug Delivery, **Silence Therapeutics AG**

14.45 Afternoon Tea

SPOTLIGHT SESSION

15.15 Targeted cytoplasmic delivery of oligonucleotides

- Sapreme's SPT001 compound improves cellular delivery of non-permeable biomolecules such as nucleic acids by up to 1000 fold by enhancing their escape from the endosome
- SPT001 conjugation to a targeting ligand can drive payload internalization and cytoplasmic delivery in a cell- or tissue specific manner – further improving the therapeutic window of any given antisense oligo or siRNA
- We will highlight recent proof-of-principle studies on nucleic acid delivery in vitro and in vivo

Guy Hermans, Chief Executive Officer, **Sapreme Technologies B.V.**

15.50 Clinical development of AsiDNA, a first in class decoy agonist oligonucleotide targeting DNA damage response in tumor cells

- Introduction to platON™: proprietary chemistry platform based on a library of decoy agonist oligonucleotides which generates disruptive compounds acting on intracellular DNA-binding targets
- Introduction to AsiDNA the leading decoy agonist generated from platON and targeting DNA damage response function
- Recent preclinical highlights: AsiDNA abrogates resistance to multiple anti-cancer targeted therapies
- Recent clinical development of AsiDNA
- Outlining next steps of clinical development

Wael Jdey, Head of Biology, **Onxeo S.A.**

16.25 Chair's Closing Remarks and Close of Day Two

Nagy Habib, Professor of Surgery, Imperial College, Co-founder MiNA therapeutics, **Imperial College London**

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HALF DAY PRE-CONFERENCE WORKSHOP

13.00 - 17.00

Workshop Leader:
Martin Akerman, Chief Technology Officer, **Envisagenics**

Featured Guest Speakers From:
Envisagenics, Eli Lilly, InteRNA Technologies, HAYA Therapeutics, Stoke Therapeutics and ARNAY Sciences

Target Discovery for RNA Therapeutics

Workshop overview:

The field of RNA therapeutics has been rapidly gaining momentum. In parallel, methodologies for early discovery have been taking a new form. Combining the now-accessible resources such as big data, multi-omics, and high-performance computing, this new ecosystem of R&D approaches has been surfacing.

This workshop will explore:

- Different perspectives on building a multi-disciplinary team
- Data-driven innovation for a biotechnology company
- Novel discovery platforms with horizontal applications
- Strategic insights in the field of RNA therapeutics

Programme:

13.00 Registration and Coffee

13.30 Opening Remarks

Martin Akerman, Chief Technology Officer, **Envisagenics**

13.40 RNA Therapeutics in Oncology: Advances and Challenges

- With the support of Envisagenics' proprietary machine learning modules, high performance computing, and splicing analytics, Envisagenics identified a novel target and designed and validated RNA therapeutic compound in 8 months
- Focusing on antisense oligonucleotides as a viable therapeutic modality in oncology and other applicable therapeutic areas
- Overcoming limitations to computational outputs and executing necessary validation experiments for in-silico identified targets



Gayatri Arun, Vice President of Biology, **Envisagenics**

14.10 PANEL DISCUSSION: The Evolution and Expansion of RNA-based Therapeutics

- Defining applicable therapeutic areas for RNA-based therapeutics and the current promising and accepted disease areas
- Investor outlook on RNA therapeutics and their appetite for RNA-based companies
- Spectrum of RNA therapeutics (miRNA, ASO, mRNA, siRNA, etc.)
- Roles of small molecules in RNA therapeutics
- Modality comparison (small molecule vs. antisense; delivery vs. generalizable drugs) and pros and cons of RNA-based therapeutics



PANEL MODERATOR:

Martin Akerman, Chief Technology Officer, **Envisagenics**



PANELISTS:

Michelle Lynn Hall, Senior Director, **Eli Lilly**



Michel Janicot, Chief Development Officer, **InteRNA Technologies**

15.00 Afternoon Tea

15.30 Targeting the Noncoding Genome for the Development of RNA Therapies

- New concepts for the identification of tissue, cell-type, and disease specific regulatory ncRNA targets
- RNA-targeting modalities and approaches to tame the genome's dark side
- Translational potential of next-generation lncRNA targets



Samir Ounzain, CEO, **HAYA Therapeutics**

16.00 PANEL DISCUSSION: The Successes and Failures of RNA-based Therapeutics and Future Outlook

- Considerations of important characteristics and biology targeting RNA molecules directly.
- Pipeline and process overview of target selection criteria and ensuring therapeutic viability and specificity.
- Transforming antisense into a drug and taking sequence into consideration to understand potential off-target effects.
- Drug delivery considerations, chemistry considerations, and IP strategy
- Future outlook of RNA-based therapeutics (impact of COVID in the RNA field) and innovative companies in the last 10 years in this respective field



PANEL MODERATOR:

Martin Akerman, Chief Technology Officer, **Envisagenics**



PANELISTS:

Eric Lim, Associate Director, Bioinformatics, **Stoke Therapeutics**



Samir Ounzain, CEO, **HAYA Therapeutics**



Gayatri Arun, Vice President of Biology, **Envisagenics**



Sudhir Agrawal, Founder and President, **ARNAY Sciences**

16.50 Closing Remarks

Martin Akerman, Chief Technology Officer, **Envisagenics**

17.00 End of Workshop



Martin Akerman is the Co-founder and CTO of Envisagenics. He is the inventor of the SpliceCore® platform, Envisagenics' flagship AI technology for the discovery of splicing-based therapeutic targets. Martin trained as a post doctorate fellow with Dr. Adrian Krainer from Cold Spring Harbor Laboratory. He received his PhD in Bioinformatics from Technion, Israel Institute of Technology. As a first-time entrepreneur, Martin represented Envisagenics in winning the J&J AI for Drug Discovery QuickFire challenge in 2017 and Microsoft's Innovate.AI challenge in 2018. His goal is to combine cutting-edge computation with RNA domain expertise to develop innovative drugs for cancer and genetic diseases.

About the organisation:

Envisagenics is an AI-driven biotech company that focuses on developing novel therapeutics to modulate RNA splicing errors and produce the desired protein isoforms. SpliceCore® is Envisagenics' discovery platform that re-envision the human genome with a validated exon-centric approach, combined with machine learning algorithms and high-performance computing. Using innovative tech and RNA expertise, we aim to accelerate the development of highly specific therapeutics that modulate RNA splicing events that drive pathogenesis of Oncology, Neurodegenerative, and Genetic Diseases.

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