FDA Releases Draft Guidance on CMC For Individualized ASO Therapies

SAE Media Group reports: the Oligonucleotide Therapeutics Conference will touch on the Draft Guidance on CMC for Individualized ASO Therapies

LONDON, NON UNITED STATES OR CANADA, UNITED KINGDOM, July 8, 2022 /EINPresswire.com/ -- SAE Media Group proudly presents the return of the Oligonucleotide Therapeutics & Delivery Conference on the 21st and 22nd September 2022 in London, UK. The two-day conference will bring you high-quality insights and industry connections on the latest clinical trial candidates and a platform for exchanging ideas for tackling the biggest challenge: DELIVERY.

Personalized medicine continues to be at the cutting edge of healthcare, pharmaceuticals, and biotechnology. For patients afflicted with a unique disease state or those with diseases resistant or inadequately treated by existing therapies, personalized treatments are a last, best hope.

However, for pharmaceutical companies, the safe and ethical development of individualized treatments is, as with any new pharmaceutical, an expensive and time-intensive endeavor. This creates a conflict between the need for these therapies and the lack of a large patient population that may participate in clinical trials and ultimately purchase an approved treatment to offset the initial development costs.

This issue was recognised by the FDA and on December 7th, 2021, a new draft guidance was published: "IND Submissions For Individualized Antisense Oligonucleotide Drug Products For Severely Debilitating Or Life-Threatening Diseases: Chemistry, Manufacturing, And Controls Recommendations, Guidance For Sponsor-Investigators.1"*

The CMC Guidance entails:
•difficulties inherent in manufacturing these individualized treatments
•in turn it offers research and manufacturers the opportunity to create policies and procedures that are more likely to be condoned by the FDA in an IND submission

Presenting on this in more detail at the conference will be Chris Chorley, Associate Director, Global Regulatory CMC from Biogen who will speak about "Current CMC Regulatory Challenges In ASO Development" and Sergio Leone, Research Associate, MRC Toxicology Unit from University of Cambridge who will be presenting on "Molecular Mechanisms Of Antisense Oligonucleotide Cytotoxicity".

Chris Chorley's presentation will be touching on:

•Overview of key CMC regulatory challenges during the clinical development phase
•Regulatory strategies for use of platform data and prior knowledge

Sergio Leone's presentation will be touching on:

•Introduction to the mechanistic action of ASOs in cells after delivery
•Insight into in vivo and in vitro models for the study of ASO cytotoxicity
•Exploring molecular mechanisms of ASO cytotoxicity to better design future ASO therapeutics
•Discussion of balancing safety and efficacy of ASOs

There will also be two pre-conference workshops on 20th September 2022 in London UK.
The first workshop will be discussing "Oligonucleotide Therapies- Overcoming The Challenges Of Delivery" led by Ritwick Sawakar, MRC Investigator, MRC Toxcology Unit, University Of Cambridge, Nick Lench, Executive Director, UKRI/MRC Nucleic Acid Therapy (NATA) and Peter Oliver, Head of Biology, UKRI/MRC Nucleic Acid Therapy (NATA).

The second workshop will be focused on "Managing CMC Activities For The Development Of Oligonucleotide Therapeutics" and this will be led by Mia Kiistala, Principal Consultant, Aurora CMC Consulting.

Interested parties can register for the conference and workshop at:
http://www.oligonucleotide.co.uk

For sponsorship opportunities, please contact Andrew Gibbons on +44 (0) 20 7827 6156 or email: agibbons@smi-online.co.uk

For media enquiries or a press pass contact Marketing, Nikisha Galoria on +44 (0) 20 7827 6154 or email ngaloria@smi-online.co.uk

2nd Annual Oligonucleotide Therapeutics & Delivery Conference
21-22 September 2022
London, UK
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Nikisha Galoria
SMi Group
02078276000
email us here