September 18-19, 2019 | Boston, MA
www.exosomebased-tx.com

BOOK EARLY TO SAVE $1100

Exosome Based Therapeutic Development

Dedicated to Translating Exosome Therapeutics into a Clinical & Commercial Reality

Expert speakers include:

Shelley Hartman
Co-Founder & Chief Executive Officer
Aegle Therapeutics

Xandra Breakefield
Professor, Neurology & Geneticist, Neurology & Radiology
Harvard Medical School & **Massachusetts General Hospital**

Richard Brudnick
Chief Business Officer & Head of Strategy
Codiak Biosciences

Shaun Stapleton
Vice President, Regulatory Affairs & Pharmacovigilance
ReNeuron

Linda Marban
Chief Executive Officer
Capricor Therapeutics

Jan Lötvall
Professor & Chief Physician, Asthma, Allergy, Inflammation & Eosinophils
University of Gothenburg

Ian McNiece
Chief Executive Officer & Chief Scientific Officer & Vice President, Research & Development
Oncocyclist & **Biocardia** & **Aegle Therapeutics**

Steven Stice
Co-Founder & Chief Scientific Officer & Professor
ArunA Biomedical & **University of Georgia**

Susanne Gabrielsson
Professor, Medicine
Karolinska Institute

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Exosome Based Therapeutic Development Summit 2019

The exosome field is evolving rapidly, as scientific understanding grows and companies consistently produce robust preclinical data. As the industry quickly approaches clinical development, companies are positioning themselves to enter trials in the next few years; **at the same time**. If the boom in immunotherapies has told us anything about drug development, it's that **being first to market is game changing**.

The inaugural **Exosome Based Therapeutic Development Summit 2019** will unite biotech, academia, pharma and technology providers to **accelerate the discovery, development and commercialization** of safe and effective exosome based therapeutics. As the race to the clinic intensifies, this summit will help industry leaders and newcomers alike overcome key challenges and improve the end-to-end development of these therapeutics, from discovery to market delivery.

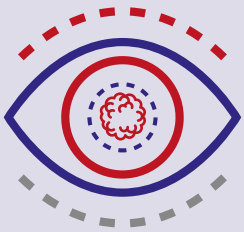
Focused **exclusively on therapeutic applications**, Exosome Based Therapeutic Development Summit 2019 is a must attend for those looking to explore the **target identification**, **therapeutic potential**, **delivery** and **scaling** of exosome and extracellular vesicle (EV) derived products as effective next generation drugs.

Why Are You Excited to Participate?

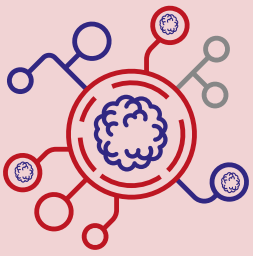
"Exosome-based therapeutics represent a most promising next generation approach for treating a diverse array of diseases. As we transition from the laboratory to the clinic, this timely meeting will bring academia and industry together, and will provide an exciting platform to showcase current cutting-edge advances in the exosome field"

Gareth Willis, Instructor, Pediatrics, Boston Children's Hospital, Harvard Medical School

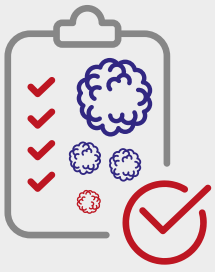
Key Topics for 2019:



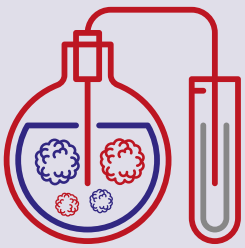
Understanding key **mechanisms and interactions** of exosomes to **uncover novel targets** and drive informed decision making with insights from **Karolinska Institute**, **Harvard Medical School** & **UC Davis**



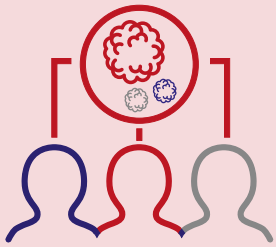
Ensuring **preclinical development** sets you up for success with translatable and reliable data with lessons in **exosome purification, isolation and preclinical development** with **Oncocyclist**, **Boston Children's Hospital** & **George Mason University**



Exploring the **regulatory state-of-play** and its impacts to product development with **ReNeuron**, and the journey of **Aegle Therapeutics** to gain FDA clearance



Building **effective manufacturing platforms** to maintain high quality, consistent and reproducible exosomes and EVs with **Karolinska Institute** & **ReNeuron**



Key considerations for **streamlined market access** to break through competition and be the first to the clinic, with insights from **Evox Therapeutics** & **Capricor Therapeutics**

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YOUR EXPERT SPEAKERS

Johnathon Anderson
Assistant Professor, Department of Otolaryngology
University of California Davis

Xandra Breakefield
Professor, Neurology & Geneticist, Neurology & Radiology
Harvard Medical School & **Massachusetts General Hospital**

Richard Brudnick
Chief Business Officer & Head of Strategy
Codiak Biosciences

Randolph Corteling
Head, Research
ReNeuron

Samir El-Andaloussi
Associate Professor, Laboratory Medicine & Co-Founder & Head, Protein Engineering
Karolinska Institute & **Evox Therapeutics**

Susanne Gabrielsson
Professor, Medicine
Karolinska Institute

Shelley Hartman
Co-Founder & Chief Executive Officer
Aegle Therapeutics

Fatah Kashanchi
Professor & Director, Laboratory of Molecular Virology
George Mason University

Raj Kishore
Professor, Pharmacology & Medicine, Professor, Center for Translational Medicine, Director, Stem Cell Therapy Program
Temple University

Jan Lötvall
Professor & Chief Physician, Asthma, Allergy, Inflammation & Eosinophils
University of Gothenburg

Per Lundin
Co-Founder & Chief Operating Officer
Evox Therpaeutics

Linda Marban
Chief Executive Officer
Capricor Therapeutics

Ian McNiece
Chief Executive Officer & Chief Scientific Officer & Vice President, Research & Development
Oncocyclist & **Biocardia** & **Aegle Therapeutics**

Shaun Stapleton
Vice President, Regulatory Affairs & Pharmacovigilance
ReNeuron

Steven Stice
Co-Founder & Chief Scientific Officer & Professor
ArunA Biomedical & **University of Georgia**

Gareth Willis
Instructor, Pediatrics
Boston Children's Hospital, Harvard Medical School

"Extracellular vesicle based therapies offer a substantial opportunity to change how we think about regenerative medicine. I look forward to participating in the discussion regarding developments in this ground breaking field"
Shelley Hartman, Co-Founder & Chief Executive Officer, Aegle Therapeutics

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CONFERENCE DAY ONE
WEDNESDAY, SEPTEMBER 18, 2019

8.50 **Chair's Opening Remarks**

Uncovering Exosome Interactions & Mechanisms for Informed Therapeutic Development

Xandra Breakefield
Professor, Neurology & Geneticist, Neurology & Radiology
Harvard Medical School & **Massachusetts General Hospital**

9.00 **Exploring Cargo & Interactions of Extracellular Vesicles for Therapeutic Delivery**

- Utilizing extracellular vesicles as biologic delivery systems for DNA, RNA, protein and drugs
- Exploring the intrinsic immune-modulatory and regenerative properties of extracellular vesicles
- Overcoming common hurdles and exploring the promising future applications of EVs as drug delivery systems

Johnathon Anderson
Assistant Professor, Department of Otolaryngology
University of California Davis

9.30 **Properties of Exosomes Derived from Primed Mesenchymal Stem Cells**

- Uncovering the composition of exosomes (pMEX) derived from primed MSCs
- Exploring the functional properties of pMEX in vitro
- Applying the functional therapeutic properties of pMEX in animal models of inflammation associated diseases

Susanne Gabrielsson
Professor, Medicine
Karolinska Institute

10.00 **Allogeneic Dendritic Cell Derived Exosomes for Cancer Immunotherapy**

- Showcasing data highlighting the requirement for the whole antigen to induce T cell responses to exosomes, with MHC-peptide complexes not enough
- Increasing the feasibility of exosome-based cancer vaccines through the utilization of allogenic exosomes, which are shown to be as efficient as autologous exosomes

10.30 **Speed Networking & Morning Refreshments**

Maximizing Translatability of Preclinical Studies for Streamlined Clinical Trial Progression

Ian McNiece
Chief Executive Officer & Chief Scientific Officer & Vice President, Research & Development
Oncocyclist & **Biocardia** & **Aegle Therapeutics**

11.15 **Challenges to Translating Exosomes to Clinical Trials**

- Manufacturing exosomes for clinical trials: What characterization and purity will be required by regulatory agencies?
- Comparison of approaches using isolated exosomes compared to cellular products producing exosomes
- Analyzing different isolation methodologies for exosomes

Steven Stice
Co-Founder & Chief Scientific Officer & Professor
ArunA Biomedical & **University of Georgia**

11.45 **Neural Stem Cell Derived Exosomes as Potential Treatment of Neurodegenerative Disorders**

- In diverse animal models, neural stem cell derived exosomes have anti-inflammatory activity and neural/neurovascular protective and repair properties
- Neural exosomes penetrate the blood brain barrier in injury and non injury models
- Neural stem cell derived exosomes are more highly concentrated in areas of the central nervous system associated with motor and cognitive function
- These exosomes can be loaded with cargos and delivered to the central nervous system

Fatah Kashanchi
Professor & Director, Laboratory of Molecular Virology
George Mason University

12.15 **Purification of Exosomes Away from Viruses & Their Use in Therapeutics**

- Showcasing methods to purify various size EVs and exosomes away from viruses, as well as their physical and functional characterization
- How exosomes can be used to package gene editing DNA to target virally infected cells

12.45 **Networking Lunch**

Reliable Preclinical Development to Advance Exosome Based Therapeutics into a Clinical Reality

Gareth Willis
Instructor, Pediatrics
Boston Children's Hospital, Harvard Medical School

13.45 Good Things Come in Small Packages: The Application of Exosome-Based Therapeutics in Neonatal Lung Injury

- Preclinical development of mesenchymal stem cell derived-exosomes in experimental models of bronchopulmonary dysplasia
- Assessing the immunomodulatory capacity, biodistribution and metabolic fate of mesenchymal stem cell derived-exosomes
- Toward exosome-based therapeutics: Isolation, heterogeneity, and fit-for-purpose potency

Raj Kishore
Professor, Pharmacology & Medicine, Professor, Center for Translational Medicine, Director, Stem Cell Therapy Program
Temple University

14.15 Stem Cell Exosomes for Cardiac Repair: Sacks Full of Goodies or Not?

- Exploring stem cell-derived exosomes and suitable cell lines for cardiac tissue regeneration
- Understanding external influencing factors to exosome cargo and their effect on exosomal function and therapeutic efficacy
- Maximizing translatability of exosomes as natural therapeutic agents to enhance reproducibility and reliability in future clinical trials

14.45 Panel Discussion: Are Exosomes Ready for Clinical Trials?

- What we know so far: Drawing on our knowledge for trial strategies and combatting potential safety issues in clinical trials
- Defining exosome characteristics from cytokine contents to membrane proteins: How are we all working towards this?
- Methods for correct dosing and minimizing differentiation between exosome batches for reliable trials
- What do we each understand about regulation, and what impacts does this hold on the design of clinical trials moving forward?

Randolph Corteling
Head, Research
ReNeuron

Samir El-Andaloussi
Associate Professor, Laboratory Medicine & Co-Founder & Head, Protein Engineering
Karolinska Institute & **Evox Therapeutics**

Shelley Hartman
Co-Founder & Chief Executive Officer
Aegle Therapeutics

Steven Stice
Co-Founder & Chief Scientific Officer & Professor
ArunA Biomedical & **University of Georgia**

15.30 Afternoon Refreshments

Commercial Considerations in Gaining Market Access for Exosome Based Therapeutics

Per Lundin
Co-Founder & Chief Operating Officer
Evox Therpaeutics

16.00 Development & Commercialization of Exosome-Based Therapeutics

- Exploring IP strategies for protecting exosome-based therapeutics
- Tackling common challenges in drug development through successful collaborations
- Establishing secure and mutually valuable connections to streamline development and commercialization of novel therapies

Linda Marban
Chief Executive Officer
Capricor Therapeutics

16.30 Staying Ahead: Capricor Therapeutics on Drug Development & Commercialisation of Novel Therapeutics

- Key considerations throughout drug development to ensure your pipeline is set up for success
- Tying together drug development and commercialisation: Common pitfalls in drug development causing industry-wide setbacks
- Strategies from Capricor Therapeutics to streamline market access

17.00 Chair's Closing Remarks

17.05 End of Day One

CONFERENCE DAY TWO
THURSDAY, SEPTEMBER 19, 2019

8.50 Chair's Opening Remarks

Navigating the Complex Regulatory Landscape of a Novel Therapeutic Approach

Shaun Stapleton
Vice President, Regulatory Affairs & Pharmacovigilance
ReNeuron

9.00 Regulatory Control of Exosomes: US & EU Classifications & Implications for Development

- How will therapeutic (native) exosomes and exosomes as delivery vehicles be regulated in the US and EU?
- How will this impact development plans for these products?
- What are the key regulatory challenges likely to arise with exosome products?

Shelley Hartman
Co-Founder & Chief Executive Officer
Aegle Therapeutics

9.30 Moving Extracellular Vesicle Therapy into the Clinic

- How Aegle approached FDA for clearance to progress into clinical trials
- Strategies to implement these learnings to your pipeline development to stay ahead in the current competitive climate

10.00 Panel Discussion: Exploring the Commercial Requirements for Exosome Based Therapeutic Development

- What are healthcare, payer and regulator expectations on future exosome based therapeutics?
- To what degree must exosomes be purified to demonstrate clinical efficacy?
- How do expectations differ across geography and how does this impact your development decisions?

Per Lundin
Co-Founder & Chief Operating Officer
Evox Therpaeutics

Shaun Stapleton
Vice President, Regulatory Affairs & Pharmacovigilance
ReNeuron

Richard Brudnick
Chief Business Officer & Head of Strategy
Codiak Biosciences

Linda Marban
Chief Executive Officer
Capricor Therapeutics

10.45 Morning Refreshments

Tools & Technology Platforms to Establish Manufacturing Guidelines for the Development of Clinically Applicable & Consistent Exosome Based Therapeutics

Samir El-Andaloussi
Associate Professor, Laboratory Medicine & Co-Founder & Head, Protein Engineering
Karolinska Institute & **Evox Therapeutics**

11.15 Production of Engineered Extracellular Vesicles

- Principles of extracellular vesicle engineering and how to implement for biomedical applications
- Best practice for the production, isolation and phenotyping of extracellular vesicles

Jan Lötvall
Professor & Chief Physician, Asthma, Allergy, Inflammation & Eosinophils
University of Gothenburg

11.45 Utilizing Bacterial Extracellular Vesicles for Therapeutic Purposes

- Gram negative bacteria release extracellular vesicles called Outer Membrane Vesicles (OMVs)
- OMVs can be made therapeutic, for example through engineering
- Examples by which OMVs can regulate immune responses will be presented

Randolph Corteling
Head, Research
ReNeuron

12.15 An Exosome-Based Drug Delivery Platform Derived from a Human Neural Stem Cell (hNSC) Line

- Producer cell immortalisation and clonal isolation as a practical strategy for consistent, functionally bioactive exosomes to ensure the scale required for clinical research and commercialisation
- Utilizing the Phase II, clinical-grade (GMP) stem cell line CTX0E03 as an abundant producer of exosomes which can be readily isolated and purified at scale
- Directing the expression of a variety of cargoes while maintaining key characteristics of the parental cell line through rapid and efficient modification of the CTX cell line to allow natural tissue tropism and targeted cargo delivery

12.45 Networking Lunch

14.00 Roundtable Discussion: Strategizing & Implementing Novel Manufacturing Standards

How are we each preparing for the run-up to clinical trials and inevitable up-scale of exosome production?

Which methods of scaling up exosome production has seen success? What can we improve?

How do we deal with the current regulatory landscape as a limitation in decisive trial design?

Which factors are a priority in investment across upscaling exosome manufacture?

15.00 Chair's Closing Remarks

15.15 End of Day Two & Close of Exosome Based Therapeutic Development Summit 2019

"I am looking forward to participating in the Exosome Based Therapeutic Development Summit to hear from other speakers and delegates how this fascinating new area of drug development is progressing and to gain insight into the wide range of potential applications of exosomes as new therapies in their own right and as novel drug delivery tools"

Shaun Stapleton, Vice President, Regulatory Affairs & Pharmacovigilance, ReNeuron

"Extracellular vesicles have the potential to be the next immunotherapeutic tool in cancer, and I look forward to sharing experiences with other scientists to take it one step further to the clinic"

Susanne Gabrielsson, Professor, Medicine, Karolinska Institute

BECOME A COMMERCIAL PARTNER

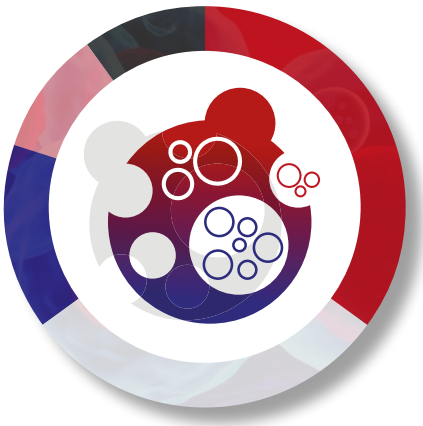
To unite the right partners that, together, will advance these novel therapeutics into a clinical reality.

The Exosome Based Therapeutic Development Summit unites key stakeholders from pharma, biotech, healthcare, academia and technology providers to not only showcase latest advances and innovations, but also explore the overarching roadblocks faced throughout drug development for exosome based therapeutics.

Partner with us to:

- Connect with the who's-who of the up-and-coming regenerative medicine, exosome and EV communities
- Showcase your expertise to leading organizations through our exhibition space or a position on our expert speaker faculty
- Create connections with pioneers striving for novel technology and research partnerships, advancing in line with their work
- Cement existing relationships through speed networking, personal introductions and multiple industry-wide touch points with the exclusive help of our on-site delivery team

Who's Attending Exosome Based Therapeutic Development Summit 2019?



Pharma: 35%
Biotech: 30%
Academia: 15%
Solution & Technology Providers: 10%
Other: 10%

CXO: 20%
VP: 25%
Head: 25%
Director: 20%
Other: 10%

*Based on market research and previous events' statistics

GET IN CONTACT

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Partnership Director, Exosome Based Therapeutic Development Summit
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READY TO REGISTER?

3 EASY WAYS TO BOOK

www.exosomebased-tx.com/register

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Email: register@hansonwade.com

1. Uncover novel targets by exploring the latest findings in exosome mechanisms and interactions
2. Develop translatable and reliable trials through the reduction of variation across exosomes
3. Explore innovative platforms for exosome manufacture and scale-up to maintain consistency

Team Discounts*

- **10% discount – 3 delegates**
- **15% discount – 4 delegates**
- **20% discount – 5 or more delegates**

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.
Contact: register@hansonwade.com

SECURE YOUR PLACE

Package Details	Register & Pay Before 05/24/19	Pre-Event Registration	On The Door
Industry (Conference Only)	$1,599.00 **SAVE $1100**	$2,399.00	$2,699.00
Academic & Not-For-Profit (Conference Only)	$899.00 **SAVE $1100**	$1,699.00	$1,999.00

T&Cs apply.

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