Tuesday, 4 June 2019

9:00	**Welcome: Opening Remarks & Introductions**	Kerstin Wilken, *PDA Europe* Conference Co-Chairs: Manuel Carrondo, *ibet* Dayue Chen, *Eli Lilly*
9:15	**Keynote: Developing CARTs - The Kymriah Story**	**Rosa Catera,** *Novartis*
Opening Plenary: Regulatory Challenges and Perspectives for ATMPs		*Moderator:* **Dayue Chen,** *Eli Lilly*

Good understanding of regulatory expectations and challenges is critical for ATMP development and realization. This session outlines challenges anticipated in translating innovations to life-saving products and provides a general overview of the regulatory requirements & expectations for ATMP development and marketing in EU member states.

9:45	**Development and the Use of ATMPs in EU / Lithuania**	Romaldas Mačiulaitis, *Lithuanian University of Health Sciences*
10:15	**ATMPs System Wide Challenges from Innovation to Uptake – Pragmatic Supportive Regulation and Standards**	Alistair Gibb, *MHRA*
10:45	**Coffee Break, Poster Session & Exhibition**	
Session 1:	**Current Approaches: Rapid Detection**	*Moderator:* **Margarida Menezes-Ferreira,** *Infarmed*

Risk of transmission of infectious diseases is the main concern from the very start of clinical development. No human exposure can be accepted without properly validated methodologies to provide the reassurance required for trial approval. This session aims to discuss the more recent methods that may overcome difficulties often encountered with ATMPs due to batch size or shelf life.

11:15	**From Individualized to Standardized Microbiological Quality Control in ATMP Manufacturing**	Isabelle Bekeredjian-Ding, *Paul-Ehrlich-Institut*
11:45	**Next Generation Sequencing-based Testing of ATMPs**	Kai Sohn, *Fraunhofer IGB*
12:10	**Analytical Development and Automation for Detection of Replication Competent Lentivirus (RCL)**	Rui Andre Saraiva Raposo, *Oxford BioMedica*
12:35	**Panel Discussion with Regulators & Industry**	
13:00	**Lunch Break, Poster Session & Exhibition**	
Session 2:	**ATMP Development**	*Moderator:* **Manuel Carrondo,** *ibet*

ATMPs are few but some already succeeded in changing the paradigm from promise to cure. Understanding how and which developments are needed to achieve better products for improved clinical outcome is the aim of this session.

14:00	**ATMPs in Europe – Are We There Yet?**	Christopher Bravery, *Advanced Biologics*
14:25	**Multi-Purpose CDMO Operating on ATMPs**	Raquel Fortunato, *GENibet*
14:50	**Clinical Data on Oncolytic Viruses in Treatment of Cancer**	Akseli Hemminki, *University of Helsinki, Helsinki University Hospital*
15:15	**Q&A, Discussion**	
15:30	**Coffee Break, Poster Session & Exhibition**	

Session 3: Enabling New Cell Therapies *Moderator:* **Fabio D'Agostino,** *Alira Health*

The use of living cells as the therapeutic agent is among the greatest advances of medicine in the 20th century. Pluripotent stem cells are a power cell type which is poised to revolutionise cell therapy, if proven successful. To date, significant progress has been made but many challenges still remain unsolved. From academia to industry, our speakers will give us an overview of what is new in this area of cell therapy.

16:00	**Biomanufacturing of Cardiac Cells from Human Induced Pluripotent Stem Cells**	Sean Palecek, *University of Wisconsin*
16:30	**Translating Pluripotent Stem Cell Therapeutics for the Heart, Brain and Blood**	Jennifer Moody, *BlueRock Therapeutics*
17:00	**Bioengineering Approaches for Functional Maturation of Human Pluripotent Stem Cells Derived Cardiomyocytes**	Paula Alves, *ibet*
17:30	**Q&A, Discussion**	
18:00	**End of Day 1 & Networking Event**	

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PDA IS PROUD TO INVITE YOU TO A VERY SPECIAL NETWORKING EVENT

Join us for an atmospheric evening starting with a guided tour of the old town of Vilnius and ending in the modern Restaurant Grey. With colourful food and grilled specialities, the building has magnificent views over the city.

4 June 2019

18:25h – Meeting Point: Hotel Lobby
Departure guided walking city tour (approx. 60 min)
19:30h – Dinner, Restaurant Grey, Pilies str. 2, Vilnius
21:00h – Return walk (20 min) to Conference Hotel

Wednesday, 5 June 2019

Session 4: Safety of Cell-Based Medicinal Products *Moderator:* **Thomas R. Kreil,** *Takeda*

Traditionally, the safety of biological medicinal products has been safeguarded by the selection of low risk starting materials, the testing of raw materials / process intermediates, and the virus inactivation / removal capacity of the manufacturing process, i.e. the safety tripod concept. For cell-based medicinal products, the implementation of some of these traditional elements is intrinsically impossible. Alternative approaches towards maintaining adequate virus safety margins for cell-based medicinal products will be discussed.

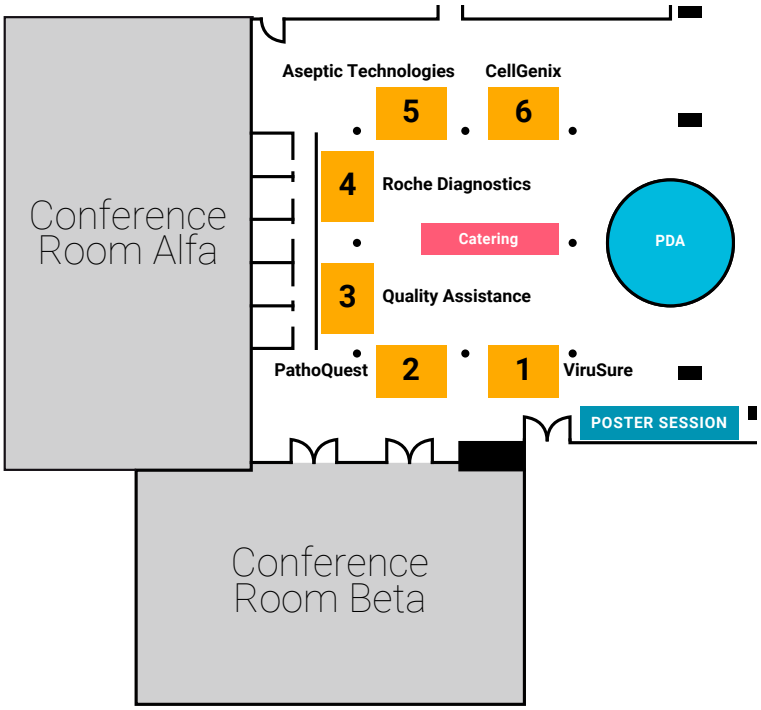
9:00	**Viral Safety of Cell-Based Medicinal Products**	Johannes Blümel, *Paul-Ehrlich-Institut*
9:30	**Virus Testing of Cells: A New Method Based on Next Generation Sequencing**	Marc Eloit, *PathoQuest*
10:00	**New Contaminant Detection Technologies to Allow Rapid Release of ATMPs**	Martin Wisher, *Merck KGaA, BioReliance*
10:30	**Q&A, Discussion**	
11:00	**Coffee Break, Poster Session & Exhibition**	

PARALLEL TRACKS

Session 5:	**TRACK A**	**TRACK B**
	Practical Approaches to ATMPs	**Manufacturing and Automation Strategies**
	Moderator: Kerstin Wilken, *PDA Europe** This session shall address the topic from different angles: What can we learn about shipment of ATMPs for clinical trials, how to navigate the regulatory framework, and what is the perspective of an experienced QP?	**Moderator:** Martin Wisher, *BioReliance** This session will present three case studies: The scale-up of the production of cell therapies using a single-use bioreactor designed to handle adherent cells in a low shear environment; how optimal automation strategies can be developed on the basis of comprehensive product planning, and the manufacturing and characterization of mRNA constructs for clinical trials.
11:30	**Regulatory, Clinical and Logistics Challenges of ATMP Trials** Andrea Zobel, *PAREXEL*	**Automation Strategies for the Production of ATMPs: Planning is Half the Battle** Andreas Traube, *Fraunhofer IPA*
11:55	**Tools for Navigating the European Regulatory Framework for ATMPs** Giovanni De Grandis, *University College London*	**Scale-Up of Allogeneic Cell Therapy Manufacturing in Single-Use Bioreactors** Max Lee, *PBS Biotech*
12:20	**QbD for ATMPs. Seeing the Big Picture – A QP Perspective** Jasbir Rattu, *CeutiQus*	**Manufacturing and Characterization of mRNA Constructs for Clinical Trials** Ulrich Blaschke, *CureVac*
12:45	**Q&A, Discussion**	**Q&A, Discussion**
13:00	**Lunch Break, Poster Session & Exhibition**	

Session 6: Viral Vector Production for Gene Therapy		*Moderator:* **Dayue Chen,** *Eli Lilly*
Lentivirus and adeno-associated virus (AAV) are the two proven viral vectors for gene delivery, each with distinct advantages and challenges. In this session, GSK and Takeda each will provide a latest update on GMP production of these vectors in order to meet the needs of a rapidly advancing ATMP portfolio.		
14:00	**Next Generation Lentiviral Vector Manufacturing – Opportunities, Challenges and Ways Forward**	Paul S. Carter, *GSK*
14:30	**Coffee Break, Poster Session & Exhibition**	
15:00	**Manufacturing Process Design for AAV-based Gene Therapy Vectors**	Barbara Kraus, *Takeda*
15:30	**Q&A, Panel Discussion: Challenges & Future Impact of ATMPs**	
16:00	**Closing Summary by the Conference Co-Chairs**	Manuel Carrondo, *ibet* Dayue Chen, *Eli Lilly*
16:30	**Closing Remarks and End of Conference**	Kerstin Wilken, *PDA Europe*

Floorplan



TO EXHIBIT

PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibition and Sponsorship Opportunities are available. A basic exhibition package for this event is priced **1.995 Euro net (table-top).** For more information please contact **expo-europe@pda.org.**

- Table Top
- Poster Session
- Catering
- PDA Registration