MARKETSANDMARKETS

3rd Annual

# Bioprocessing of Advanced Cellular Therapies Congress

## 29th - 30th May 2018 | Frankfurt, Germany

## Event overview:

After spending lots of time and efforts on clinical testing, these unique "living medicines" are finally poised to hop from the realm of clinical research to the world of mainstream medicine. To give these therapies their best chance of success, the cell and gene therapy industry needs to ensure that each step of the drug development and delivery process is as robust and cost-effective as possible.

The main challenges still lie in the manufacturing and delivery processes which needs to be closely examined for optimization opportunities to further maximize the chances for effectiveness in patients.

At the **3rd Annual Bioprocessing of Advanced Cellular Therapies Congress,** we aim to address these exact challenges from the manufacturing processes of cell and gene therapy to safety, quality, logistics and regulatory hurdles. We will also be discussing the implementation of automated, highly validated protocols and tools which can give these therapies the best chance of success.

## Key highlights:

- Regulatory and Reimbursement
- CAR-T & Cell Therapy Processing
- Viral Vector & Gene Therapy Manufacturing
- Analytics & Quality Control
- Logistics & Up-scale Processes

## Exhibitors:

CellGenix | eppendorf | TrakCel

For more information please contact Amit at **amit.shelke@marketsandmarkets.com | +91 20 30108 284**

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## Advisors panel:

- **Manuel Carrondo,** Director, **Institute of Experimental Biology and Technology (iBET), Portugal**
- **Stefano Baila,** Holding F.I.S, **Belgium**
- **Tiffany Rau,** Head of Technical Operations (Process Development to Commercialization (Vial thaw to API) and Bioreactor Development), **Evonik, San Fransisco, USA**
- **Benoît Champluvier,** Chief Technology and Manufacturing Officer, **BONE THERAPEUTICS S.A, Brussels, Belgium**
- **Peter Hollands,** Group Chief Scientific Officer and Executive Director, **WideCells Group PLC, UK**

## Speaker panel:

- **Klaus Cichutek,** President, **Paul-Ehrlich-Institut, Germany**
- **Giuliana Vallanti,** Development & Quality Control Director, **Molmed, Italy**
- **Joanne Mountford,** Honorary Associate Professor, **University of Glasgow, Scotland**
- **Bo Kara,** Head Process Development, Cell & Gene Therapy Platform CMC, **GSK, United Kingdom**
- **Matthew Durdy,** Chief Business officer, **CT Catapult, United Kingdom**
- **Mannuel Carrando,** Vice President, **IBET, Portugal**
- **Stefano Baila,** Holding F.I.S, **Belgium**
- **Angeliki Grammenos,** Manager Regulatory Affairs, **Bone Therapeutics, Belgium**
- **Shimon Slavin,** Professor of Medicine, **Biotherapy International, Israel**
- **Robert Thomas,** Professor of Manufacturing for Cell and Gene Therapies, **Loughborough University, United Kingdom**
- **Vicki Coutinho,** Director, Regulatory Affairs, **Autolus Ltd., United Kingdom**
- **Sarah Snykers,** QC Manager, **Celyad, Belgium**
- **Jef Pinxteren,** Director process development, **Promethera, Belgium**
- **Yuan Zhao,** Leader, Gene Therapy Section, **NIBSC, United Kingdom**
- **Lior Raviv,** VP Development, **Pluristem Therapeutics, Israel**
- **Pierre Heimendinger,** Head of Pharmaceutical Development, **TxCell, France**
- **Lisa O' Flynn,** Head of Process Development, **Orbsen Therapeutics, Ireland**
- **Jean-Charles Epinat,** Chief Technological Officer, **Cellectis, France**

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## Day 1 Tuesday, 29th May 2018

**08:00** **Registrations**

**08:45** **Welcome address by MarketsandMarkets**

**08:50** **Welcome note by the chairman**

### Regulatory & Reimbursement

**09:00** **Keynote Address: The Critical and Changing Interface of Regulation and Bioprocessing: Adaptive Trial Pathways**
**Klaus Cichutek,** President, **Paul-Ehrlich-Institut, Germany**

**09:25** **Overcoming challenges of evaluating and funding new cell & gene therapies**
**Angeliki Grammenos,** Manager Regulatory Affairs, **Bone Therapeutics, Belgium**

**09:50** **Regulatory viewpoints on the development of advanced cellular therapies**
- Pre-clinical requisites
- Regulatory engagement
- Clinical trial authorisations
- Other development needs i.e. companion diagnostics

**Vicki Coutinho,** Director, Regulatory Affairs, **Autolus Ltd., United Kingdom**

**10:15** **Solution Provider Presentation**

10:30 Morning Refreshments | One to One Meetings | Poster Presentations | Networking

**11:10** **Panel Discussion: Need for standard regulations – what are companies thinking?**

### CAR-T & Cell Therapy Processing

**11:40** **CD362 to ORBCEL: the rapid development of a novel stromal cell therapy**
- Identification of novel defined stromal cell population
- Development of closed automated process - application of a novel chip based cell sorter and bioreactor application.
- Process development to clinical trails

**Lisa O' Flynn,** Head of Process Development, **Orbsen Therapeutics, Ireland**

**12:05** **Large scale production of LV and RV for T- and Cd34+ cells transduction**
**Giuliana Vallanti,** Development & Quality Control Director, **Molmed, Italy**

**12:30** **Translating pluripotent cell therapies to the clinic**
- Pluripotent stem cells offer huge advantages but their translation to large scale clinical use still presents challenges
- Creating new cell lines under GMP conditions and assuring quality of the final product are critical components
- Global initiatives are working to establish minimum quality expectations and guidelines for testing new allogeneic cell lines to ensure PSC lines can be used many countries, thereby maximizing access to these valuable resources.

**Joanne Mountford,** Honorary Associate Professor, **University of Glasgow, Scotland**

**12:55** **Dynamic Mechanistic Modelling for Optimisation of Cell Therapy Process Development and Manufacture**
- Discuss the challenge of modelling cell therapy manufacture processes to understand quality risk and process efficiency
- Describe a workflow compatible with limited data and complex dynamics to support process optimisation
- Introduce a novel toolset supported by case studies of process improvement in hematopoietic lineage culture systems

**Robert Thomas,** Professor of Manufacturing for Cell and Gene Therapies, **Loughborough University, UK**

**13:20** **Solution Provider Presentation**

13:35 Lunch Break | One to One Meetings | Poster Presentations | Networking

**14:35** **New Purification Processes for Cellular Therapies**
**Mannuel Carrando,** Vice President, **IBET, Portugal**

**15:00** **Cell therapy for treatment of cancer; combining eradication of chemotherapy-resistant cancer cells and induction of long-lasting anti-cancer immunity**
- No conventional treatment is effective for treatment cancer cells resistant to chemotherapy and radiation
- Cancer stem cells, the cancer initiating cells, are a priori resistant to all available anti-cancer modalities
- Every cancer begins with transformation of a single cell, yet, even one million cells - the size of the head of a pin - cannot be visible so innovative treatment and new treatment strategies are indicated to eliminate minimal residual disease including resistant cancer cells.
- Cell-mediated immunotherapy can cure otherwise incurable patients with cancer especially when applied at the stage of minimal residual disease which can be accomplished at an early stage of the disease by conventional treatment

**Shimon Slavin,** Professor of Medicine, **Biotherapy International, Israel**

## Viral Vector & Gene Therapy Manufacturing

**15:25** **Approaches for improved viral vector manufacture**
**Bo Kara,** Head Process Development, Cell & Gene Therapy Platform CMC, **GSK, United Kingdom**

**15:50** **Development of the First World Health Organization (WHO) Lentiviral Vector Standard**
- The concept of developing a first World Health Organization (WHO) International Standard,
- The intended use of the standard to standardize production process, product batch to batch comparability assessment, to enable comparison of cross-trial and cross-manufacturing results and to monitor patients for long-term safety and for further treatment options

**Yuan Zhao,** Leader, Gene Therapy Section, **NIBSC, United Kingdom**

16:15 Afternoon Refreshments | One to One Meetings | Poster Presentations | Networking

**16:55** **Solution Provider Presentation**

**17:10** **Development of first manufacturing process to produce CAR-Treg cells for clinical use**
- TxCell has completed the development of its first-generation production process for its proprietary CAR-Treg technology
- TxCell has isolated a subset of Treg cells that have shown to be stable and to display a strong anti-inflammatory activity. Despite the rarity of the selected Treg subset, TxCell has successfully produced its CAR-Treg cellular product within two weeks (before post-production quality control)
- IND and/or CTA filing is planned in Q4 2018 in order to launch first-ever CAR-Treg clinical trial in solid organ transplantation. TxCell will transfer its process to a CMO before the start of this first-in-man trial

**Pierre Heimendinger,** Head of Pharmaceutical Development, **TxCell, France**

**17:35** **Critical operational parameters in the AVV manufacturing process**
Tentative: **Otto-Wilhelm Merten,** Head of the Applied Vectorology and Innovation group, **Généthon, Paris**

**18:00** **Drinks Reception**

**End of Day 1**

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## Day 2 Wednesday, 30th May 2018

**08:15** **Registrations**

**08:45** **Welcome address by MarketsandMarkets**

**08:50** **Welcome note by the chairman**

**09:00** **Keynote presentation: The advanced cellular therapeutics bioprocessing challenge: targeting, prioritization and decision making for profit**
**Matthew Durdy,** Chief Business officer, **CT Catapult, United Kingdom**

### Analytics & Quality Control

**09:25** **Production of gene-edited allogeneic T-cells – challenges and approaches**
**Jean-Charles Epinat,** Chief Technological Officer, **Cellectis, France**

**09:50** **Establishing quality attributes of cell-based products**
**Speaker TBA**

**10:15** **Solution Provider Presentation**

10:30 Morning Refreshments | One to One Meetings | Poster Presentations | Networking

**11:10** **Panel Discussion: Collaborative approach in upscaling the manufacture of cell & gene therapies**

**11:40** **Turning Ideas into products: Process development and changing the art of growing cells into an industry**
- Reproducible manufacturing techniques - the basics of process development
- The importance of closed and automated manufacturing technologies
- Data management for improvement of process understanding and control

**Lior Raviv,** VP Development, **Pluristem Therapeutics, Israel**

### Logistics & Up-scale Processes

**12:05** **Challenges in scaling a xenofree cell therapy product**
- Moving from serum to xenofree media
- Scaling from 2D to bioreactors
- Combining xenofree media with bioreactors
- Comparison of the original product with the new formulation

**Jef Pinxteren, Director process development, Promethera, Belgium**

**12:30** **Ensuring quality during the supply chain of autologous CAR-T: challenges and solutions**
- Quality Control throughout manufacturing of autologous CAR-T
- Some assume that a process = a product; so, what if the process changes?
- GMP, ICH, USP & PhEur guidance

**Sarah Snykers,** QC Manager, **Celyad, Belgium**

**12:55** **Tracking of product and tracing the identity of patient**
**TrackCel**

13:10 Lunch Break | One to One Meetings | Poster Presentations | Networking

**14:10** **Overcoming challenges in delivering therapies to patient**
**Speaker TBA**

**14:35** **Overcoming challenges in clinical trial logistics procedures**
**Speaker TBA**

**15:00** **Role of logistics in commercialization of cord blood therapies**
**Speaker TBA**

**15:25** **Closing remarks by the chair**

**15:30** **Afternoon Refreshments and End of The Conference**