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25-27 February, 2019 | London, UK

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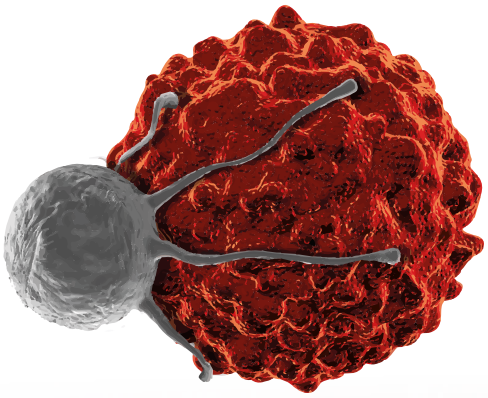
CAR-TCR Summit Europe

Engineering a Cancer-Free World



Dedicated to the Delivery of Safe and Effective Next Generation CAR and TCR Immunotherapies in Europe

30+ Expert Speakers Including:

Christian Itin
Chief Executive Officer
Autolus

Barbra Sasu
Chief Scientific Officer
Allogene Therapeutics

Stephane Depil
Senior Vice President, Research & Development & Chief Medical Officer
Cellectis

Dolores Schendel
Chief Executive Officer & Chief Scientific Officer
Medigene

James McBlane
Preclinical Assessor, **MHRA** & Member, Committee for Advanced Therapies (CAT)
EMA

Pilar Pinilla-Dominguez
Senior Scientific Adviser
NICE

Harpreet Singh
Chief Executive Officer
Immatics US

Tony Ho
Executive Vice President, Head of Research & Development
CRISPR Therapeutics

Nina Pinwill
Head of Commercial Operations
NHS England

Lead Partner:

TERUMOBCT

Unlocking the Potential of Blood

Welcome to the Annual CAR-TCR Summit Europe

Your comprehensive guide to developing and delivering novel, accessible and commercially successful cellular immunotherapies.

Following the EMA and NHS approvals of Yescarta and Kymriah, the CAR-TCR drug development field steps up and proves its potential to become the next generation of curative cancer treatment for patients in need.

The **CAR-TCR Summit Europe** is your opportunity to join the expert CAR and TCR pioneers to learn about never-before-seen clinical updates and novel technology to improve **solid tumour targeting**, advance **allogeneic therapy development** and **automate manufacturing** processes to reduce the cost of goods.

If you are looking to initiate clinical trials in Europe, join us to navigate the complex **regulations** and **reimbursement** landscape to understand and overcome **market access** challenges.

And if you are looking to drive progress in scientific discovery, join us as we discuss novel breakthroughs with innovations with **gamma delta** and **NKT** cells, innovative **antigen screening** platforms and **genetic engineering** strategies to create, translate and develop the next generation of CAR and TCR therapies.

What Hanson Wade's attendees have said about our meetings

"An excellent meeting - well organised, highly focused and just the right size to network and identify new collaborators"

TC Biopharm

"The meeting was extremely well run with expert speakers across a variety of specializations within the CAR-TCR field. A valuable learning tool for anyone working in CAR-TCR"

Legend Biotech

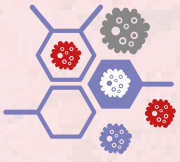
What can you expect?

- **250+** ATTENDEES
- **40+** WORLD CLASS SPEAKERS
- **33+** CASE STUDIES
- **2** TAILORED AND CONTENT PACKED TRACKS
- **6** DEEP DIVE DISCUSSION SESSIONS

Your Checklist to Improving your Clinical and Commercial Strategies:

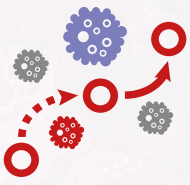
1. Novel Technologies to Create the Next Generation of CAR and TCR Therapies

Join industry leaders **Celyad, Servier** and **Cellectis** as they explore their challenges in the development of an allogeneic therapy.



2. Strategies to Improve Solid Tumour Targeting

Explore the different engineered CARs and TCRs from **Leucid Bio** and **Marker Therapeutics** which target novel solid tumour antigens to reduce off-tumour toxicity and overcome anti-tumour activity.



3. Automate Manufacturing to Reduce CoGs

Learn current strategies from **UCL** which utilize an automated high-throughput microbioreactor system to ensure process consistency alongside the non-viral gene transfer of **Ziopharm Oncology** to reduce the complexity of manufacture.

4. Navigate the European Regulatory Challenges to Initiate your Trials Across Multiple Countries

Hear first-hand experience from **Medigene** on the process of obtaining clinical trial authorisation in Germany, supported by discussion of regulatory framework and advice from the **EMA**.

5. Pricing Strategies to Prepare for Accessible Reimbursements

With **NICE** and the **CVER** sharing their guidance on pricing and valuing of these potentially curative therapies, join the conversation now to understand the pricing approvals for current CAR-T therapies.

Your Expert Speakers

Dale Ludwig
Chief Scientific Officer
Actinium Pharmaceuticals

Barbra Sasu
Chief Scientific Officer
Allogene Therapeutics

Christian Itin
Chief Executive Officer
Autolus

Emma Chan,
Senior Scientist, Process Development
Autolus

Vicki Coutinho
Senior Director, Regulatory Affairs
Autolus

Kai Wilkens
Senior Director Europe ACD
Bio-Techne

Jie Jia
Vice President, Strategic Alliances
CARsgen Therapeutics

Zonghai Li
Chief Executive Officer
CARsgen Therapeutics

Tony Ho
Executive Vice President, Head of Research & Development
CRISPR Therapeutics

Stefanos Theoharis
Senior Vice President, Corporate Development & Partnering
Cell Medica

Stephane Depil
Senior Vice President Research & Development & Chief Medical Officer
Cellectis

David Gilham
Vice President, Research & Development
Celyad

Jens Hasskarl
Senior Director, Research Development, Clinical & Medical
Celgene Corporation

Detlev Parow
Head of Department of Medicines, Therapeutic Appliances & Remedies Product & Billing Management Division
DAK-Gesundheit

Maureen Graham
Managing Director
Diamond Pharma Services

Bob Valamehr
Chief Development Officer & Vice President Cancer Immunotherapy
Fate Therapeutics

Cedrik Britten
Head of Oncology Cell Therapy Research Unit
GSK

Andreas Göbel
Head of Competence Center Cloud Architecture
Hypertrust Patient Data Care

Harpreet Singh
President & Chief Executive Officer
Immatics US

Lei Xiao
Chief Executive Officer
Innovative Cellular Therapeutic Co.

Menno Aarnout
Executive Director
International Association of Mutual Benefit Societies

Will Singleterry
Associate Director, Business Development
Isoplexis

Marc Kamp
Director CAR-T Product Distribution & Supplier Quality Management
Kite Pharma

Vijay Chiruvolu
Head of Process Development
Kite

John Maher
Chief Scientific Officer
Leucid Bio

Juan Vera
Chief Development Officer
Marker Therapeutics

Peter L. Hoang
President & Chief Executive Officer
Marker Therapeutics

Dolores Schendel
Chief Executive Officer & Chief Scientific Officer
Medigene

Kai Pinkernell
Chief Medical Officer & Chief Development Officer
Medigene

James McBlane
Preclinical Assessor, **MHRA** & Member, Committee for Advanced Therapies (CAT)
EMA

Katharina Winnemöller
Marketing Manager for Clinical Cell Processing & T Cell Applications
Miltenyi Biotec

Mario Marcondes
Senior Medical Director, Clinical Development
Nektar Therapeutics

Tony Pagliuca
Medical Director, Networked/Specialist Care, Professor of Stem Cell Transplantation
NHS England

Nina Pinwill
Head of Commercial Operations
NHS England

Pilar Pinilla-Dominguez
Senior Scientific Adviser
NICE

Therese Choquette
Analytical Project Leader, Cell & Gene Therapy Development & Manufacturing
Novartis

Francesco Marincola
Chief Scientific Officer
Refuge Biotech

Jim Freeth
Co-managing Director
Retrogenix

Véronique Blanc
Immuno-Oncology Program Director
Servier

Michael Leek
Chief Executive Officer
TC Biopharm

Alfonso Quintás Cardama
Chief Medical Officer
TCR2 Therapeutics

Dan Ollendorf
Director, Value Measurement & Global Health Initiatives
Tufts University Center for the Evaluation of Value and Risk in Health, CEVR

Qasim Rafiq
Senior Lecturer in Bioprocessing of Regenerative, Cellular & Gene Therapy
UCL

Miguel Forte
Chief Executive Officer
Zelluna Immunotherapy

Laurence Cooper
Chief Executive Officer
Ziopharm Oncology

Conference Day One | Tuesday 26th February

8.00 Coffee & Registration

8.30 Chairman's Opening Remarks

8.45 Terumo BCT Presentation

- Content to be confirmed

TERUMOBCT
Unlocking the Potential of Blood

9.15 Industry Leaders' Fireside Chat

With the first CAR-T product approved in Europe, what are the next steps and where do we go now?
Take this opportunity to ask the leaders what their future plans are and what we can expect from the CAR-TCR space over the next few years.
Topics to be discussed:

- Is the future of CAR-T off-the-shelf?
- Perspectives on the clinical potential of novel and innovative next generation CAR-T products
- Experience with the setting up and running of clinical trials in Europe
- Strategies to reduce the overall cost of CAR-T therapeutics acknowledging manufacturing processes and hospitalisation costs
- Regulatory challenges when applying to different fragments of the EMA

Christian Itin
Chief Executive Officer
Autolus

Barbra Sasu
Chief Scientific Officer
Allogene Therapeutics

Miguel Forte
Chief Executive Officer
Zelluna Immunotherapy

10.15 The Need for Decentralisation in Closed Loop Supply Chain Management

- Take a closer look at closed loop supply chain processes of personalized medicine
- Learn how distributed ledger technology can secure and optimize the chain of identity and custody of personalized medicine

Andreas Göbel
Executive and Technology Lead
Hypertrust Patient Data Care

10.45 Speed Networking & Morning Refreshments

Track A: Research & Development

Novel Technologies to Create the Next Generation CAR & TCR

11.45 The TRuC Platform – Overcoming CAR-T and TCR Limitations

- Discuss the first engineered T cell platform to use the complete TCR complex without the need for HLA matching
- Explore the results from *in vivo* studies demonstrating anti-tumour activity compared to CAR-T, lower levels of cytokine release and longer persistence
- Identify the potential of TRuC for solid tumours

Alfonso Quintás Cardama, Chief Medical Officer, **TCR2 Therapeutics**

Track B: Manufacturing & Commercialization

Strategies to Automate Manufacturing to Reduce Cost and Scale up

11.45 Process Development and Manufacturing Strategies for ATMPs

- Advance process development of primary T-cell using an automated high-throughput microbioreactor system
- Increase the control of raw materials to significantly reduce variation and improve process consistency, resulting in fewer batch failures and reduction in overall process cost
- Establishing the development of an automated manufacturing facility for the scalable production of ATMPs

Qasim Rafiq, Senior Lecturer in Bioprocessing of Regenerative, Cellular & Gene Therapy, **UCL**

12.15 Next Generation TCR-T Cell Therapies Can Offer Improved Safety and Enhanced Efficacy

- Review the need for cutting-edge *in vitro* technologies to fill a critical gap in pre-clinical safety and efficacy studies of TCR-T therapies in the absence of adequate animal models
- Evaluate how genetic modifications of recipient T cells can give them additional capacity to display enhanced functions in hostile tumour microenvironments
- Turning negative signals into positive signals through expression of chimeric co-stimulatory proteins to enhance effector cell functions and overcome negative effects of tumour cells

Dolores Schendel, Chief Executive Officer & Chief Scientific Officer, **Medigene**

12.15 Current Strategies to Reduce Cost of Manufacture

- Explore the optimal T cell phenotype which does not require extensive culture times
- Discuss how off-the-shelf therapy reduces cost of manufacture as autologous therapy requires a new supply chain for every patient and less manipulation results in less contamination and simplicity in process

Juan Vera, Chief Development Officer, **Marker Therapeutics**

12.45 Screening CAR-T Cells for Target Specificity using Human Cell Microarray Technology

- Discuss how to outline the optimisation of the human cell microarray technology for off-target screening of whole engineered CAR-T cells, in addition to antibodies and ScFvs
- Explore an efficient approach for specificity screening of novel cell therapies to support safety assessment and provide key data prior to IND submissions

Jim Freeth, Co-managing Director, **Retrogenix**

12.45 The Future of CAR-T Cell Manufacturing

- Adopting the CliniMACS Prodigy T Cell Transduction process for fast clinical development
- Assess the characterisation of CAR T cell manufacturing process and final cell product
- Upscaling the CAR T cell production process

Katharina Winnemöller, Marketing Manager for Clinical Cell Processing & T Cell Applications, **Miltenyi Biotec**

13.15 Lunch & Networking

14.15 Novel Technology Presentation

- Content to be confirmed

Yescarta Case Study

14.15 Optimizing the Process Development of Yescarta

- Content to be confirmed

Vijay Chiruvolu, Head of Process Development, **Kite**

15.00 Overcome Antigen Escape with Dual Targeted TCR Products

- Improve efficacy by increasing the number of antigen targets
- Overcome variable antigen expression and antigen loss through dual targeting to maximise initial treatment effect and minimise the risk of relapse

Bob Valamehr, Chief Development Officer & Vice President - Cancer Immunotherapy, **Fate Therapeutics**

14.45 Novel Supply Chain Routes to Enhance Accessibility and Cost Efficiency

- Reflect on industry experience in site selection of geographical distribution centres to increase patient accessibility
- Explore methods to reduce cost of supply chain logistics for patient specific therapies
- Optimise current tracking processes to monitor logistics

Marc Kamp, Director CAR-T Product Distribution & Supplier Quality Management, **Kite Pharma**

15.15 *In Situ* Monitoring of CAR-TCR Cell Therapy: Tumor Infiltration, Efficacy, and Adverse Events

Kai Wilkens, Senior Director Europe ACD, **Bio-Techne**

15.15 Diamond Pharma Presentation

Maureen Graham, Managing Director, **Diamond Pharma Services**

15.45 Afternoon Refreshments & Poster Session

16.15 Panel Discussion: The Future of CAR-T Therapy with Next Generation Technology

- Explore the benefits of next generation CAR-T products to overcome the tumour microenvironment and antigen escape
- What are the common challenges that need to be addressed?

Stefanos Theoharis, Senior Vice President, Corporate Development & Partnering, **Cell Medica**

Dale Ludwig, Chief Scientific Officer, **Actinium Pharmaceuticals**

16.15 Panel Discussion: Explore the Need to Reduce the Cost of Manufacturing in Order to Ensure Feasible Reimbursements

- Discuss the future of CAR-T manufacture to ensure accessibility of therapy
- Explore current strategies to reduce expensive processes and streamline methods

Laurence Cooper, Chief Executive Officer, **Ziopharm Oncology**

Qasim Rafiq, Senior Lecturer in Bioprocessing of Regenerative, Cellular & Gene Therapy, **UCL**

Exploration of CAR in Alternative Cell Types to Reduce Toxicity

16.45 Use of CAR-NKT Cells for the Development of Off-the-Shelf Products that do not Require Gene Editing

- Learn how NKT cells are an invariant sub-type of T-cell that do not cause GvHD and are therefore optimal for off-the-shelf applications
- Hear how Cell Medica's proprietary platform is based on the use of NKT cells for CAR-T applications
- Understand how CAR-NKT cell products are further engineered to secrete IL-15, to further enhance activation, persistence and efficacy

Stefanos Theoharis, Senior Vice President, Corporate Development & Partnering, **Cell Medica**

17.15 Pharmaceuticalizing CAR-T with Allogeneic Gamma-Delta T Cells

- What's special about gamma-deltas?
- Building an allogeneic cell therapy platform – clinical and regulatory considerations
- Overcoming logistic challenges of allogeneic approaches

Michael Leek, Chief Executive Officer, **TC Biopharm**

17.45 Exploiting the Potential of Vδ1 Gamma-Delta T Cells

- Exploit the unique characteristics of Vd1 gamma delta T cells
- Discuss results from isolating large numbers of high quality, tissue-resident γδ T cells from human tissues
- Discuss how this platform is being developed for clinical translation

Natalie Mount, Chief Scientific Officer, **Gamma Delta Therapeutics**

Enhance Final Products through Analytics and Process Development

16.45 Cellular Characterisation by Flow Cytometry of CTL019 Final Product

- Review the final characteristics and phenotype of the final product for Pediatric ALL
- Contrast this to the final product for DLBCL
- Discuss the characterisation of cell products and how they relate to the overall safety and efficacy of the CAR-T therapy

Therese Choquette, Analytical Project Leader, Cell & Gene Therapy Development & Manufacturing, **Novartis**

17.15 Process Development for CAR-T Cell Manufacturing

- Optimisation of the CAR-T cell manufacturing process and analytics to supply clinical trials
- CMC challenges of product consistency and scale to enable widespread distribution and commercialization of CAR T-cell technology

Emma Chan, Senior Scientist, Process Development, **Autolus**

18.30 Chairman's Closing Remarks

18.45 End of Day 1

Conference Day Two | Wednesday 27th February

8.00 **Coffee & Networking**

8.30 **Chairman's Opening Remarks**

9.00 **Late Breaking Abstracts**

Key companies will present new data for the first time at the CAR-TCR Summit Europe. Be sure not to miss the session of the year and be the first to hear these new clinical trial readouts.

unpublished data

9.30 **GE Healthcare Presentation**

Content to be confirmed

10.00 **Morning Refreshments & Networking**

Track A: Research & Development

Improve Solid Tumour Targeting to Overcome Tumour Escape

10.30 T4 Immunotherapy of Head and Neck Cancer Using Pan-ErbB Retargeted CAR-T Cells

- Reviewing an engineered CAR using a promiscuous ligand that engages 8 distinct ErbB dimer species
- Identify the anti-tumour activity which has been demonstrated in several pre-clinical solid tumour models
- Phase 1 evaluation is ongoing in patients with head and neck cancer, using intra-tumoural delivery and phased dose escalation to mitigate risk

John Maher, Chief Scientific Officer, **Leucid Bio**

11.00 Innovative Antigen Screening Methods

- Develop a manufacturing process to identify, activate and expand T cells specific for multiple tumour-associated antigens
- Learn how this process yields a product that is comprised of a number of very rare T cell clones that often drive a disproportionately large contribution of anti-tumour effect in patients
- Explore the clinically meaningful response rates of this therapy, with highly durable complete responses and negligible incidence rates of serious associated toxicities (grade 3 or higher)

Peter L. Hoang, President & Chief Executive Officer, **Marker Therapeutics**

11.30 Methods to Predict CAR-T Patient Response: Using Single Cell Proteomics to Evaluate CAR-T Function

- Review how pre-infusion CAR-T PSI correlates significantly with objective response in Zuma-1
- Characterise functional changes between murine and human scFv's
- Test CAR manufacturing methods and constructs (varying scFv's, co-stim domains, cytokines in co-culture during generation) while comparing to killing assays to demonstrate the functional changes in expansion, killing capacity, etc.

Will Singleterry, Associate Director, Business Development, **Isoplexis**

Track B: Manufacturing & Commercialization

Experience Initiating Clinical Trials in Europe

10.30 Setting Up and Running Clinical Trials in Europe

- Hear industry expertise on the planning and execution of clinical trials when managing different regulatory standards across Europe
- Identify challenges when filing for approval across different European jurisdictions

Jens Hasskarl, Senior Director, Research Development, Clinical & Medical, **Celgene Corporation**

11.00 Obtaining Clinical Trial Authorisation for TCR-Modified T Cells in Germany

- Discuss how the TCR field is early and clinical development is just ramping up worldwide, exposing regulatory agencies to these novel therapies
- Share the experience of gaining clinical trial authorisation of MDG1011, a PRAME specific, autologous TCR modifief T cell therapy in Germany
- Review how Germany poses some special considerations due to its federal structure in order to facilitate clinical site start

Kai Pinkernell, Chief Medical Officer & Chief Development Officer, **Medigene**

12.00 **Lunch & Networking**

Novel Strategies to Overcome the Tumour Microenvironment

13.00 Panel Discussion: Overcome Tumour Microenvironment to Tackle Solid Tumours

- Discuss novel strategies to traffic CAR-T cells through the TME
- Understand safety limitations with different indications
- Which component of the TME is most important to focus on and is it tumour type dependant?

Francesco Marincola, Chief Scientific Officer, **Refuge Biotech**

Cedrik Britten, Head Oncology Cell Therapy Research Unit, **GSK**

Mario Marcondes, Senior Medical Director, Clinical Development, **Nektar Therapeutics**

13.30 Driving the CAR Beyond the Checkpoints

- Explore the semantics of cancer immune responsiveness, and the biology behind it Reflect on the lessons learned from checkpoint inhibitor therapy to search for new horizons
- Understand the essential role played by adoptive cell transfer: training smarter killers before deployment by reprogramming their function
- The promise of synthetic biology; pitching a role for CRISPR activation and CRISPR interference

Francesco Marincola, Chief Scientific Officer, **Refuge Biotechnologies**

14.00 HLA Class II TCRs: A Novel Adoptive T Cell Approach for Solid Cancers

- Outline the current challenges in lymphocyte targeting approaches, adoptive cell therapy, for the treatment of solid tumours
- Discuss the development of TCR adoptive cell therapies, autologous and off the shelf, with a focus in solid tumours
- Evaluate the opportunity of an HLA class II restriction mechanism of action in the approach for solid tumours

Miguel Forte, Chief Executive Officer, **Zelluna Therapeutics**

14.30 Progress in a First-in-class Dominant Negative PD-1 Armored CD19 in Clinical Trials

- An introduction to Innovative Cellular Therapeutics (ICT)
- Summarise the development and manufacture of ICTCAR014 in closed and semi-closed systems
- Review the current clinical data

Lei Xiao, Chief Executive Officer, **Innovative Cellular Therapeutic Co.**

13.00 Panel Discussion: Bringing a CAR-T Therapy to Market; Current Guidelines and Experience

- Reflect on past experiences of bringing CAR-T therapy through to market penetration
- Discuss expectations from regulatory bodies when filing for clinical trials and approval

James McBlane, Preclinical Assessor, **MHRA** & Member, Committee for Advanced Therapies (CAT), **EMA**

Dan Ollendorf, Director, Value Measurement & Global Health Initiatives, **Tufts University Center for the Evaluation of Value and Risk in Health, CEVR**

Tony Pagliuca, Medical Director, Networked/Specialist Care, Professor of Stem Cell Transplantation, **NHS England**

13.30 Personalised T-Cell Therapies to Target Novel Solid Tumour Antigens

- Identification of novel solid tumour targets with the XPRESIDENT platform
- Understand the clinical application in highly personalised T-cell therapy trials
- Explore the regulatory landscape in US and Europe for novel T-cell therapies

Harpreet Singh, President & Chief Executive Officer, **Immatics US**

14.00 Regulation and Development of CAR-T Cells for Patients with Cancer

- Outline regulatory framework for cell therapy development
- Discuss issues in assessing CAR-T cell products
- Hear first hand regulators' advice on development

James McBlane, Preclinical Assessor, **MHRA** & Member, Committee for Advanced Therapies (CAT), **EMA**

15.00 Afternoon Refreshments & Networking

Is the Future Off-the-Shelf?

15.30 Development of "Off-the-Shelf" Allogeneic CAR-T Cells

- Hear gene editing approaches to produce allogeneic CAR-T cells devoid of Graft-Versus-Host potential
- See preclinical data as well as first clinical results
- Discuss the main challenges associated with allogeneic therapy and present the different ways of improvement

Stephane Depil, Senior Vice President - Research & Development & Chief Medical Officer, **Cellectis**

15.30 An Industry's Perspective and Experience with Market Penetration of CAR-T Therapy

- Hear industry insights in the market approval of CAR-T therapy in Europe
- Understand what to expect and how to prepare efficiently

To be confirmed

16.00 Hairpins and Peptides: Development of a Non-Gene Edited Approach for Allogeneic CAR-T Cell Therapy

- Discuss our first non-gene edited approach which involves the co-expression of a peptide inhibitor of T cell receptor signaling with a NKG2D-based CAR which achieved FDA approval in 2018
- Evaluate our next generation approach involving RNA interference to disrupt the TCR thereby providing a platform approach for allogeneic CAR T cell therapy

David Gilham, Vice President, Research & Development, **Celyad**

Reimbursement Models for European CAR-T Products

16.00 The NHS Experience with making CAR-T Available

- Explain the role of NHS England in the context of CAR-T and other Advanced Therapeutic Medicinal Products (ATMPs)
- Explain how NHS England implemented CAR T for ALL and lymphoma
- Update on the current status; how many patients are on the treatment pathway and have received treatment using CAR-T
- Explore the balance between demand and capacity?
- Understand how the relationship between NHS England, providers, JACIE, and industry made implementing CAR-T at pace possible
- Lessons learned from the current commissioning process
- How does NHS England see the use of ATMPs change the status quo and what does NHS England need to do to get ready for future waves and to meet these challenges?

Nina Pinwill, Head of Commercial Operations, **NHS England**

16.30 Non-viral Gene Transfer to Commercialize T-cell Therapies

- Understand the role of DNA plasmids from Sleeping Beauty (SB) system to reduce the cost and complexity of manufacturing T cells which express chimeric antigen receptor (CAR) and T-cell receptor (TCR)
- Exploit personalized T-cell therapy using DNA plasmids from SB system to target neoantigens from solid tumours
- Identify the expression of cytokines to improve the therapeutic potential and improve safety of genetically modified T cells

Laurence Cooper, Chief Executive Officer, **Ziopharm Oncology**

16.30 Valuing and Paying for CAR-TCR Therapy: The Ideal, the Reasonable, and the Feasible

- Challenges in valuing a potentially curative therapy with uncertainty in the data at time of launch
- How can we feasibly structure payment now, and what could we change in future to support innovative payment?
- What is the way forward for patients, manufacturers, and health systems to make the necessary headroom for these innovations?

Dan Ollendorf, Director, Value Measurement & Global Health Initiatives, **Tufts University Center for the Evaluation of Value and Risk in Health, CEVR**

17.00 Allogeneic CAR-T Reality and Future Directions

- Overview of current allogeneic approaches
- Update on Serviers' 1st allogeneic CAR-T cell product
- Explore future directions for allogeneic CAR-T

Véronique Blanc, Immuno-oncology Program Director, **Servier**

17.00 CAR-T from the Perspective of HTA

- Evidence development for CAR-T outlining the challenges and solutions
- NICEs' experience evaluating CART-T so far: what have we learnt?

Pilar Pinilla-Dominguez, Senior Scientific Adviser, **NICE**

17.30 Chairman's Closing Remarks

17.45 End of Day 2 & Close of Summit

Pre-Conference Workshop Day | Monday 25th February

Workshop A

8.00-10.00 Discovery of Novel Targets and T-cell Receptors for Cancer Immunotherapies

- Outline XPRESIDENT; a unique platform for identification, selection and validation of novel cancer targets
- Understand how XPRESIDENT can guide the discovery and toxicity screening for novel T-cell receptors
- Explore the clinical application of novel targets and TCRs

Harpreet Singh, President & Chief Executive Officer, **Immatics**

Workshop B

8.00-10.00 Manufacturing Challenge and Opportunity for Global Clinical Trial of CAR-T Cell Therapy

- Discuss challenges and considerations in the manufacturing of CAR-T cell product for solid tumour treatment
- Explore the CMC regulatory challenge and solution in support of the global clinical trial of CAR-T cell therapy
- Opportunities in the development of standardized manufacturing process to reduce cost and improve process consistency

Jie Jia, Vice President, Strategic Alliances, **CARsgen Therapeutics**

10.00 Morning Refreshments

Workshop C

11.00-13.00 Can we CRISPly Treat any Patient to Create a Potent, Safe CAR-T Therapy?

- Explore current strategies to gain IND approval of allogeneic CAR-T to initiate clinical trials
- Gain a clear understanding of the benefits of allogeneic therapy compared to autologous
- Optimise the building of CAR products through precise CRISPR editing to reduce off-target effects creating a safer therapeutic
- Learn strategies to enhance CAR potency in solid tumours and the challenges this environment provides
- Understand methods to overcome the suppressive nature of the tumour microenvironment with synthetic biology to prevent T cell exhaustion and initiate endogenous immune response

Tony Ho, Executive Vice President, Head of Research & Development, **CRISPR Therapeutics**

Workshop D

11.00-13.00 The Challenges of Initiating CAR-T Clinical Trials

- Discuss experience initiating both US and EU clinical trials and the challenges faced with different regulatory boards
- Understand the Clinical Trial Authorisation (CTA) applications
- Consider and discuss other authorisations and logical considerations

Vicki Coutinho, Senior Director, Regulatory Affairs, **Autolus**

13.00 Lunchtime Refreshments

Workshop E

14.00-16.00 Understanding Clinically-Relevant Antigen-expression Thresholds for Engineered TCR and CAR-T Cells to Drive Next Generation Cell Therapies in Solid Cancer

- Explore clinical responses in patients with high and low expression of NY-ESO
- Identify the antigen-thresholds in NSCLC that drive functional responses in TCR-T cells *in vitro*
- Efficacy-engineering of TCR-T cells to increase their activity in solid cancer

Cedrik Britten, Head Oncology Cell Therapy Research Unit, **GSK**

Workshop F

14.00-16.00 Payment and Reimbursement for CAR-T: Elements for Selective Contracts

- Gain an overview of the perspectives and positioning of payers in Europe
- Advance your understanding of differences between health insurers and their views on market access, payment and reimbursement
- Understand how CAR-T as a "hospital only drug" is reimbursed in Germany according to hospital reimbursement regulations
- Review how CAR-T is assessed by Germany's health technology assessment body G-BA, within AMNOG assessment framework, to have a clear understanding of what data is required for approval
- Determine how to include elements like risk-share and pay for performance in selective contracts in the triangle of manufacturers, hospitals and health insurance companies to secure accessible reimbursement arrangements

Detlev Parow, Head of Pharmaceutical Tools, **DAK-Gasundheit**
Menno Aarnout, Executive Director, **International Association of Mutual Benefit Societies**

16.00 Evening Refreshments

PARTNERS

Lead Partner

TERUMOBCT
Unlocking the Potential of Blood

Terumo BCT, a global leader in blood component, therapeutic apheresis and cellular technologies, believes in the potential of blood and cells to do even more for patients than they do today. Terumo BCT's Cell Therapy Technologies business enables researchers, developers and manufacturers to create next-generation cell and gene therapies. We do this through flexible, automated solutions that help meet your evolving needs for reproducibility, quality and scale through the phases of development, from translational research to current good manufacturing practice (cGMP) for commercial manufacturing. One example, the Quantum® Cell Expansion System automates and optimizes cell culture to meet the needs of a variety of cell types in a consistent, controlled and functionally closed environment. We are also looking further downstream in the process to provide innovative solutions, like the FINIA® Fill and Finish System, to support your needs into the future.
www.terumobct.com/machineefficiency

Expertise Partners

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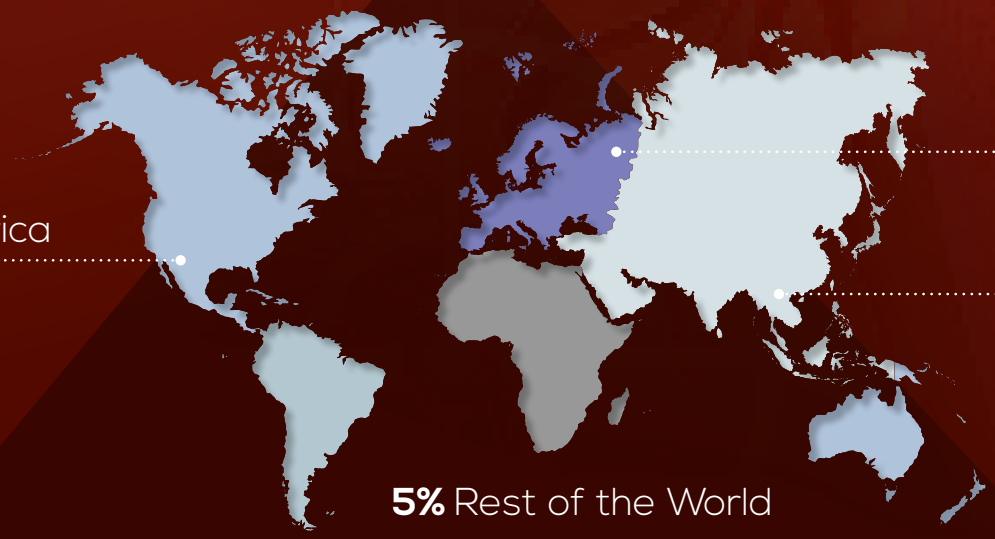

20% North America

70% Europe

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*T&Cs Apply: A start-up discount is available to allow newer, less established drug developers to attend this meeting. The biotech must have 15 or fewer employees to be eligible. All bookings at this rate are subject to organizer approval. Email info@hansonwade.com to enquire about the rate or apply.

SECURE YOUR PLACE

Pharma & Biotech ** Drug Developer Pricing	Register and Pay by Friday 21st December, 2018	Final Online Price
Gold: Conference + Workshop Day	£2198 + VAT* **(save £300)**	£2498 + VAT
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Standard Pricing	Register and Pay by Friday 21st December, 2018	Final Online Price
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Academic/Not for Profit Pricing	Register and Pay by Friday 21st December, 2018	Final Online Price
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Bronze: Workshop Day Only	£599 + VAT	

*VAT will be charged at 20%
** Start-up discounts available. Please email info@hansonwade.com for more information.

Venue

Novotel London West
1 Shortlands, Hammersmith, London. W6 8DR
United Kingdom

For further information or assistance, please visit www.novotellondonwest.co.uk