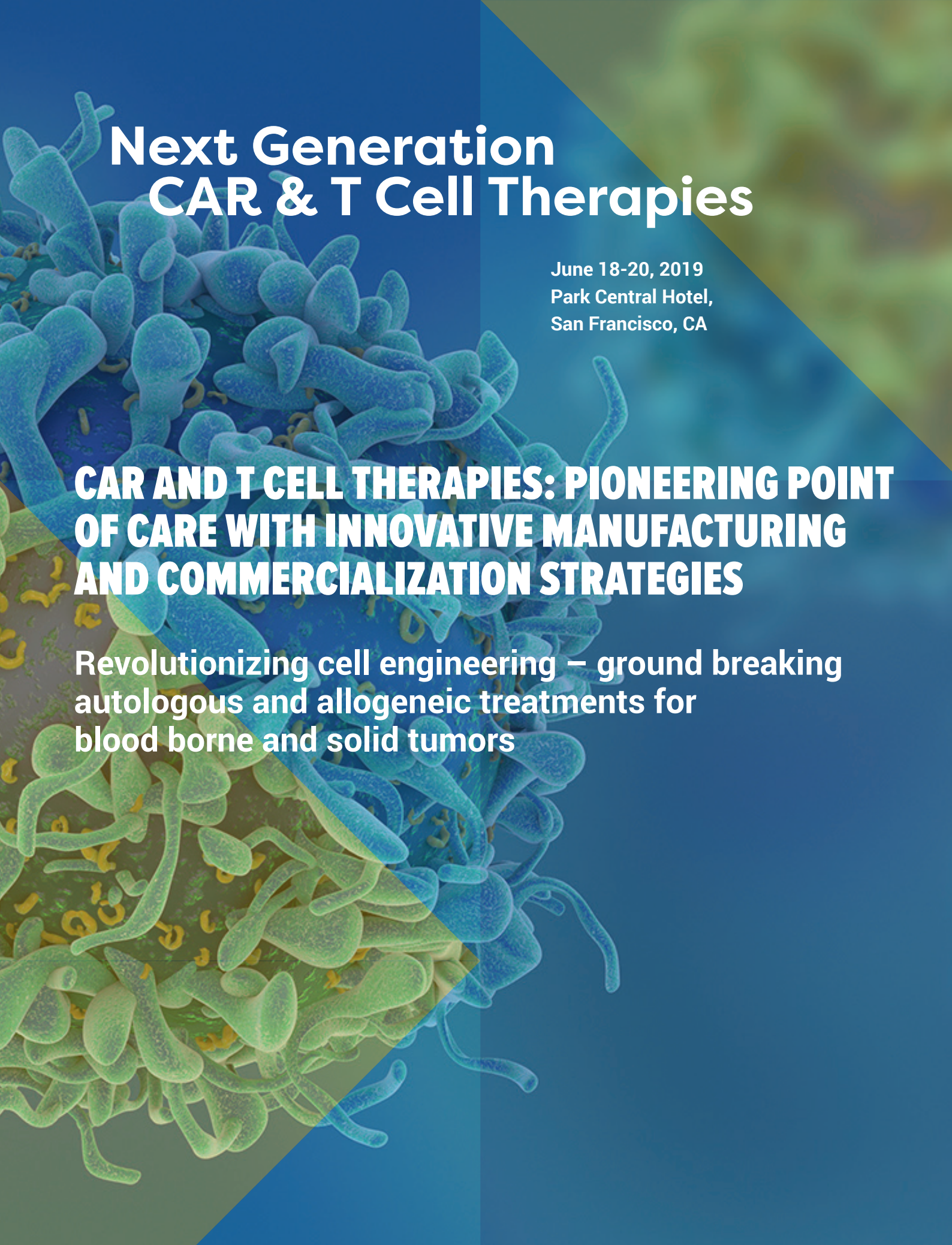
Next Generation CAR & T Cell Therapies

June 18-20, 2019
Park Central Hotel,
San Francisco, CA



CAR AND T CELL THERAPIES: PIONEERING POINT OF CARE WITH INNOVATIVE MANUFACTURING AND COMMERCIALIZATION STRATEGIES

Revolutionizing cell engineering – ground breaking autologous and allogeneic treatments for blood borne and solid tumors

https://lifesciences.knect365.com/car-t/

CONFERENCE DAY ONE

June 18th 2019

7.30 am - Registration

8:05am – Conference Opening and Welcome
Anthony Davies, *Founder & CEO*, Dark Horse Consulting, USA

Solid Tumours – New Modalities, Combination Therapies and Novel Cancer Treatment

8.15am - Virus Specific T Cells as Platform for Solid Tumor Immunotherapy

The ability to simultaneously monitor changes in multiple immune parameters holds great discriminatory and instructive power for the purpose of biomarker validation and mechanistic target discovery. In the case of Virus Specific T cell therapy for solid tumors, an examination of the systemic, cellular and local immune environment during the course of treatment has yielded a series of predictive biomarkers correlating with immunogenicity, response to therapy and overall survival on trial. An analysis of antigen specific T-cells have identified anti-viral responses with positive prognostic value. Differences in the immunosuppressive state of the patient's activated regulatory T-cells (Tregs) and the expansion or contraction of the myeloid-derived suppressor cell (MDSC) compartment, point to a mechanism of action for the therapy.

Confirmed speaker: Richard Hopkins, Research Director, R&D, Tessa Therapeutics, Singapore

8.45am – Allo CAR T TM targeting CD70 for the treatment of renal cell carcinoma

Confirmed speaker: Siler Panowski, *Associate Director, Solid Tumors*, Allogene Therapeutics, USA

9.15am – Safety and efficacy of TCR-mimic technology in hematologic and solid cancers, from discover concept to in-vitro and in-vivo validation to clinical results

The advents of the genetically modified T cells, specially the CAR-T and TCR-T cell technologies represents one of the most astounding steps in cancer therapy. However, those technologies have had major challenges:
CRS and Neurotoxicity are the major safety issues, Especially in hematologic malignancies

1. In solid tumors the antigen accessibility and thus lack of efficacy, as well as cross reactivity have been major impediments
2. A new TCR-mimic technology intends to address both limitations
3. The models (preclinical and human) used in are CD 19 positive NHL and AFP+HCC

Confirmed speaker: Bijan Nejadnik, *Chief Medical Officer,* Eureka Therapeutics, Inc., USA

9.45am - Morning Coffee and Networking

Solid Tumours – New Modalities, Combination Therapies and Novel Cancer Treatment

10:30am – Repurposing Endogenous Immune Pathways to Tailor and Control Chimeric Antigen Receptor T-cell Functionality

Confirmed speaker: Julien Valton, *Team Leader Innovation*, Cellectis, USA

11. 00am – **Developing an Allogeneic TCR-T Approach based on Gamma Delta T Cells**

- Case study

Confirmed speaker: Ali Mohamed, *VP, CMC*, Immatics, USA

11.30am - dCas9/CAR T platform: Efficacy and safety all-in-one therapy

Combination of CAR T cell therapy with immune checkpoint (ICP) inhibitors is a transformative therapy that may produce sustained clinical benefits for cancer patients. However, as ICPs function as "immune-brakes", systemic administration of ICP inhibitors can elicit immune-related adverse events such as colitis, pneumonitis, and hepatitis. To reduce ir-SAEs without comprising anti-tumor efficacy, Refuge Biotechnologies has developed a proprietary CAR-T platform with an integrated dCas9 transcriptional modular which downregulate inhibitory receptor(s) in CAR-T cells upon tumor recognition. The goal is to deliver an effective and safer therapy to cancer patients.

Confirmed speaker: Monique Dao, *Senior Director of I/O Preclinical Dev*, Refuge Biotechnologies, USA

12:00pm – Spotlight Presentation: Precision NanoSystems, Inc.

Confirmed speaker: Samuel Clarke, *Director of R&D*, Precision NanoSystems Inc., Canada

12.30 – Sponsored Luncheon Presentations

Safety Switches, Synthetic Biology and Mechanisms to Improve Safety and Efficacy

1.45pm - Improving the in vivo persistence and function of tumor-specific T-cells

Confirmed speaker: Cliona Rooney PhD, *Professor*, Center for Cell and Gene Therapy, Baylor College of Medicine, The Houston Methodist Hospital, Texas Children's Hospital, USA

2:15pm – Small molecule CAR T cell control: making the Switch

Confirmed speaker: Stephen Santoro, *Principal Scientist*, Kite Pharma, a Gilead company, USA

2.45pm – Genetic modification of T cells to express CD19-specific CAR in two days

Confirmed speaker: Harjeet Singh, *Instructor, Department of Paediatrics*, UT MD Anderson Cancer Center, USA

3.15pm - Afternoon Coffee

Safety Switches, Synthetic Biology and Mechanisms to Improve Safety and Efficacy

4:00pm – Triumvira Immunologics Case Study

Confirmed speaker: Jonathan Bramson, Ph.D., *Co-Founder & CSO*, Triumvira Immunologics, Inc., USA

4.30pm – 961 GM-CSF Blockade during Chimeric Antigen Receptor T Cell Therapy Reduces Cytokine Release Syndrome and Neurotoxicity and May Enhance Their Effector Functions

Despite its efficacy, chimeric antigen receptor T-cell therapy (CART) is limited by the development of cytokine release syndrome (CRS) and neurotoxicity (NT). While CRS is related to extreme elevation of cytokines and massive T cell expansion, the exact mechanisms for NT have not yet been elucidated. Preliminary studies suggest that NT might be mediated by myeloid cells that cross the blood brain barrier. This is supported by correlative analysis from CART19 pivotal trials where CD14+ cell numbers were increased in the cerebrospinal fluid of patients that developed severe NT (Locke et al, ASH 2017). Therefore, we aimed to investigate the role of GM-CSF neutralization in preventing CRS and NT after CART cell therapy via monocyte control.

Confirmed speaker: Cameron Durrant, *Chairman and CEO*, Humanigen, Inc., USA

5.00pm – Cocktail Reception in Exhibit & Poster Hall

CONFERENCE DAY TWO

19th June 2019

8:00am – Chairperson's Opening Remarks

Angela Scott, *Founder & Chief Operating Officer,* TC Biopharm, UK

CAR-T 3.0: Allogeneic CAR-T

8:15am – Transforming cell therapy with TALEN®-mediated gene-editing: the case of allogeneic "off-the-shelf" CAR T-cells

- First lessons learnt in manufacturing and clinical experience with "off-the-shelf" allogeneic CAR-T
- How gene-editing is instrumental in the ongoing cell therapies transition from the world of grafts to pharmaceutical products
- What is the learning curve in the industrialization of off-the-shelf immune cellular products
- Outlook to the next stage: gene editing powered designer cell therapy concepts and manufacturing

Confirmed speaker: David Sourdive, *Vice President, Corporate Development,* Cellectis, France

8.45am – CYAD-101: A Non-Gene Edited Allogeneic Approach

Confirmed speaker: Philippe Parone, *Industrialisation Lead,* Celyad, USA

9.15am – The Allo-Evolution: How first-generation learnings and infrastructure can influence a safer and faster delivery of next-generation therapies

Confirmed speaker: Jamie Margolis, *Director, Cell and Gene Therapy Operations*, Be The Match Biotherapies, USA

9:45am – Refreshment Break in the Exhibit & Poster Hall

Beyond CD19 – Novel CARs and Next Generation Cell Therapies

10.30am – Antibody Coupled T cell Receptor (ACTR); a novel technology that utilizes a single construct for multiple targets

Confirmed speaker: Jessica Sachs, *Vice President, Clinical Sciences*, Unum Therapeutics, USA

11:00am – CMV specific CAR T cell therapy for cancer and beyond

Confirmed speaker: Xiuli Wang, Ph.D., *Research Professor, T Cell Therapeutics Research Laboratory,* Department of Hematology and Hematopoietic Cell Transplantation, City of Hope National Medical Center, USA

11.30am – Gamma Delta T cells for the treatment of Cancer

- Case study
- Gamma delta cells – are they a safer alternative to CAR-T?
- MHC recognition and 'off the shelf' ability

Confirmed speaker: Michael Leek, Chief Executive, TC Biopharm, UK

12.00pm – Networking Luncheon in the Exhibit & Poster Hall

Beyond CD19 – Novel CARs and Next Generation Cell Therapies

1.15pm – 3T Bioscience Case Study

While sequencing of TCRs (T-cell receptors) from tumor infiltrating lymphocytes (TILs) yields valuable information regarding T-cell clonality, the nature of the antigens recognized TCRs remains largely elusive. To overcome these current limitations in target antigen identification of TCRs, 3 T Biosciences has developed a high throughput, yeast display technology platform to identify cognate ligands recognized by the most prominent TCRs expressed on TILs. The 3T platform is based on a series of highly-diverse, unbiased peptide-HLA (human leukocyte antigen) yeast-display libraries representing the major allotypes (HLA class I+II) fused to a comprehensive set of peptides covering all exome sequences (Birnbaum et al., Cell 2014). This method has been applied successfully to identify novel ligands for TCRs of unknown specificities, including novel, shared antigens present across cancer patients and tumor indications (Gee et al., Cell 2018).

For the development of adoptive T-cell therapies, TCRs inducing the highest level of T-cell activation and anti-tumor activities were frequently selected for clinical development. In contrast, the preclinical safety assessment of TCRs has been hampered due to the lack of appropriate TCR screening technology and preclinical animal models to select against TCRs binding to additional pMHC complexes present on normal tissues. To overcome these limitations, we took advantage of our yeast display technology to monitor differences in target antigen specificity between lead TCRs and selected the most active and tumor specific TCRs for further development. An update on the preclinical development of our lead TCR-T and cancer vaccines programs will be provided.

Confirmed speaker: Hanspeter Gerber, *SVP & CSO*, 3T Biosciences, USA

Beyond CD19 – Novel CARs and Next Generation Cell Therapies /Critical Challenges in Effective Scalability and Point of Care Manufacturing

1.45pm - CAR Macrophage Immunotherapy to target Solid Tumors

- Does this offer an opportunity to attack solid tumors?
- Macrophages and their ability to penetrate tumor nodules
- Will they allow for a more robust immune response?

Confirmed speaker: Michael Klichinsky, *Co-Founder & VP, Discovery Research*, Carisma Therapeutics, USA

2.15pm – Get an In-line and Label-free QC of your cell therapy product with the iLine-F microscope

Confirmed speaker: Emilie Viey, *Chief Executive Officer*, Ovizio Imaging Systems, Belgium

2.45pm – Final Refreshment Break in the Exhibition Hall

3.15pm – Challenges in manufacturing CAR T cells in the academic setting

Confirmed speaker: Isabelle Rivière, *Director,* Memorial Sloane Kettering Cancer Center, USA

3.45pm - Developing Manufacturing Platforms for Complex Gene-Edited T-cell Therapies for Auto Immune Disease

Confirmed speaker: Shyam Subramanian, *Cell Therapy Lead*, Casebia Therapeutics, USA

Critical Challenges in Effective Scalability and Point of Care Manufacturing /Vector Bottlenecks in the Manufacture of Cell and Gene Therapies

4.15pm - Avoiding CMC Pitfalls: Roadmap for Cell Therapy Commercialization

Confirmed speaker: John Tomitshen, *Associate Director of Manufacturing, CMC*, Legend Biotech Co., USA

4.45pm Reinvention and Optimisation of Vector Production Platforms

- Investment and developments in vector production platforms
- How can we improve scalability, robustness and productivity?
- Moving away from adherent cell culture platforms

Confirmed speaker: David Jen, *Head of Clinical Manufacturing*, Eureka Therapeutics, USA

5.15pm – End of Day 2

CONFERENCE DAY THREE

20TH June 2019

8:40am – Chairperson's Opening Remarks

Monitoring Quality Across the Process - Process and Automated Analytics for Cell Therapies

8:45am - Analytical method establishment and qualification

- What type of qualification activities are appropriate
- What will this look like when the method is validated further along in the process?
- Specific case studies

Confirmed speaker: Andrea Rossi Moore, Director, Analytical Development, Tmunity Therapeutics Incorporated, USA

9.15am - Talk title TBC

Process Validation (PV) poses a unique set of challenges. Those challenges are compounded when the process inputs include an uncontrollable set of variables. Terminology commonly related to traditional aspects of PV, such as "consistent" and "reproducible", are redefined when the process begins with patient specific material

and yields limited data point due to small batch sizes and low yields. Especially when a life can depend on the success of the process. Welcome to patient specific cell therapy processing. New challenges to the Validation Community.

Confirmed speaker: Tom Elefante, *Process Validation Lead, Cell & Gene Therapy*, Novartis, USA

9:45am – Refreshment Break in the Exhibit & Poster Hall

Monitoring Quality Across the Process - Process and Automated Analytics for Cell Therapies

10:30am – Lentiviral Vector Characterization for CART Therapy

Confirmed speaker: Wei Dang, *Senior Manager, Quality Control*, Center for Biomedicine and Genetics Beckman Research Institute of City of Hope, USA

11.00am – Improving Confidence in Cell Therapy Analytical Methods: Online and Inline Monitoring

- Case study on the use of inline and online monitoring
- Specific case study in relation to cell counting and flow cytometry

Confirmed speaker: Damien Marshall, *Director of Industrialisation, new and enabling technologies*, Cell and Gene Therapy Catapult, UK

11.30am – Implementation of Biopreservation Best Practices in Cell and Gene Therapy Manufacturing

Confirmed speaker: Alireza Abazari, *Scientific Applications Director,* Biolife Solutions, Inc., USA

12.00pm – Networking Luncheon in the Exhibit & Poster Hall

Raw Materials for Cell Therapy Manufacture

1.30pm – From Cells to Cellular Drug Product: A Path Less Travelled

Confirmed speaker: Kuldip Sra, Senior Director, CRISPR Therapeutics, USA

2.00pm – Networking Refreshment Break

3.00pm – End of Conference