

Agenda at a Glance

February 24-27, 2020
London, UK



New this year

Workshop Day February 24, 2020			Day One February 25, 2020			Day Two February 26, 2020			Focus Day February 27, 2020	
Registration			Registration			Breakfast Briefing			Registration	
Networking			Plenary Talks			Plenary Talks			Solid Tumour Track	Clinical Management Track
Networking			Speed Networking			Networking			Cell Trafficking	Toxicity Management
A	B	C	Translation Track	Manufacturing Track	Development & Commercialisation Track	Translation Track	Manufacturing Track	Development & Commercialisation Track		
Networking			Optimal T Cell Products	Disrupt Manufacturing Processes	Clinical Development	Translating Effective Allogeneic Therapies	Technology Transfer	Market Access Innovations	Networking	
D	E	F	Lunch & Networking			Lunch & Networking			Driving Potency	Institutional Readiness
Networking			Optimal T Cell Products	Disrupt Manufacturing Processes	Initiating Trials in EU	Translating Effective Allogeneic Therapies	Cell Characterization	IP & Legal	Networking	
G	H	I	Networking			Afternoon Refreshments			Tumour Targeting	Patient Management
Networking			Toxicity Management	Vector Supply	Early Evidence Criteria	Closing Presentations			Closing Presentations	
			Drinks Reception							



Translation

A Learning from Success with Solid Tumours

- TIL therapy and checkpoint inhibitors demonstrate that, unlike CAR-T therapy, natural T-cells can eradicate solid tumours
- Dissection of these successes shows that dominant T-cell clonotypes do not target neoantigens but instead target novel shared epitopes and antigens
- Knowing what works rekindles hope for therapeutic cancer vaccines

Andrew Sewell, Research Director of the Institute of Infection and Immunity, **Cardiff University**

D Redefining Preconditioning Standards for Malignancies Beyond CD19

- Review potential solutions for preconditioning toxicity
- Strategies to reduce the dose of preconditioning to allow quick supply and safe treatment, securing the value in patient safety
- Case study: T4 immunotherapy of head and neck cancer (Phase I trial) – the case for lymphodepletion
- Preclinical evaluation of pan ErbB targeted T4 immunotherapy
- Dose escalation of intratumoural T4 immunotherapy in SCCHN
- Plans and experience to date with lymphodepletion prior to intratumoural T4 immunotherapy

John Maher, Immunology Consultant, King's College London / CSO, **Leucid Bio**

G CAR T Cells for Solid Tumours, To Do List (TEO):

- **Traffic** (how to get to the tumours, relevant to silent, non-chemoattractant or chemorepulsive tumours)
- **Engage** (how to penetrate and engage with tumour cells, relevant to immune excluded tumours)
- **Overcome** (how to overcome immune suppression/compensatory immune suppression, relevant to inflamed tumours)

Francesco Marincola, CSO, **Biotech Refuge**

Zhifen Yang, Senior Scientist, **Refuge Biotech**

Manufacturing

B Manufacturing for an Allogeneic Future

- Overcome variation in starting materials with uniform cells sourced from healthy donors
- Control and predict safety and efficacy with standardised cell banks
- Creating reproducible and consistent products, managing quality specifications
- Explore methods to carry out large scale expansion whilst preserving efficacy and potency
- Lessons learned to translate reproducible, safe and virus free constructs

E Novel Process Technologies to Improve Scalability and Reduce Cost of Production

- Review how manufacturing processes can affect quality attributes of living drug products
- Outline technology to scale manufacture whilst overcoming negative effects on potency, quality and durability
- Discuss methods to improve process development based on cell biology

Lothar Germeroth, SVP, MD, **Juno Therapeutics**

H Driving Analytical Development to Reduce Time and Cost

- Innovations in analytical testing with automation in batch records
- Discuss the need to speed up the process for QP to release product
- Overcome the burden of release through novel quality, safety and efficacy testing

Therese Choquette, Analytical Project Leader & Senior Fellow, **Novartis**

Development & Commercialisation

C Building Flexibility in Clinical Trial Structure to Meet Unique Trial Needs

- Operational experience executing clinical trials across Europe
- Managing patient population change or new manufacturing aspect without changing clinical trial structure through master protocols
- Understand the agreements in place in trial design protocol to carry out sub studies in a shorter time frame

Reuben Benjamin, Consultant Haematologist, **Kings College Hospital, NHS**

F Getting a TCR-T cell Trial Approved in Europe - Focus on Germany

- Main approval streams in a gene modified cell therapy trial
- Interplay of the different submissions: pitfalls and solutions
- Timeline considerations to achieve a successful start

Kai Pinkernell, CMO & CDO, Medigene & **Klaus Tressl**, VP, Quality Assurance and Regulatory Affairs, **Medigene**

I Early Evidence Needs to Improve Access and Commercial Potential of CAR-TCR products

- Review value frameworks used by global HTA agencies for marketed CAR-T case studies and impact on reimbursement status in global markets
- Explore ramifications of payer value frameworks on evidence needs for CAR and TCR therapies and requirements to support value-based pricing of autologous and allogeneic products
- Explore requirements to displace 1st generation cell therapies with 2nd gen products

Aura Mackenzie, Senior Director, AVES, Market Access, **bluebird bio**

8.00 Registration & Coffee

8.30 Industry Leader's Fireside Chat

- Business insights to tackle the unmet need in solid tumours
- Experience and advice on navigating the European regulatory boards
- Future plans for CAR-TCR development



Michael Koslowski
CMO
GammaDelta Therapeutics



Andre Choulika
CEO
Collectis



Dolores Schendel
CEO & CSO
Medigene

9.30 Driving Automation in Cell Therapy Manufacturing

- Challenges in cell therapy automation
- Suspension cell expansion in a perfusion-based hollow-fiber bioreactor
- Downstream processing challenges in final formulation

Dalip Sethi
Manager, Senior Scientist, Cell Therapy
Technologies
Terumo BCT

10.00 Speed Networking & Morning Refreshments

Translation Track

Selecting & Expanding Optimal T Cell Products

11.00 FasT CAR Technology: New Practice from Lab to Clinic

- FasT CAR technology enables overnight cell manufacturing, setting up new industry standards
- Preclinical study reveals superior CAR-T cell characteristics in contrast to conventional CAR-T cells
- Beyond CD19, FasT CAR technology is broadly applicable to CAR-Ts against other targets
- Safety profile and efficacy of FasT CAR-19 investigational study

William Cao, CEO, **Gracell**

Manufacturing Track

Disrupting Current Processes to Shorten Manufacturing Times

11.00 Strategies to Improve Manufacturing Turnaround Time

- Discuss the risk of disrupting regulatory norms to revolutionise timescale to 1-5 days
- Review data to decipher whether it is possible to carry out release testing before material is placed into manufacturing machinery
- Outline QA test or electronic test records to speed up the availability of drugs

Ali Mohamed, VP, CMC, **Immatic**

Development & Commercialisation Track

Clinical Development Decision Making

11.00 Strategies for Acceleration of Cell Therapies into the Clinic

- Discuss science and risk-based approaches to getting cell therapy ready for the clinic
- Outline the importance of multidisciplinary collaborations which are critical to finding efficiencies
- Provide commentary on development pathway for next generation of a lead asset

Delfi Krishna, Director, Strategy, Portfolio, Operations, Cell & Gene Therapy Platform, **GlaxoSmithKline**

11.30 Evaluating Cell Potency with Single Cell Proteomics – Polyfunctionality and Correlation with Clinical Outcome

- Discussion on the interplay between polyfunctionality, proliferation and persistence and their correlation with clinical outcomes
 - Use of single cell proteomics as a method for evaluating the potency of cell products to select optimal targets and construct designs for improved tumor control in vivo mouse models
 - Applications for using single cell potency as a functional biomarker for improved bioprocessing methods that correlate directly with improved viability and fold-expansion
- Will Singleterry**, Director, Collaborations, Cancer Immunology Team, **IsoPlexis**

12.00 Empowering T Cell Therapies through Pharmacologic Regulation of Engineered Immunomodulatory Factors

- CAR-T therapy has lacked significant efficacy in treating solid tumors due to multiple factors, including inadequate CAR-T cell expansion, the immunosuppressive TME, and tumor escape
 - Engineering CAR-T cells to produce factors such as IL15, IL12, or CD40L has been shown to enhance functional activity, however clinical utility is limited by systemic toxicities
 - We are using cytoDRiVETM technology to couple titratable regulation of immunomodulatory factors with clinically approved drugs to enable safe and efficacious CAR-T therapies
- Steven Shamah**, SVP, Scientific Affairs & Technology, **Obsidian Therapeutics**

12.30 Lunch & Networking

12.30 Aldevron Luncheon

Attendance through invitation only



13.30 Clinical Use of Gamma-delta T Cells to Treat Haematological Malignancies – Translation to Phase 3

- Translation from autologous to allogeneic therapies
- Allogeneic gamma-delta's in treatment of AML
- Gamma-delta CAR-T's for solid cancers

Michael Leek, CEO, **TCBiopharm**

11.30 Automated Cell Therapy Manufacturing Using the CliniMACS Prodigy

- Outline the T-cell engineering process on the CliniMACS Prodigy
- Discuss different manufacturing models for commercial scale CAR T manufacturing
- Review Data on distributed manufacturing of CAR T cells using this process
- Provide outlook on possible implementation strategies of presented models

Nicolas Danzenbaeche, Senior Product Manager, **Miltenyi Biotec**

12.00 Towards Proof of Concept of TEGs Based on a Point-of-care Manufacturing Model

- Analyse the recoveries of cells in different patient populations, alongside the levels of viable cell production, after infusion to understand how culture conditions can affect expansion
- Automating manufacture to reduce cost and time of production

Tol Trimborn, COO, **Gadeta**

11.30 Panel Discussion: What Infrastructures Need to Be in Place to Ensure Successful Commercial Delivery of CAR-TCR Therapies?

- Building centers of excellence
- Transport and logistics of commercial delivery of a CAR-TCR product
- Patient case management and scheduling
- Educating and training to drive CAR-T and TCR adoption
- Dealing with the huge patient demand

12.00 Translating Academia to Industry - Multi-tumour-associated Antigen-specific (MultiTAA) T Cells

- MultiTAA recognize multiple antigens via native TCR without genetic engineering due to selection process during manufacturing
- Since lymphodepletion is not required for MultiTAA T cell approach, not only is tumor eliminated via direct killing by infused T cells, but also through recruitment of the endogenous immunity
- Clinical data for both hematological malignancies and solid tumors shows both the safety and efficacy of MultiTAA approach

Mythili Koneru, Senior Vice President, Clinical Development, **Marker Therapeutics**

13.30 Delivery of Advanced Therapies in the UK Landscape

- Establishing the Advanced Therapy Treatment Centre (ATTC) Network Infrastructure
- Collaborative approach across commercial, clinical and academic partners
- Scale-up of activities across the UK

Fiona Thistlethwaite, Medical Oncology Consultant & Director of **iMATCH**

14.00 Fitting Products to Processes: De-risking Raw Materials to Enhance Scalability

- Bio-Techne offers novel technologies to improve and simplify cell and gene manufacturing workflow
- An overview of how working closely with raw materials suppliers can de-risk supply of critical materials and also enhance scalability
- Saving time and effort in the development pathway of commercial CGTs

Lindsey Clarke, Head of Cell & Gene Therapy, **Bio-Techne Corporation**

Overcome Tumour Resistance to Improve Durability of Response

14.30 CT053, Anti-BCMA CAR T-cell Therapy for Relapsed/Refractory Multiple Myeloma: Long-term Results from a Phase I Study

- Patients with relapsed and refractory multiple myeloma have poor prognoses despite latest treatment advance
- CT053, a fully human anti-BCMA CAR-T cell is being developed to address the following issues: (1) significant adverse events observed in other BCMA programs; (2) lack of durable response in the high-risk population; (3) lack of persistence of CAR T cells with a non-human anti-BCMA CAR construct; and (4) patients may relapse after other anti-BCMA modalities
- CT053, BCMA CAR-T proof of concept phase I clinical trial results with long-term follow-up will be reported

Hong Ma, SVP, Clinical Development, **CARsgen Therapeutics**

CMC Control to Develop Consistent Quality Products

14.00



14.30 Standardising Raw Material & their Supply

- Review the availability of raw materials and variability
- Discuss the need to normalise raw materials including patient materials and culture material

Manel Juan, Head of Immunotherapy Platform, **Barcelona Children's Hospital and Hospital Clinic**

Regulatory Guidance to Initiate Clinical Trials in Europe

14.00 Round Table Discussion: Building a Regulatory Strategy for Global Clinical Trials

- Outline the different types of authorities that require approval
- Experience working with various European countries
- Considerations for which country to start trials in to ensure clinical growth and timely execution
- Review the framework in Europe for new innovations



14.30 Navigating GMO & Environmental Requirements

- Insights into GMO submission processes across different countries in context of ATMP
- Overview of recent developments to streamline GMO submission and assessment process for ATMPs in Europe
- Recommendations for alignment with CTA process in context of forthcoming implementation of Clinical Trials Regulation

Jacquelyn Awigena-Cook, Associate Director, Regulatory Policy & Intelligence, EMEA Regulatory Affairs, **Celgene**

15.00 Afternoon Refreshments & Poster Session

Share your work with the pioneers of CAR-TCR therapeutic development! Bring a poster and gain feedback on your latest research with this expert community.



Toxicity Management

16.30 Mechanisms, Predictive Markers and Progress with Management of Axicel-related Toxicities

- Explore the mechanism of toxicity and strategies to manage it with early clinical biomarkers and immune-monitoring tests
- Review clinical outcomes of combination trials to manage safety without interfering with clinical efficacy

Adrian Bot, VP, Translational Medicine, **Kite, a Gilead Company**

17.30 Translational Strategies to Prevent Toxicity

- Discuss the need to overcome CRS and NT to enable the delivery of these therapies in an outpatient setting
- Review alternative strategies to design the next-gen T-cells with enhanced efficacy and optimised activation and regulatory pathways
- Analyze clinical results outlining reduced CRS and NT

Cheng Liu, CEO, **Eureka Therapeutics**

16.30 CMC for CAR-TCR Therapies – Shifting the Quality Paradigm

- Best practices for the application of Quality by Design (QbD) principles to cell and gene therapy
- Standards development in the areas of starting materials, cell collection, and supply chain logistics
- Evolving regulatory guidance for CMC - compare and contrast EMA to FDA

Michael Lehmicke, Director, Science & Industry Affairs, **Alliance for Regenerative Medicine**

Overcoming Vector Supply Bottlenecks

17.00



17.30 Overcoming Challenges in Obtaining High, Quality Sustainable Vector Supply

- Holistic view in terms of vector, formulation, clearance and lead
- Experience sourcing vector supply as a raw material and building up with a global supply chain
- Outline which grade of vector, and type, should make up a final product

Cindy Jung, Director, Vector Process Development, **GlaxoSmithKline**

16.30 Navigating the Regulatory System for an ATMP

- Outline how different national agencies have different attitudes
- Address the need to make early contact with the regulator
- Review the perspective of the regulator, understanding that there will be on-going validation of assays and control over processes

John Johnston, Clinical Assessor, **MHRA**

Early Evidence Criteria to Achieve Access & Reimbursement

17.30 Evidence Generation and Access to CAR-T Therapies: A Health Technology Assessment Approach

- Advances in precision medicine, including CAR-T therapies, mean treatments are becoming increasingly tailored to individuals with patients being offered more personalised therapeutic options
- CAR-Ts have a disruptive impact on current health delivery processes leading to capacity issues in some therapeutic areas
- Early/limited evidence generation impacts the health technology assessment and economic evaluation of these agents necessitating novel approaches to funding and adoption
- Address how these complexities are being managed and where further work is needed

Deborah Morrison, Principal Scientific Advisor, **National Institute for Health & Care Excellence**

18.00 Chair's Closing Remarks & End of Summit Day 1

18.15 Drinks Reception

8.30 Chair's Opening Remarks

9.00 Industrialising Cell Therapies: Managing Complexity Across the Ecosystem



9.30 Late Breaking Abstracts

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

10.00 CAR-TCR Landscape Review

- Comprehensive analysis of all CAR-T and TCR trials
- A review of target distribution and trends
- Insight into the rapidly evolving pipeline and key movements in the field

Pippa Gledhill
Research Analyst
Beacon Targeted Therapies

10.30 Morning Refreshments & Tech slam

Translation Track

Translating Effective Allogeneic Therapies

11.30 Human Vd1+ T Cells; an Allogeneic 'Off-the-Shelf' T Cell Therapy Platform

- Exploring strategies to use the unique properties of Vd1 gd T cells to:
 - Generate an allogeneic platform for the treatment of solid tumours and hematologic malignancies
 - Improve the tumour targeting and safety profile of engineered cell therapies

Alice Brown, VP, Research & Gene Engineering,
GammaDelta Therapeutics

Manufacturing Track

Technology Transfer & Scalability

11.30 Challenges Carrying Out Tech Transfer for Manufacturing Sites

- Experience managing different raw materials which require different supply agreements and approval status
- Introduction to the GMP requirements for the EU region to avoid challenges moving cross-country
- Managing process changes without impacting the product quality and different product

Therese Solstad Saunders, Senior Adviser, **Norwegian Medicines Agency**

12.00 Streamlining CAR-T Discovery and Lentiviral Manufacture for Cell and Gene Therapies

- A self-labelling integral mammalian display platform: from target to therapeutic lead all in mammalian cells
- Technology overview and case study demonstrating identification of novel binders to complex membrane proteins
- Suspension, serum free, stable lentiviral packaging and producer cell lines for GMP applications
- Scalable systems for cost-effective manufacture of high volume, high titre lentiviral vectors

Ryan Cawood, CEO, **Oxgene**

Development & Commercialisation Track

Market Access Innovations for CAR-T Therapies

11.30 Development and Execution of Clinical Trials in Europe

Helen-Tayton Martin, CBO, **Adaptimmune**

12.00 Crossing borders: Supply Chain Strategies That Foster Sustainability in a Rapidly Advancing International Environment

- Overcoming customs complexities and regulatory differences when crossing international borders
- Scaling the cell therapy supply chain to handle large volumes of therapies when preparing for commercial approval
- Implementing standards and efficient processes to ensure starting material quality and minimize room for error across expansive collection networks

Mark Flower, VP, Business Development, **Be The Match BioTherapies®**

12.30 Exploiting NK Cell Receptors for Autologous and Allogeneic CAR T Cell Therapy

- Targeting hematopoietic and solid malignancies with NKG2D-based CAR T cells
- Development of non-gene edited allogeneic CAR T cells
- Efficacy and safety of autologous and allogeneic CAR T cells targeting solid tumours

Peggy Sotiropoulou, Director, Research & Development, **Celyad**

12.30 Process Intensification and Technology Development for CAR-T therapies

- Establishing a process control strategy facilitates process intensification, increasing yield and efficiency
- Automated strategies for process and product development enables increased consistency
- Improved control allows for the potential of patient-specific adaptive manufacturing

Qasim Rafiq, Associate Professor, Cell & Gene Therapy Bioprocessing, **University College London**

12.30 Overcoming Cross-border Restrictions for Access

- Describe cross-border challenges for patients without central funding, creating an untimely process
- Expanding centres across Europe to overcome the geographical access challenges

Annie Hubert, Senior Director, Section & Public Policy, **Alliance for Regenerative Medicine**

13.00 Lunch & Networking

14.00 Panel Discussion: Review Cell Sources to Optimise Cell Functionality and Persistence

- Discuss the strengths and weaknesses of TILs, non-engineered T cells and iPSC cells
- What is the best cell source for sustainability in autologous and allogeneic therapies?

Cedrik Britten, VP, Oncology Cell Therapy Research Unit, **GlaxoSmithKline**

David Gilham, VP, Research & Development, **Celyad**

Blake Aftab, VP, Head of Preclinical & Translational Sciences, **Atara Biotherapeutics**

14.00 Panel Discussion: How to Improve Process Development for CAR-TCR 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

Michal Besser, Head of Laboratory, Director, **Sheba Medical Center**

14.00 Panel Discussion: How Does the Lack of a Centralised Process in Europe Impact Clinical Development?

- Compare how the EMA regulatory requirements compare to the FDA
- Discuss the need for a harmonised approach in Europe to improve patient access

Annie Hubert, Senior Director, Section & Public Policy, **Alliance for Regenerative Medicine**

Vicki Coutinho, Head of Global Regulatory Affairs, **Autolus**

Oezlem Anak, VP & Senior Global Head of Clinical Program, **Novartis**

15.00 Development of an Allogeneic, Off-the-Shelf T-cell Immunotherapy Cell Therapies and Derivation of a Next-Generation CAR-T Platform

- Clinical development of allogeneic off-the-shelf T cell immunotherapies in oncology and autoimmune disease
- Clinical and translational studies provide insight into functional biomarkers correlating to efficacy and in vivo expansion
- Applying clinical and translational findings to the development of next gen allogeneic off-the-shelf CAR-T cell therapies

Blake Aftab, VP, Head of Preclinical & Translational Sciences, **Atara Biotherapeutics**

Cell Characterisation

15.00 Leveraging High-Dimensional '-omics' Technologies for Comprehensive Profiling of CAR T cells to Resolve Drug Product Complexity

- Highlight a need for deeper characterization of the PBMC starting material/drug product for cell therapy products
- Use if bulk vs single analysis for characterization work
- Data demonstrating how single cell analysis has improved our understanding of the cellular complexity within the final formulated drug product

Eric Alonzo, Senior Scientist, Cell Analytics, **bluebird bio**

15.00 Legal Challenges for Next Generation Therapies

- Considerations for the manufacturing, supply and commercialization of advanced therapy medicinal products (ATMPs)

Lisa Kinsella, Head Legal NTO, Biologics, Cell & Gene, **Novartis**

Stefan Ibing, Attorney at Law, Head of Legal NPhS, **Novartis**

15.30 Close of the Summit

8.30 Registration & Coffee

Solid Tumour Track

Chair- **David Gilham**, VP, Research & Development, **Celyad**

Cell Trafficking and Tumour Penetration

9.00 ACTallo®: Off-the-Shelf, TCR-Engineered V γ 9 δ 2 T Cells for the Treatment of Solid Cancer

- V γ 9 δ 2 T cells have a natural ability to infiltrate solid cancer, independent of the presence of $\alpha\beta$ T cells
- When present in patients' cancer, V γ 9 δ 2 T cells correlate with positive prognosis
- With ACTallo®, we intend to leverage V γ 9 δ 2 T cells to develop a novel generation of TCR-engineered allogeneic cell therapies, with features distinctive from other off-the-shelf modalities

Yannick Bulliard, Director, Translational Development, **Immutics**

9.30 Overcoming CAR-T Cell Metabolic Antagonism in the TME

- Describe the metabolic states during the life of an antitumor T cell
- Examine the metabolism of the CAR-T cell at the tumour site to understand how the microenvironment could impact their function
- Assess engineering strategies to help expand cells in these detrimental environments
- Basic analysis of protein expression, gene expression and cell interaction in the TME

Alessandra Cesano, At-large Director, SITC; Co-chair of **Adoptive Cell Therapy Working Group**

10.00 Morning Refreshments & Networking

Driving Potency in Suppressive Environments

11.30 Solid Tumour Immunotherapy Using Parallel CAR T Cells

- Analyse the rationale for parallel CAR configuration
- Share experience of pCAR immunotherapy of haematological tumours compared to experience of pCAR immunotherapy for solid tumours

John Maher, Immunology Consultant, King's College London / CSO, **Leucid Bio**

New this year

Clinical Management

Chair- **Peter Olagunju**, VP, Global Patient Operations, **Bluebird Bio**

Preparing Institutional Readiness in Europe

9.00 Enroll to Infusion- Supporting Patient Treatments

- What is Therapy Services
- Potential challenges in the treatment pathway
- Success factors for commercial success

Peter Olagunju, VP, Global Patient Operations, **Bluebird Bio**

9.30 Toxicity Management

- Review predictive biomarkers to identify early signs of toxicity.
- Discuss the training needed by clinical trial staff to manage patient toxicity
- Standardise algorithms to manage toxicity

Agnes Schubert, Global Program Safety Lead, **Novartis**

Preparing Institutional Readiness in Europe

11.30 Considerations for Recruitment and Preparation of Clinical Sites Participating in a TCR-T Study

- Explore what kind of training must be carried out to ensure the setting is registration ready
- Understand which Standard Operating Procedures must be in place before dosing begins
- Experience on scheduling training plans to ensure a successful CAR-T trial

Jens-Peter Marschner, CMO, **Zelluna Immunotherapy**