

Participants

14 participants for Cell and Gene Therapy Matchmaking Event.

Atelerix Ltd

Organisation

Country	United Kingdom
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Web	www.atelerix.co.uk



Person

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Organisation

Atelerix has invented a simple, low cost system capable of preserving the viability and functionality of cells and tissues at hypothermic temperatures (4°C to 21°C) for extended periods of time by encapsulating them in alginate hydrogels. Used as a method of cell storage and transport, it overcomes the acknowledged problems associated with cryo-shipping. Cells are encapsulated by in situ formation of the gel for shipping in plates, beads or vials, and can be rapidly released from the gel by the addition of a simple buffer. There are no other products currently available on the market with the capability to do this. The Company plans to capitalise on this by adopting a business-to-business approach that enables our customers to develop new, high value products that are either not feasible with current methods or are prohibitively expensive. Following short, low-cost, co-development projects with the customer, the Atelerix technology will be licensed to the customer who will use it to make and sell their products, paying the Company for supplies of alginates on a per unit basis.

Marketplace Opportunities

PRODUCT

Transport of human cells at room temperature

We are looking to supply our technology for the shipment of cells at room temperature to companies developing cell therapies. Our approach extends the shelf life of short-lived therapies, increasing the reliability and reproducibility and improving commercial viability

Cell and Gene Therapy Catapult

Organisation

Country United Kingdom
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Person

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Organisation

The Cell and Gene Therapy Catapult was established as an independent centre of excellence to advance the growth of the UK cell and gene therapy industry, by bridging the gap between scientific research and full-scale commercialisation. With more than 120 employees focusing on cell and gene therapy technologies, it works with partners in academia and industry to ensure these life-changing therapies can be developed for use in health services throughout the world. It offers leading-edge capability, technology and innovation to enable companies to take products into clinical trials and provide clinical, process development, manufacturing, regulatory, health economics and market access expertise. Its aim is to make the UK the most compelling and logical choice for UK and international partners to develop and commercialise these advanced therapies. The Cell and Gene Therapy Catapult works with Innovate UK. For more information please visit ct.catapult.org.uk or visit <http://www.gov.uk/innovate-uk>.

Marketplace Opportunities

SERVICE

Industrialization and commercialization of cell and gene therapy

Non-clinical, clinical development, process/analytical development, manufacturing, regulatory, health economics and market access for cell and gene therapy

Cell Medica

Organisation

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Organisation

Cell Medica develops, manufactures and markets personalized cellular immunotherapeutics for cancer and infectious diseases.

We are committed to improving patients' lives through the significant therapeutic potential of cellular immunotherapy. Our approach is to apply innovative technologies with the aim of improving the treatment of cancer and immune reconstitution following hematopoietic stem cell transplant.

Marketplace Opportunities

PRODUCT

CMD-003 EBV-Specific autologous T-cells

CMD-003 consists of patient-derived (autologous) Epstein-Barr virus (EBV)-specific T cells. The T cells specifically target four EBV epitopes (LMP1, LMP2, EBNA and BARF1).

EBV infects more than 90% of the human population on a latent basis and is connected to a variety of cancers. Cell Medica is developing CMD-003 for the treatment of patients with non-Hodgkin lymphoma (NHL) and Hodgkin lymphoma (HL) as well as nasopharyngeal carcinoma (NPC) and post-transplant lymphoproliferative disease (PTLD).

The initial clinical development of CMD-003 focused on extranodal natural killer T cell lymphoma (ENKTCL), a type of non-Hodgkin lymphoma, being investigated in the CITADEL trial.

We have recently expanded indications under study to include EBV-positive diffuse large cell lymphoma (DLBCL), Hodgkin lymphoma and post-transplant lymphoproliferative disease (PTLD), which are being investigated in the CIVIC trial.

PRODUCT

CMD-501 CAR-NKT Product

We are developing CMD-501 for the treatment of neuroblastoma and small cell lung cancer. CMD-501 is an autologous cell therapy which utilizes our natural killer T (NKT) cell platform technology in combination with genetically engineered chimeric antigen receptors (CARs) and secretion of the IL-15 cytokine to sustain the activity of the therapeutic cells within the immunosuppressive tumor microenvironment. The product is currently in pre-clinical development with the Phase 1 study planned for Q2 2018.

PRODUCT

CMD-502 Allogeneic Off-the-shelf for hematological cancers

CMD-502 is an off-the-shelf allogeneic product which is under development for the treatment of hematological cancers (target undisclosed). CMD-502 will be manufactured in large amounts to enable the treatment of patients on an immediate basis.

CMD-502 takes advantage of the unique characteristics of NKT cells for an off-the-shelf product. The T cell receptor of NKT cells is invariant and does not target human antigens. Allogeneic CAR-modified NKT cells can be administered to patients with minimal risk of toxicity due to Graft vs Host Disease.

PRODUCT

CMD-602 Dominant TCR WT1 Product

CMD-602 targets a range of cancers which express the WT1 antigen. Cell Medica acquired this product from the Cell and Gene Therapy Catapult (CGT Catapult). The original research was conducted at University College London (UCL) and Imperial College London. CGT Catapult has progressed the clinical development studying the safety and efficacy of the product in patients with acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS). With eight patients treated, the product has demonstrated promising results.

Cell Medica plans to continue the current clinical development investigating the WT1-TCR for AML and MDS while also preparing a second-generation product which incorporates the Dominant TCR technology licensed from UCL in 2016. Applying the Dominant TCR technology is expected to achieve greater efficacy in the solid tumor setting and the Phase 1 trial for the second-generation product is targeted for late 2018.

INVESTMENT OPPORTUNITY

Investment in Cell Medica's Pipeline for Japan

Investment is welcomed into CMD-003, CMD-501, CMD-502, CDM-602, or other Cell Medica products for entry into Japan. Global field will be considered. Investment can be in the form of licensing or other financing vehicle.

Cells4Life Group LLP

Organisation

Country	United Kingdom
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Person

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Organisation

Cells4Life Group LLP (Cells4Life) is the UK's leading stem cell storage company with over 50% of the UK market, more UK samples in storage than any other bank and one of the fastest growing companies in its sector. The Company is also the largest provider of stem cell banking services in the Middle East and has offices in several European countries. Cells4Life's success is based on its class leading, patented stem cell processing technology, TotiCyte, which provides patients with 2 – 5 times more stem cells than any other method at the point of treatment, giving the Company a unique and sustainable competitive advantage. Cells4Life is also the only stem cell bank that splits stem cell samples into multiple units and across two sites for maximum usability and security. Since the Company was established in 2002, Cells4Life has released samples for various treatments to clinicians both in the UK and internationally.

Cells4Life is an innovator in the regenerative medicine field, having developed a revolutionary new blood separation technology, TotiCyte, which is the first of its kind to remove of more than 99% of the haematocrit in a blood sample, whilst retaining almost all of the useful white cell fraction. TotiCyte is a CE marked solution of three chemicals routinely used in blood therapy. When added to blood TotiCyte causes the erythrocytes to sediment and form a rouleau. The pure red cell concentrate can then be removed, retaining the plasma containing all of the white cell fraction for further processing. This technology is potentially transformative to any blood processing protocols that require minimum red cell retention and maximum white cell retention. These include various regenerative medicine applications, including cord blood stem cell therapy, bone marrow stem cell therapy, Platelet-Rich-Plasma (PRP) and CAR-T therapy.

Marketplace Opportunities

PRODUCT

TotiCyte

TotiCyte is a transformational blood processing technology that enables the removal of over 99% of red cells with minimal loss to the white cell fraction of blood. This makes it transformational for a range of processes that require the isolation of blood components.

TotiCyte has already been applied to cord blood processing, delivering 2 to 5 times more CD34+ cells at the point of treatment than any other system. A TotiCyte protocol has also been developed to manufacture the world first entirely cell free, concentrated platelet-rich-plasma, with excellent clinical

outcomes in animals.

Cells4Life is now looking to develop bone marrow and T-cell protocols using TotiCyte and seeks a research partner with which to do this.

TotiCyte is also available for sale in 200ml units, and Cells4Life would also consider licensing of the technology.

Cobra Biologics

Organisation

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Person

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Organisation

Cobra Biologics is a leading international contract development and manufacturing organisation (CDMO) providing DNA and viral vectors for pre-clinical, clinical and commercial supply. As a trusted provider and a key partner in the drug development and commercialisation process, we take pride in our manufacturing excellence and comprehensive range of services to the pharmaceutical and biotech industries.

Marketplace Opportunities

SERVICE

DNA manufacture

Non-GMP, High Quality (HQ), and GMP plasmid DNA manufacturing for preclinical and clinical supply. Since 1998, Cobra's success has come from the experience and expertise gained as a solution provider for DNA vaccines, gene and immunotherapies.

SERVICE

Viral vector manufacture

As an experienced manufacturer of cGMP viral vectors (AAV, Adeno and Lenti viral vectors) for gene therapies and vaccines, Cobra's goal since 2002 has been to deliver customers' virus programs in a cost effective and timely manner for clinical and commercial supply.

SERVICE

Antibiotic-free Maintenance System

No potential for residual antibiotic contamination of plasmid DNA. Provides a plasmid backbone with an improved safety profile that maximises the efficiency of therapeutic gene delivery. Smaller plasmids for improved gene delivery.

Engitix Ltd

Organisation

Country	United Kingdom
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Person

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Organisation

Engitix is a spin-out company founded in 2016 from University College London (UCL) Institute for Liver and Digestive Health (IDLH), focusing on liver disease, a global concern. Liver disease prevalence is increasing because of unhealthy lifestyles (obesity and alcoholism) and hepatitis B + C infections. Moreover, the main current treatment, liver transplant, is heavily limited by donor organ shortages. Against that backdrop, Engitix is engineering proprietary 3D human spheroids and is the first company in the world to produce human tissue-specific and disease-specific extra-cellular matrix (ECM) scaffolds. These human liver scaffolds are supplied to biotech and pharmaceutical companies who pay to use them for disease modelling and drug screening purposes (fibrosis and NASH, liver cancer, liver metastasis and pancreatic cancer). Since the beginning of 2017, 3 commercial contracts have been signed. A further 4 contracts are in advanced negotiation and 2 are expected to be closed during Q1 2018. Longer term, the human liver scaffolds will be used to support a range of innovative, regenerative medical products. These will include tissue-specific bio-inks for 3D printing, biomarkers and eventually, whole human livers for transplant. In addition to the ECM scaffolds, Engitix is also developing an external Bioartificial liver (BAL) device, with two successful pre-clinical trials completed (41 pigs). The company is currently exploring, with its established clinical network lead by Professor Norifumi Kawada (Head of Hepatology at Osaka University) and coordinated through Chairman and Co-Founder, Professor Massimo Pinzani, the potential to use a clinical trial expedited pathway in Japan. The use of small pilot studies under recently enacted legislation (PMDA Act 2014) may allow Engitix' BAL to come to market in Japan in three years, rather than the normal time of six or more years. In the UK, Engitix is planning to use its relationship with the UK Government's Human Cell Therapy Catapult to accelerate its design and development process for its BAL. Demand for ECM scaffolds and BAL products represents a very large (>\$1Bn) future market. The company is now looking to raise £20m in a series A round (£10m for a BAL human clinical trial in 2 x £5m tranches, and £10m for ECM related R&D).

Marketplace Opportunities

SERVICE

Human 3D-models for fibrosis and cancer drug screening

Engitix is the first in the world to provide engineered human tissues (e.g. liver, intestine, pancreas) for disease models, drug screening, biomarkers discovery and regenerative medicine. Our in vitro discovery

platform has a key USP related to the preservation of natural ECM (healthy and diseased) which is a key factor in modulating cell phenotype. Engitix 3D models can be also applied for the in vitro study immune response as well as for testing immuno-therapeutic ('immune oncology') products such as CAR-T, NK and vaccine induced T Cells.

PRODUCT

Engitix Regenerative Medicine Pipeline

Engitix regenerative medicine pipeline is characterized by three pillars which are: i) Bioartificial liver device, ready for phase I/II clinical trial (safety and efficacy showed in two pre-clinical trials using pig liver failure model) ii) implantable liver tissue patches, based on engineered human ECM hydrogels (potential bio-ink for 3D printer) as tissue patches reseeded with primary hep or iPSC-Hep, currently in pre-clinical phase and iii) whole organ engineering, currently in R&D for the recellularization part. Obviously, all those programs have extensive data that we are happy to share in case of positive feedback.

Some links to key publications related to our regenerative medicine products below:

Relevant publications for the BAL are:

- 1st pre-clinical trial in pig (published in 2013)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3867376/pdf/pone.0082312.pdf>

-2nd pre-clinical trial in pig (published in 2017)

<https://www.nature.com/articles/s41598-017-15021-4>

- BAL cryopreservation (supporting the feasibility of generating an off-the-shelf product)

<https://www.ncbi.nlm.nih.gov/m/pubmed/28841674/?i=1&from=selden%20c>

<https://www.ncbi.nlm.nih.gov/m/pubmed/27298755/?i=3&from=selden%20c>

- Relevant publication for whole organ engineering

<https://www.nature.com/articles/srep13079>

INVESTMENT OPPORTUNITY

Multi-billion dollar market potential for Engitix products

Demand for ECM scaffolds and BAL products represents a very large (>\$1Bn) future market.

The company is now looking to raise £20m (£10m for a BAL human clinical trial in 2 x £5m tranches, and £10m for ECM related R&D). An NPV and company financial forecast are available to interested potential investors.

Importantly, the company is also exploring, with its established clinical network coordinated through Chairman and Co-Founder, Professor Massimo Pinzani, the potential to use a clinical trial expedited pathway in Japan. The use of small pilot studies under recently enacted legislation (PMDAct 2014) may allow Engitix' BAL to come to market in Japan in three years (early conditional approval), rather than the normal time of six or more years. In the UK, Engitix is planning to use its relationship with the UK Government's Human Cell Therapy Catapult to accelerate its design and development process for its BAL.

Freeline Therapeutics

Organisation

Country	United Kingdom
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Organisation

Freeline Therapeutics is a biopharmaceutical company focused on the development of gene therapies for rare, debilitating disorders. The Company is currently based at the Royal Free Hospital, London and is planning to relocate to Stevenage Bioscience Catalyst in early 2018. Freeline was launched in December 2015 with a £25 million Series A financing from Syncona Ltd. Freeline has generated a next-generation AAV gene therapy platform building on the work of Professor Amit Nathwani, Founder and Chief Scientific Officer of Freeline as well as Professor of Hematology at University College London. This technology is based on proprietary AAV vector technology that use human adapted, novel and potent capsids combined with highly optimized expression cassettes designed to deliver functional copy of therapeutic gene into the human liver to offer durable secretion of therapeutic enzymes in the patient's blood. In addition, this platform builds on the successful hemophilia B phase I/II clinical trial conducted by Prof. Nathwani in collaboration with St. Jude Children's Research Hospital. The results of the study, published in the New England Journal of Medicine in 2011, demonstrated that all ten treated hemophilia B patients showed safe and sustained expression of blood clotting Factor IX from a single treatment. In 2016, Freeline acquired the Adeno-Associated Virus manufacturing platform developed by Rentschler Biotechnologie GmbH (Rentschler), a world leading contract manufacturer of biopharmaceuticals. In conjunction with the acquisition, Freeline has also established operations in Munich to further its manufacturing technology and maintain its leadership position for best in class manufacturing processes for AAV. Dr Markus Hörer, previously Director of Virus-based Biologics at Rentschler, has joined Freeline as founder and head of Freeline GmbH and Freeline's Chief Technology Officer (CTO). Freeline has further improved the expression cassette and is initiating a new clinical trial to demonstrate the superiority of the selected construct. Subsequent programs are already being developed which leverage this platform, focused on the treatment of lysosomal storage disorders and other rare diseases.

Our business is based on the discovery, clinical development, manufacture and commercialization of Adeno-Associated-Virus-based therapy for the treatment of debilitating disorders. Our most advanced clinical program is Factor IX for the treatment of hemophilia B. Alongside, numerous follow-up programs are being explored for finding treatments where liver-expressed proteins can be used as a long-term therapeutic modality following a single vector administration. Our second most advanced program targets lysosomal disorder. Other therapeutic areas of similar nature are also looked at using our unique platform. Whilst we have a strong presence in Europe (UK/ Germany), we strive to reach out globally. We are seeking: - opportunities to expand our business to include Japan's commercial market

and to gain access to Japanese patients and/or clinical site(s) - ways to accelerate our clinical programs towards commercialization, - collaboration with academic groups or biotech/pharma companies to discover, develop and commercialize novel AAV-based medicines -in-licensing opportunity of novel discoveries/programs that have a strategic fit with our company business.

LIFT BioSciences Ltd

Organisation

Country	United Kingdom
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Person

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Organisation

LIFT BioSciences is a socially-minded Biotech start-up developing The World's First Cell Bank of Cancer Killing Neutrophils (a type of white blood cell). The Cell Bank will enable us to provide a range of potentially life-saving immuno-oncology cell therapies for different solid tumour types. Our innate immunity platform is known as Leukocyte Infusion Therapy (LIFT). LIFT BioSciences Ltd was set-up with Prof Zhen Cui of Wake Forest University, a leading pioneer in LIFT, following his discovery of a cancer resistant (SR/CR) mouse that proved to have transferable innate immunity, with 70-100% cure rate in mice. Early indicative work in humans shows 50-80% tumour necrosis. LIFT BioSciences recently received a lot of press attention for their clinical breakthrough with Kings College of producing The World's first Neutrophils from Stem Cells to demonstrate Cancer Killing Ability. The breakthrough means we now have the building blocks for a scalable, patented, safe and potentially curative cell therapy for treating a range of solid tumours. The first targeted indication is pancreatic cancer. The EMA has classified LIFT as an Advanced Therapeutic Medicinal Product (ATMP), which sets us up for accelerated approval (early access scheme) and enhanced proprietary protection (market and data exclusivity), subject to trial results. We were initially grant funded by MedCity & Merck for work we are doing with Kings College London. We are now completing a £500K investor round, and are now starting to line-up BioPharma partners for commercialisation/development deals.

Marketplace Opportunities

INVESTMENT OPPORTUNITY

Post-SEED Investment for Human Clinical Trials

We are seeking £2.5-5m funding for our human clinical trials of our potentially curative Leukocyte Infusion Therapy. Our therapy has proven to be curative in mice, and a less scalable variation has showed 40-80% tumour necrosis in 3 end-stage human cancer patients.

We are now planning a small proof-of-concept trial in Pancreatic Cancer and soft-tissue sarcoma patients before moving to our Pivotal Trial. We are also seeking commercial partners for commercialisation that may coincide with the investor if trade.

PRODUCT

Immuno-Oncology Cell Therapy Platform for All Solid Tumours

We are developing the world's first cell bank of innately cancer killing neutrophils for potentially curing

a range of solid tumours using Leukocyte Infusion Therapy (LIFT). We have developed a way to mass produce these innately cancer killing cells and store them. LIFT has demonstrated 100% cure rates in mice, and 40-80% tumour necrosis in 3 late-stage cancer patients. We are now seeking partners for bringing the product to market and commercialising it, such as exclusive out-license deals for different countries and indications.

REQUEST

Stem Cell Expansion Capabilities

We are looking for development partners with the expertise to potentially expand haematopoietic stem cells into the trillions.

N4 Pharma Plc

Organisation

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City	England
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Person

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Organisation

N4 Pharma is a specialist pharmaceutical company which reformulates existing drugs and vaccines to improve their performance.

N4 Pharma's reformulation work falls under two divisions:

- generic, already commercialised, drugs; and
- delivery of novel and existing vaccines.

Nuvec® is an engineered silica nanoparticle, which has been designed for the intracellular delivery of large nucleic acids such as pDNA and mRNA and is in the advanced research phase. The intention of the system is to effectively deliver nucleic acids into cells leading to the cellular production of proteins with potential activity as therapeutic entities or antigens for cancer vaccines.

N4 Pharma's business model for vaccines is to undertake the required clinical work to demonstrate the capability of its delivery system as a cancer vaccine or therapeutic treatment so that it can license the technology to major players developing treatments in this area, again in return for up front milestone and royalty payments associated with the licence.

Marketplace Opportunities

PRODUCT

Nuvec microporous silica nanoparticles for DNA/RNA delivery

Nuvec is a silica nanoparticle with a unique spiky structure that allows superior binding and release of DNA/RNA

N4 has produced exciting data to show the ability of nuvec to aid in-vivo transfection of DNA and RNA with no toxicity.

Key advantages of using Nuvec® for DNA or RNA vaccine delivery

High vesicle loading – Easy loading of pDNA into the silica vesicle to achieve high loadings with little/no degradation of the pDNA

Good encapsulation – of the pDNA to minimize breakdown by nucleases and protect pDNA from attack.

Low toxicity – proven low toxicity of the silica vesicles

Strong cellular uptake – Optimisation of particle size and surface chemical functionality to enable efficient transport across the cell membrane and entry into the cell nucleus

Nucleic acid protection - prevents attack from nuclease

PROJECT COOPERATION

evaluation partners

N4 is seeking partnerships with Japanese companies to evaluate its ability to improve transfection of the partner's antigens.

N4 will provide the silica particles free of charge under a material transfer agreement to allow the partner to undertake internal evaluations or can provide this service to the partner if preferred (for an agreed feasibility project)

Nanogenic Solutions Ltd

Organisation

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Person

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Organisation

Nanogenic Solutions is a privately owned biotech company. During the past 5 years a growing number of gene therapy companies in the USA and Europe have focused on developing treatments for a limited range of genetic diseases. Their selection of diseases has been determined by the limitations of the delivery systems available. Most viral and lipid nanoparticle delivery vehicles end up in the liver, and consequently most companies are developing treatments for a limited number of hepatic genetic diseases. We are capable of targeting other tissues, including tumours, lung, brain and the cardiovascular system. We can deliver a wide range of bio molecules – DNA, mRNA, siRNA to name the most important. Our particle is suited to a wide range of delivery routes, including systemic (Intra Venous). The particle can be nebulised for inhalation, and can be stored long term. Most gene therapy companies opted for viral delivery systems, but the limitations of those systems are now widely recognised. Viruses have limited reach in terms of tissues that can be targeted, they cause immune responses which severely limit their utility, and they are very expensive to manufacture. Our nanoparticles can target a variety of tissues, are not immunogenic and are very inexpensive to manufacture. We are truly providing a timely solution to a severe bottleneck in the development of the Advanced Therapies sector. We plan to widen the range of tissues we can target over the coming years, and are already receiving requests from different companies to target particular tissues. We currently have two sub-licensees, and several of the world's foremost gene therapy companies in the USA and Europe are testing our delivery system. One big pharma company is currently evaluating our technology. We don't know much about the Japanese biotech sector, but we would expect that there is a growing gene therapy sector there and we would like to meet them. Our non-viral, targeted gene delivery system is world-leading technology, and we intend to keep it that way through a program of ongoing improvement.

Marketplace Opportunities

PRODUCT

Targeted delivery of gene therapies

We are capable of targeting many tissues, including tumours, lung, brain and the cardiovascular system. We can deliver a wide range of bio molecules – DNA, mRNA, siRNA to name the most important. Our particle is suited to a wide range of delivery routes, including systemic (IV) and inhalation. Formulated particles can be lyophilised and freeze dried for long term stable storage.

INVESTMENT OPPORTUNITY

Investors wanted

We are seeking investment to widen our ability to target tissues and also to develop our own gene therapies.

Oxford MESTar Ltd

Organisation

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Person

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Organisation

Oxford MESTar is a spin-out company from the Institute of Biomedical Engineering at the University of Oxford University. We apply our bioengineering expertise to challenges in cell therapy and regenerative medicine and specialise in automated manufacturing systems for cellular products and biomaterials (including 3D printing). We have developed a closed automated cell expansion bioreactor for adherent (stem cell) and suspension (T-cell) culture, which we are looking to launch into the market in 2018. We are developing a perfusion reactor for 3D cell culture and looking for new technologies to augment future products. We also carry out bespoke projects for clients.

Marketplace Opportunities

PRODUCT

Automated cell expansion system

Later in 2018 we will launch a new modular bioreactor for automated culture of adherent and suspension cell lines such as MSCs and T-cells. The device and its closed single-use reactor sets are designed for clinical GMP manufacturing of cell therapies. The system is also suitable for R&D use, and enables easy transfer of R&D protocols to clinical manufacturing.

PRODUCT

3D perfusion bioreactor

The use of 3D cell culture is growing rapidly as it provides a more realistic model of living tissue than suspension or adherent techniques. We are developing a system that allows 3D cell culture to be performed under perfusion conditions in 96-well plates, allowing optimal growth conditions, testing of external inputs such as drugs or growth factors and analysis of cell metabolites.

SERVICE

Bioengineering and bioprocess automation solutions

In the early phases of development, manufacturing of cellular or tissue-based products is carried out using small-scale, open, manual processes. Manufacturing for clinical trials and commercial launch, however, must be reliable, efficient and scale-able. Oxford MESTar can help you make this transformation by using our expertise to develop and build a bespoke system to automate your manufacturing process.

REQUEST

Label free cell analysis technology

We are seeking technologies that will allow us to monitor, in real-time, the growth and vitality of cells in a closed bioreactor system.

REQUEST

Traceless cell separation and activation technologies

We are seeking reagents and technologies that allow cells to be separated and or activated via cell surface antigens, but that can be easily removed from the cells afterwards.

Pplus Skin Care Ltd

Organisation

Country	United Kingdom
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Person

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Organisation

Our vision behind Pplus products is to make one of the safest and most natural treatments in the field of regenerative medicine universally available. We have already developed the first prototype of the Pplus Kit and tested it on a number of patients who have shown great results. Trademark and design rights have been registered and an international patent is pending (including in Japan). Dr Najafi has funded everything herself in the last 4 years of R&D but is currently trying to raise further funds and form new collaborations with universities to carry out a few more studies to then be able to register the Pplus kit as a medical device with Notified Body. After that the products will be ready for CE marking, manufacturing (ideally in the far east) and international commercialisation. Pplus products will be the first of its kind in the market place, a real game changer which opens up the uses of PRP across medicine. PRP is an autologous treatment modality that has shown considerable promise in applications across medicine. Its potential to be tailored to a specific indication and positively impact a disease process to improve outcomes has tremendous potential. Its clinical utility is based on the increase in the concentration of growth factors which are able to maximize the healing process at the cellular level while at the same time carrying a minimum risk of immune reactions and transmission of infectious diseases to the patient. Despite the great potential the implementation of PRP is currently hampered due to the lack of studies related to the standardization of the techniques and/or insufficient description of the procedures and methods for storing PRP of high quality in the clinic. Over 50 publications on the benefits of PRP in the management and treatment of diabetic foot ulceration point to the potential for PRP in the proactive management of these costly and debilitating wounds, which cost the UK only over £1bn p.a. PRP market was valued at \$160M in 2015, expected to grow at a CAGR of 12.5% up to 2024 as clinician led awareness of PRP therapy and its benefits continue to emerge. Our company has already identified and addressed some of the challenges associated with this exciting technology which puts us ahead of the game. Our initial target sectors are Dermatology including Facial rejuvenation (with a global market that is projected to reach \$273.8 billion in 2020 from \$233.6 billion in 2015, at a CAGR of 3.2% (Ref Transparency market research) and Chronic wound care in the ageing population where the current models of care are struggling to cope with the demand.

Marketplace Opportunities

PRODUCT

pplus kit

pplus kit offers none invasive application of PRP and storage of PRP for up to a week without freezing

SERVICE

pplus technology/ products

Pplus products has the potential to be used for Facial rejuvenation/anti ageing, burns, eczema and wound care/leg ulcer treatments

PROJECT COOPERATION

academic cooperation as well as investing partners

We have already developed the first prototype and IP rights have been consolidated. We now need to obtain registration with notified body in order to commercialize our products. Later we also need to obtain FDA approval.

INVESTMENT OPPORTUNITY

Pplus is trying to raise further funds

The founder Dr Mitra Najafi has funded all the R&D herself so far but further investment is now necessary in order to register pplus products as medical devices with notified body and get FDA approval

REQUEST

manufacturing and launching pplus products in Japan

We would very much like to explore the possibility of manufacturing pplus products in japan and the possibility of launching our products in japan first together with the right partners followed by international commercialization if we raise the needed investment

TrakCel Ltd.

Organisation

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Organisation

TrakCel's cell orchestration platform (COP) is a unique software solution that facilitates efficiency in cell and gene therapy development by providing a platform by which program-critical information can be collated, tracked, and documented. Our COP software is a simple and efficient way of providing users with real-time information relating to every step of the cell and gene therapy process, from treatment development, manufacturing, to final delivery. This needle-to-needle approach enables faster decision making and process optimisation, and can provide personnel within the chain with actionable data – sending real-time updates to stakeholders.

Marketplace Opportunities

SERVICE

Supply Orchestration Software

TrakCel specialises in providing software which facilitates the comprehensive management of cell therapy products and their associated complex supply cycle. The software platform is configured to match cell therapy developers own processes to manage and document chain of custody and chain of identity information in a regulatory compliant record.

Implementation of the software platform enables TrakCel's customers and partners to create electronic forms, labels, implement user-specific workflows and record critical data at each step of the therapy supply process, including activities at starting material collection centres which may not be collocated with the therapy's manufacturing facility. TrakCel also generates compliant electronic records which detail all the activities and chain of custody information for each patient's treatment. This electronic record can be used as an alternative to paper-based recording and documenting of a therapy's supply cycle and can be used for regulatory inspections and/or filings.

Using an electronic system to manage chain of custody and chain allows its customers to scale out manufacturing by providing a software system that facilitates an increase in the number of global clinical and manufacturing sites, without compromising quality or patient safety.

Videregen Limited

Organisation

Country	United Kingdom
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Person

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Organisation

Videregen is a clinical-stage regenerative medicine company using its proprietary stem cell-based technology platform to develop a range of personalised, non-immunogenic organ replacement products for orphan indications. Its lead programme is a tissue engineered trachea replacement, and its patented technology and know-how is also being applied to the development of other organ replacement products, including larynx, mucosal lining, small bowel and liver replacements. The platform technology, which uses decellularised organ scaffolds seeded with the patient's own cells to create new organs, has the potential to generate cost-effective and curative therapies for a range of devastating diseases.

Marketplace Opportunities

PROJECT COOPERATION

Clinical trial and technology collaboration

Our objectives are to explore partnerships, collaborations and licensing opportunities for our technology in Japan to facilitate future market access. In parallel to our UK and EU clinical trials, we would like to initiate a Japanese clinical trial, establish local manufacture and collaborate for the further development of the R&D pipeline. Consequently we are interested in partnering with Japanese regenerative medicine or pharma companies with expertise in the following areas;

Regulatory pathways in Japan

Clinical trials

Clinical trial for regulatory approval and market access in Japan

GMP manufacture partner

Manufacture capability to service clinical trial and commercial supplies

R&D pipeline development

Partners/ collaborators to accelerate pipeline development

Market access

PRODUCT

Tissue engineered organ replacements

Videregen is a leader in the development of autologous tissue engineered products. Our leading

programmes are focused on the development of orphan medicinal products for airway repair and replacement (trachea, mucosal lining and larynx replacement). Clinical proof of concept and initial safety in man for the trachea replacement product have already been demonstrated in compassionate use cases.

The company's platform tissue purification technologies produce acellular biological scaffolds without significantly changing the natural three dimensional architecture of the extracellular matrix (ECM). The resulting acellular regenerative matrix retains the key topographical signals within the architecture and as all of the immunogenic epitopes have been removed from the processed organ tissues, they can be implanted into any patient without immune rejection. Therefore, the Videregen organ scaffolds can be regarded as universal donors, which by the addition of autologous cells from the patient, become personalised organ replacements.

GMP manufacturing processes are in place for the trachea and larynx products and we have an established supply chain for the production of the leading products for clinical trials and for commercial supply which is readily transferrable to additional territories.

UK MHRA and Ethics approvals are in place and formal Phase I clinical trials on the trachea and larynx replacement products are scheduled to start in the UK in 2018 and transition into pivotal trials in multiple centres in Europe thereafter.

Both the trachea and larynx and other organ replacement products are regulated in the EU as Advanced Therapy Medicinal Products (ATMP) and the tracheal product has recently been granted orphan medicinal product designation in the EU.