

# Innovate UK

**Results of Competition: Cell Therapy Manufacturing**

**Competition Code: 1609\_CRD1\_HEAL\_CTM**

**Total available funding is up to £11m from Innovate UK**

**Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.**

<b>Participant organisation names</b>	<b>Project title</b>	<b>Proposed project costs</b>	<b>Proposed project grant</b>
Cell Medica Ltd Cell Therapy Catapult Limited	Project SILKIN	£2,499,591	£1,999,652
<b>Project description - provided by applicants</b>			
Cell Medica develops novel cellular immunotherapy products for treating cancer. These therapies rely on harnessing the human immune system to treat cancer and represent a significant advance over traditional chemotherapy because the immune cells are activated to attack the malignant cells and not the healthy cells of the body. This project is a collaboration between Cell Medica, a company founded in the UK in 2007, and the Cell and Gene Therapy Catapult (CGTC). It will support increased knowledge about the functionality of these products and how to manufacture them at an acceptable cost to ensure widespread availability within the UK healthcare system. The teams will also work on ways to measure how the cells act to kill cancer cells which will then inform us how to manufacture these products for maximal patient specific benefit. We will be working closely with regulatory bodies to understand requirements to supply multiple different products in parallel from the same facility, thereby reducing further reducing costs. The experience with this project will allow the training of two 'Qualified Persons' who will become experts in the approval of products for use in humans.			

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<b>Cellular Therapeutics Limited</b> Asymptote Ltd	genTIL: Generation of a commercially viable Tumour Infiltrating Lymphocyte (TIL) therapy	£1,271,423	£889,996
<b>Project description - provided by applicants</b>			
<p>Cancer specific Adoptive T-Cell therapy (ACT) is a form of personalised medicine that harnesses the power of the patient's immune system to direct tumour-specific T-cells to kill cancer cells. The field of adoptive T-cell therapy has approached a point where the pre-clinical promise is now a clinical reality. Since the first report of use of TIL therapy in 1988, it has gone through several generations of improvement with trials using "Young TILs" unselected T cells and patient preconditioning producing excellent response rates – around 40% to 50% long term responses and around 10-20% cures. The vast potential of this field of cell therapy has been acknowledged by major pharmaceutical companies who are sponsoring multi-centre clinical trials (e.g. Novartis - CTL019, Adaptimmune/GSK - NY-ESO-1 SPEAR™). There is a market need for a robust reproducible, logistically scalable commercial process suitable for industrialisation of TIL Therapy. However, the wide-spread application of this form of cell therapy on an industrial scale is currently severely limited by the complexity associated with delivering a personalised cancer therapy. This project plans to address the major hurdles in making TIL therapy commercially viable: (i) point of collection and (ii) stabilisation of cellular material and final product.</p>			

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ReNeuron Limited Cell Therapy Catapult Limited	Cell2Sell: commercial scale next generation platform for allogeneic stem cell production	£2,266,825	£1,766,825
<b>Project description - provided by applicants</b>			
<p>This project will develop a next generation industrialised cGMP platform for the production of ReNeuron's allogeneic stem cell products which target significant, growing areas of unmet clinical need. The recent Advanced Therapy Medicinal Products Taskforce of the Medicines Manufacturing Industrial Partnership has identified that the ATMP industry is at a critical stage with the focus now on manufacturing industrialisation in order to commercialise these therapies further strengthening the UK's position as a global hub for researching, developing, manufacturing and adopting regenerative medicine. Developing the UK as a major progressive global hub for the ATMP sector will leverage further investments. This project involves organisations in Great Britain and will result in an at scale, validatable, cGMP manufacturing process for clinical and commercial supply. It will create and secure jobs in the UK, accelerate the development of skills and capabilities for individuals and organisations. ReN's products are currently in clinical trials in Stroke, Critical Limb Ischemia and Retinitis Pigmentosa, and therefore have the potential to significantly improve quality of life for large numbers of patients in areas of unmet clinical need, reducing the costs of social care therefore saving money in the economy.</p>			

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<b>Autolus Ltd</b> University College London Cell Therapy Catapult Limited	Design, Transfer and Qualification of a Commercially-Scalable Manufacturing Process for CAR-T cells	£2,457,822	£1,961,446
<b>Project description - provided by applicants</b>			
<p>Chimeric Antigen Receptor therapies (CAR-T), represent an entirely new, potentially transformative approach to treating cancer. They combine the precision of a monoclonal antibody with the potency and persistence of the human immune system. Researchers in the USA have recently reported clinical data using CAR-T in blood cancers which are causing great excitement within the medical community. High response rates are being achieved even in those patients who have proved refractory to previous treatments. Autolus, a UK spin-out company from UCL, has proprietary technology which could broaden the application of CAR-T therapies beyond liquid cancers and into common, solid tumour types. However, CAR-T products are complex, personalised advanced therapy medicines (ATMPs) and consequently require a correspondingly complex manufacturing process. For these pioneering therapies to become viable, accessible medicines; there will need to be innovation in the manufacturing technology. The project will combine leading UK expertise to develop and demonstrate a scalable, commercially-viable manufacturing process for CAR-T therapies.</p>			

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<b>NightstaRx Limited</b> Cobra Biologics Ltd	Establishing Commercial AAV Manufacturing in the UK	£2,499,465	£1,499,679
<b>Project description - provided by applicants</b>			
NightstaRx (NSR) is a biotechnology company whose mission is to restore and maintain sight by developing novel gene therapies to treat rare, degenerative diseases causing blindness. NSR are applying for this grant, in conjunction with a partner, Cobra Biologics (CB), to expedite the development of a treatment for an inherited blindness disease called Retinitis Pigmentosa. CB are a company who have the scientific expertise and accredited laboratories to help NSR complete the development of a state of the art manufacturing process to make this treatment. The result of this project will mean NSR will be able to treat patients to help improve their quality of life and keep their independence. Establishment of this type of manufacturing process would not only make manufacturing of other similar products easier, but also put CB (& the UK) in a position to be a first in class global manufacturer of viral gene therapies for late stage clinical & commercial supply. In turn it would also increase the skilled workforce and create jobs. All of these benefits will result in each company increasing their revenues, which will contribute to making the UK economy stronger.			

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