Technology Strategy Board Driving Innovation

Results of competition: Biomedical Catalyst - Early and late stage awards - Round 4

Total available funding for this competition was £20m from the Medical Research Council and the Technology Strategy Board.

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

Participant organisation names	Project title	Proposed project costs	Proposed project grant
Autifony Therapeutics Limited (lead) Hearing Biomedical Research Uni University of Nottingham	Clinical proof of concept trial of a Kv3 modulator for the treatment of tinnitus	£3,263,195	£2,183,417

Project description - provided by applicants

Tinnitus is a chronic, under-recognised condition that affects over 10% of adults, causing significant suffering. There are no approved drugs and current treatments, such as counselling, only help patients to cope with symptoms.

This project will provide clinical proof-of-concept evaluation of the efficacy of a novel ion channel drug in patients with tinnitus. AUT00063, currently completing Phase I trials, is being developed by Autifony Therapeutics for the treatment of age-related hearing loss; however, there is a strong scientific rationale to suggest potential for the drug to help control tinnitus.

Autifony will work in collaboration with leading tinnitus expert, Prof Deborah Hall, Director and Research lead for Tinnitus aetiology and management at the National Institute for Health Research, Nottingham Hearing Biomedical Research Unit, University of Nottingham, on this clinical trial as a major step towards potentially the first effective oral drug to treat tinnitus.

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Calcivis Limited	Clinical evaluation of advanced prototype medical device for dental caries assessment	£495,000	£297,000

Project description - provided by applicants

This project will design, develop, produce and clinically evaluate an advanced prototype of the Calcivis dental caries (decay) activity assessment system. There is a significant unmet need in dentistry to differentiate early dental lesions that are actively demineralising from those which are less likely to progress to cavitation.

Calcivis is unique and innovative because it deploys a photoprotein which produces light in the presence of the calcium ions being released from an actively demineralising tooth surface. In combination with a customised intra-oral camera it produces a demineralisation map of the tooth surface.

To date, a basic prototype of the camera has been used to demonstrate proof of concept in extracted teeth but this project takes a significant step forward as it enables an advanced prototype reflecting detailed input from dentists to be refined, produced and evaluated in the clinic.

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Levicept Limited	p75NTR-Fc: a novel and safe biological for the treatment of chronic pain	£11,855,208	£2,400,000

Project description - provided by applicants

With more than 1 billion people worldwide living with some type of chronic pain, a large unmet medical need for safe and effective analgesics exists. Traditional non-steroidal anti-inflammatory drugs (NSAIDs) are the most widely used drugs to treat pain and inflammation associated with osteoarthritis, but their use is limited by adverse effects on gastrointestinal and platelet function, as well as increased cardiovascular liability.

Levicept Ltd is an UK based biotechnology company developing a novel, safe and efficacious biological therapy (p75NTR-Fc) for the treatment of chronic pain: including osteoarthritis and neuropathic pain. Our plans are to develop p75NTR-Fc and test its efficacy and safety in Phase I clinical trials in OA patients.

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MGB Biopharma Limited	Phase I study to assess tolerability, safety and PK of MGB-BP-3 in healthy volunteers	£2,197,449	£1,319,669

Project description - provided by applicants

MGB Biopharma is developing a new class of antibiotic originally discovered in the UK by researchers at the University of Strathclyde. The drug, MGB-BP-3, has a novel mechanism of action which means that resistant bacteria will not be a feature as is the case with existing antibiotics.

The first indication to be developed is the treatment of Clostridium difficile infections and the Technology Strategy Board has provided grant funding to complete the human safety study. This drug, and potentially others from the same platform, shows promise for further development for the treatment of other infections, including MRSA and other serious life threatening infections against which existing drugs are becoming less effective due to the increase in resistant bacteria.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Nanoco Technologies Limited (lead) University College London	Cadmium-free quantum dots for cancer diagnostics using fluorescence imaging	£878,325	£673,062

Project description - provided by applicants

Quantum dots (QDs) are fluorescent nanoparticles with unique optical properties which have stimulated wide interest in their use for biomedical diagnostic applications.

In this project we will investigate QDs for cancer diagnostics using fluorescence imaging. Sentinel Lymph Node (SLN) mapping is a key technique in cancer therapy (e.g. breast), since identification of potentially malignant lymph nodes followed by surgical excision leads to better treatment with fewer side effects and improved survival. However current SLN mapping techniques using blue dyes and radioactive colloids have several disadvantages. Fluorescence imaging offers improved non-invasive detection capability for SLN mapping.

Nanoco has unique patented technology to synthesize cadmium-free fluorescent QDs with low toxicity in large quantities. This project aims to develop functionalised QD reagents with red/NIR fluorescence for SLN mapping and cancer diagnostics using clinically relevant experiments at UCL.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Oxford Biomedica (UK) Ltd	Clinical Development of OXB-102	£3,688,702	£2,213,221

Project description - provided by applicants

Parkinson's disease is caused by the degeneration of nerve cells in part of the brain; leading to the loss of dopamine, a chemical messenger which plays a vital role in coordinating body movement. In early stages of PD, oral levadopa (L-DOPA) medication is effective in managing the symptoms that include tremor, muscle stiffness and slow physical movement. However, the body progressively loses its ability to convert L-DOPA to dopamine thereby reducing its effectiveness and leading to the development of uncontrolled motor function.

Oxford BioMedica has developed a 'once-only' gene therapy approach to treat individuals with PD called OXB-102 that is administered once to the target region in the brain where it converts cells into a replacement dopamine factory. In essence, OXB-102 replaces a patient's own lost source of the neurotransmitter analogous to the natural dopamine supply in the absence of PD.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
OxSonics Limited	Enhancement and Mapping of Oncological Drug Delivery by Ultrasound	£3,540,472	£2,124,283

Project description - provided by applicants

The Technology Strategy Board's Biomedical Catalyst Fund will be instrumental in enabling OxSonics Limited to develop a prototype of its first product, "SonoTran", a low-cost therapeutic ultrasound device and associated consumables for the non-invasive targeted and enhanced delivery of cancer drugs to solid tumours.

SonoTran has the capability to overcome the greatest challenge facing solid tumour drug delivery: poor penetration of even the smartest drugs deep into solid tumours. A key feature of OxSonics core technology is the ability to map and intra-operatively monitor treatment in real-time and in 3D – a feature that has the potential to transform healthcare practice.

The platform technology can also be applied to a range of surgical applications including the repair of intervertebral discs for the treatment of chronic low back pain. Technology Strategy Board funding will initially enable the creation of 4 new UK jobs, rising to 24 new UK jobs by 2019.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Phico Therapeutics Limited	Development of a novel antibacterial agent against Pseudomonas aeruginosa	£1,608,346	£965,008

Project description - provided by applicants

Phico is developing a novel antibacterial technology called SASPject that can be targeted to selected harmful bacteria. SASPject is not affected by antibiotic resistance mechanisms and works by disabling bacterial DNA in a way that bacteria cannot avoid.

This project will enable Phico to complete the pre-clinical development of SASPject PT3 targeted to Pseudomonas aeruginosa (Pa). Intrinsically resistant to many antibiotics, Pa caused ~40M days of hospital therapy in 2010 due to a wide range of infections.

In this 18 month project Phico will extend efficacy data to determine the best dosing strategy in humans. Phico will also develop a manufacturing process to 15L and then transfer the process to a contract manufacturer who will scale up to a 50L GMP-ready process and produce material for a safety study. A lyophilisation process will also be developed. The safety study conducted during this project will provide sufficient data to support a clinical trial application, making SASPject PT3 ready to test in a Phase I trial.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Xention Limited	Development of a novel IKACh inhibitor for the treatment of atrial fibrillation	£2,428,166	£1,456,900

Project description - provided by applicants

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia encountered in clinical practice with around 14 million sufferers worldwide. Patients with AF have a 5-fold increased risk for stroke; indeed, in the US approximately 15-25% of all strokes can be directly attributed to AF.

The prevalence of AF is predicted to increase by 2- to 3-fold by 2050. Cost of care accounts for ~2.4% of the NHS budget and thus represents a significant burden on healthcare providers. The treatment of AF is, however, controversial and often problematic.

Antiarrhythmic drugs are used to convert the atrial arrhythmia back to a normal sinus rhythm and maintain it. However, these drugs are associated with significant and potentially lethal side-effects. There is a substantial unmet need for new safe and effective drug therapies for AF.

This programme sets out to develop an orally available drug for the safe and effective treatment of AF; with a substantially improved safety profile compared to current therapies.

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Ziarco Pharma Limited	PoC clinical study of ZPL-3893787 on pruritus and inflammation in atopic dermatitis	£2,835,878	£1,701,527

Project description - provided by applicants

Ziarco Pharma Limited, of Canterbury, Kent is developing ZPL-3893787, a novel oral treatment for the itch and inflammation associated with chronic pruritus (CP) - defined as an undesirable condition that stimulates scratching, persisting for at least 6 weeks.

It affects all ages, from young infants through to the elderly. CP can result in disturbed/lack of sleep, mood changes and a general increase in other illnesses for sufferers.

ZPL-3893787 has been studied in over 50 healthy adult volunteers so far in two different countries. Financial help from the UK Government's Technology Strategy Board will allow Ziarco to test ZPL-3893787 for relieving itch and inflammation in atopic dermatitis (eczema) patients.

Itch and inflammation are present in many diseases, and if proved successful, ZPL-389 may have the chance to treat millions of patients worldwide, from the young through to the elderly.

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