The ATMP-PIT Portfolio

An ATMP collaborative project initiated in Wallonia

ADVANCING TOGETHER
Towards next-generation therapies

Introduction

The expertise and excellence of the Belgian biotech valley in research, development, industrialisation, and commercial manufacturing of pharma products have been **internationally recognised for 50 years.** Consolidating this leading position in Europe requires strategic efforts, adequate means, and collaborative decision-making. As part of an initiative launched by the Walloon government in April 2023, BioWin - The Health Cluster of Wallonia and the SPW Economy, Employment, Research (SPW-EER) were invited to collaborate on the development of a large-scale project to strengthen the value chain of the biotech sector in Wallonia and stimulate regional economic redeployment.

This project, hereafter referred to as **ATMP-PIT** (ATMP-Partenariat d'Innovation Technologique), targets **advanced therapy medicinal products (ATMPs)** as an innovative therapeutic area with high economic and societal potential for the region. ATMP-PIT builds on an ambitious national action plan and an exhaustive national mapping of the different players involved in the field which was initiated by BioWin in 2022 (the "ATMP Hub" roadmap).

The BioWin competitiveness cluster gathered members of the Walloon ATMP ecosystem to assemble **diverse stakeholders** central to the ATMP-PIT project. This project will involve a close collaboration and connectivity (expertise, infrastructures, funding) within a partnership of **26 actors** (21 companies, 1 accredited research centre, and several research units and hospitals affiliated to 4 universities from the Wallonia-Brussels Federation).

The ATMP-PIT project has been designed with the intention of **consolidating the consortium of stakeholders active along the whole ATMP value chain within an innovative portfolio of collaborative work packages.** The present portfolio is built on **12 work packages** (evaluated by BioWin and the SPW-EER) subdivided into **3 pillars,** each dedicated to one category of next generation therapy (gene therapy, cell therapy, and novel therapeutic approaches based on exosomes and bacteriophages).

Over the 3 years of the project, the BioWin competitiveness cluster will act as the general coordinator of the ATMP-PIT project.

Advancing Together Towards Next-Generation Therapies

The Advanced Therapy Medicinal Products (ATMP) industry represents a promising sector with the potential to generate significant economic and societal impacts in the future. In alignment with this vision, BioWin is dedicated to consolidate the whole value chain through collaborative innovation between the players of this diversified ATMP ecosystem, with the end goal to make the most promising medicines and treatments widely available and affordable to patients in need as soon as possible.

This portfolio is part of the "Advancing Together" campaign launched by BioWin.

White paper

Want to know more about the ATMP landscape in Wallonia?
Scan now.

Infographic

Scan the QR code
to view the infographic on ATMPs.

WORK PACKAGE 1: CARACT'EXO

Company | Quality Assistance
Coordinator | Arnaud Delobel, *R&D and Innovation Director* | arnaud.delobel@quality-assistance.be | quality-assistance.com
Partner | Novadip
Areas of activity | Exosome manufacturing and characterisation for regenerative medicine

Project description

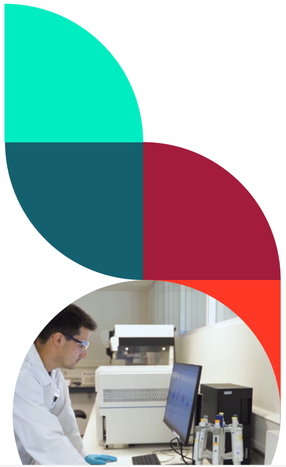
This research project is centred on enhancing the medical application of exosomes, tiny cell-produced vesicles that are crucial for cell communication and carrying various biological materials, with potential for targeted therapy and disease diagnostics. The project's main goal is to develop innovative methods for the accurate analysis and characterisation of exosomes, addressing the current limitations in assessing their quality for clinical use.

The collaboration between Quality Assistance and NOVADIP, utilising NOVADIP's 3M³ technology, is a key aspect of this project. This partnership aims to leverage NOVADIP's expertise in regenerative medicine and tissue regeneration, using their advanced technology platform to produce and analyse high-quality exosomes. This initiative is expected to lead to significant improvements in the production and therapeutic application of exosomes, enhancing their effectiveness in medical treatments.

In terms of impact, the successful development of these methods could revolutionise patient care by offering more effective, targeted treatment options. Economically, it positions both companies at the forefront of biotechnological innovation, potentially influencing the broader medical and biotech industries.

"At Quality Assistance, we recognise Belgium's vibrant ATMP ecosystem, driven by innovative academic and biotech R&D collaborations. In Wallonia, BioWin's role is pivotal, enhancing ATMP research and commercialisation through strategic support, funding facilitation, and fostering key partnerships in health sector."

- Arnaud Delobel, *R&D and Innovation Director,* Quality Assistance



WORK PACKAGE 2: EXOFASTTRACK

Companies | EXO Biologics & Xomexbio
Coordinator 1 | Hugues Wallemacq, *CEO* | h.wallemacq@exobio.be | exobio.be
Coordinator 2 | Frédéric Tonglet, *CEO* | frederik.tonglet@xomexbio.com | conveyxo.com/xomexbio
Partners | Orgenesis, LiveDrop, genflowbiosciences, CILYX, convExYO, ULB, UMONS
Areas of activity | Exosome manufacturing and loading, and analytical methods and quality controls

Project description

EXOFASTTRACK is a collaborative project focused on accelerating the development of multiple therapeutic exosomes for a rapid clinical evaluation. To this end, the consortium brings together the specific expertise of 9 partners.

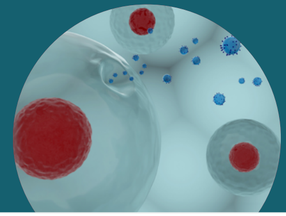
Mainly isolated from stem cells known for their regenerative and anti-inflammatory properties, exosomes are considered to be the next generation of cell therapy and ATMPs. The main function of exosomes is to act as intercellular messengers. Therapeutic exosomes are based on very large-scale reproduction (several billion copies) of an intercellular message specific to the producing cells (e.g. stem cells) in the lab. In addition, it is possible to modify the "therapeutic message" by loading a therapeutic agent specific to the targeted disease ("loading"), substantially enhancing their field of application.

The consortium aims to encourage the development of innovative therapies for indications for which there is no curative treatment. By developing innovative technological processes enabling large-scale production and loading of exosomes, the production costs per dose for the patient will be proportionately reduced, as will the impact on social security budgets. This will promote accessibility and availability to a wider public at an affordable price. The pooling of resources and access to technological platforms will reduce investment costs for each of the therapeutic partners and enable them to focus on preclinical activities to accelerate the start of a clinical phase.

The development of new automated technologies for both the production and loading of exosomes is based on a 'low footprint' approach, with the aim of significantly reducing the surface area required to implement these processes, as well as cutting energy consumption and reducing the impact in terms of greenhouse gas emissions.

"BioWin's support was pivotal in the creation of this unique consortium bringing together the main Walloon players in the field of exosome production, loading and therapeutic use, and promoting a collaborative approach pooling technological resources with a view to accelerating clinical development."

- Hugues Wallemacq, *CEO,* EXO Biologics



WORK PACKAGE 3: FunDrop

Company | Celyntra Therapeutics (working as Cellistic)
Coordinator | Elena Matsa, *Senior Vice President, Cell Therapy Research* | elena.matsa@cellistic.com | cellistic.com
Partner | LiveDrop
Areas of activity | iPSC-based allogeneic cell therapy and single cell characterisation assays

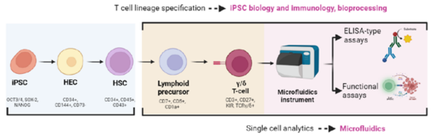
Project description

The main objective of the FunDrop project is to establish reproducible and scalable technologies for iPSC-based manufacturing and functional characterisation of T-cells by leveraging picodroplet encapsulation technologies. The project will be based on a collaboration between Celyntra Therapeutics (working as Cellistic), a cell therapy CDMO service provider with unique expertise in iPSC biology, immunology, and bioprocess development, and LiveDrop, a pioneer in microfluidics technologies with added value through its technical background in droplet microfluidics, optics, software, instrument development, and droplet bioassays for functional screening.

The FunDrop project aims to generate state-of-the-art and unique processes for T-cell manufacturing and single-cell characterisation. The collaboration is expected to create new positions, grow existing teams, and ultimately improve patient outcomes by increasing accessibility to cell therapy as first line of treatment for tumours. It is also expected to strengthen the Walloon ATMP value chain, positioning the region as a key player in global biotech and pharmaceutical sectors.

"In Wallonia and Belgium, the ATMP ecosystem thrives as demonstrated by the plethora of projects and partners involved in the ATMP-PIT calls. This is a testament to innovation, collaboration, and the pursuit of breakthroughs that is ongoing in the region and will help redefine the future of advanced therapies."

- Elena Matsa, *Cell Therapy Research,* Celyntra Therapeutics (working as Cellistic)



WORK PACKAGE 4: Guide-Pro

Company | Kaneka Eurogentec S.A.
Coordinator | Gottfried Proess, *Chief Technology Officer (CTO)* | g.proess@eurogentec.com | eurogentec.com
Partner | Quality Assistance
Areas of activity | Production methodology for guide RNAs suitable for use in human therapeutic gene editing

Project description

A recently Nobel-prize winning technology, CRISPR, is making its way into the clinic, offering promise in enhancing the health and life expectancy of people affected by diseases that lack any existing treatment. The technique is also called molecular scissor, as it allows for cutting/correcting a diseased gene at a very precise position. For this application to work, a so-called guide RNA is needed to bring the scissor to the desired position in the gene. This guide RNA is designed specifically for each application/position in a gene to be cut or corrected. Once designed, it has to be produced with exactly the required sequence and with sufficient purity to avoid unwanted cuts somewhere else in the genes. It also needs to be stabilised to avoid a quick degradation in body fluids. The project addresses the challenges related to the chemical production of gram quantities of these guide RNAs, their purification and quality control in order to reach a product quality suitable for human application. In fact, the synthesis of guide RNA represents about 400 chemical reactions versus roughly 80 for more standard RNA medicines. The length of these molecules as well as their structural characteristics makes the purification also very difficult and heavily complicates the quality control methods to ensure suitability for human use. The final goal of the work package is therefore to develop a robust and scalable production methodology for guide RNAs suitable for use in human therapeutic applications.

The necessary quality control (QC) methods for ensuring purity, safety and necessary characterisation will be developed by our partner Quality Assistance, a leading Contract Research Organisation (CRO) providing the pharmaceutical industry with all the analytical services required by EMA and FDA regulations for the development and marketing of innovative human medicinal products.

WORK PACKAGE 5: MacroTwin

Company | Celyntra Therapeutics (working as Cellistic)
Coordinator | Elena Matsa, *Senior Vice President, Cell Therapy Research* | elena.matsa@cellistic.com | cellistic.com
Partners | Pharmalex, UCLouvain
Areas of activity | Manufacturing platform and digital twin for iPSC-based allogeneic cell therapy

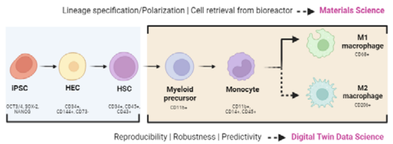
Project description

The main objective of the MacroTwin project is to establish a scaled iPSC-macrophage manufacturing platform and create a digital twin thereof for use in allogeneic cell therapy product development and manufacturing. The project will be based on a collaboration between Celyntra Therapeutics (working as Cellistic), a cell therapy Contract Development Manufacturing Organisation (CDMO) service provider with unique expertise in iPSC biology, immunology, and bioprocess development, Pharmalex, a leader in statistics, data science and analytics services for biopharmaceutical and medical product development, and the Institute of Condensed Matter and Nanosciences of UCLouvain which will introduce expertise on biomaterials necessary for bioprocess development.

The MacroTwin project aims to simplify cell therapy development pipelines through technologies such as data analytics, machine learning, and artificial intelligence to construct a digital twin, thus enhancing efficiency and productivity in biopharmaceutical manufacturing and contributing to the broader digitalisation of the industry. The collaboration is expected to create new positions, grow existing teams, and ultimately improve patient outcomes, lower cell therapy healthcare costs and strengthen the ATMP value chain in Wallonia and Belgium, positioning the region as a key player in biotech and pharmaceutical sectors globally.

"BioWin has been powering innovation in the ATMP field through enabling seamless collaboration between partners and addressing questions or concerns in a timely manner during the application process, thus facilitating success in obtaining government funding through these groundbreaking initiatives."

- Elena Matsa, *Cell Therapy Research,* Celyntra Therapeutics (working as Cellistic)



WORK PACKAGE 6: MAIDAM

Company | DNAlytics
Coordinator | Thibault Helleputte, *Founder and CEO* | thibault.helleputte@dnalytics.com | dnalytics.com
Partners | Orgenesis, UCLouvain
Areas of activity | Monitoring of decentralised ATMP manufacturing with AI

Project description

The production of ATMPs is destined to be decentralised, i.e. via multiple local production units, rather than centralised, as is the case for most traditional treatments, in order to meet a number of challenges, such as personalisation, accessibility, cost reduction and rationalisation of transport. However, this decentralised production brings with it a number of challenges. Data consolidation is difficult and sometimes impossible, if local production units are operated by different companies. Monitoring production is also more complex, because each production site generates fewer batches (statistical difficulties). A larger number of installations makes fault detection and maintenance more complex. Regular improvements to production processes are also made more difficult. The aim of the project is to respond to these challenges by developing innovative digital tools that will enable decentralised ATMP suppliers to be more competitive by exploiting as much data as possible from local production units in order to bring added value to the users of these production units, while preserving the required confidentiality.

Orgenesis Services will generate and make production data on different equipment available.. The company will take the opportunity provided by the project to integrate an OMPUL at Marche-en-Famenne. In particular, the data will illustrate autologous cell therapies. The data produced on different equipment will feed different databases, which will then be used by UCLouvain and DNAlytics to develop collaborative AI models based on federated learning to be able to use all the units' data securely and reinforcement learning to optimise the operation of each unit. These innovations will then be integrated into DNAlytics' Hercule software suite which is already in place in a number of biotech companies, but has so far been used for centralised production processes.

"The MAIDAM project will enable the Walloon Region to remain at the forefront of innovation in ATMP manufacturing, including its digital aspect. It brings together Orgenesis, a company active in the decentralised manufacture of cell therapies, TRAIL (UCLouvain) at the cutting edge of AI, and DNAlytics, a company that makes it possible to digitalise biomanufacturing processes and integrate AI into them. This project was set up with the support of BioWin."

- Thibault Helleputte, *Founder and CEO,* DNAlytics

WORK PACKAGE 7: MITOSIR

Company | Revatis
Coordinator | Justine Ceusters, *CSO/COO* | justine.ceusters@revatis.com | revatis.com
Partners | Genflow Biosciences, ULiège, ULB
Areas of activity | Modified mdMSCs to treat sarcopenia in elderly human

Project description

Sarcopenia is a geriatric syndrome that causes a decline in muscle mass. Living with sarcopenia significantly affects quality of life and frequently leads to falls and fractures, but especially affects mobility. This loss of mobility leads to an increased risk of metabolic, cardiovascular and cancer pathologies. With the ageing of the population, sarcopenia has become a major public health problem. It is estimated that between a quarter and a half of the population aged 65 or over currently suffer from it. In 2019, the cost of hospitalisation alone for patients in this age bracket was over $19 billion, not to mention the cost of associated treatments, which are currently only palliative, as no targeted treatment for this pathology is currently available.

In partnership with ULiège, Revatis has demonstrated that it is possible to obtain muscle-derived stem cells (mdMSCs), in quality and quantity, from elderly human and equine individuals. Revatis has already obtained mdMSCs from horses with pathological conditions similar to human sarcopenia. Moreover, these mdMSCs can be easily transfected, secrete large quantities of extracellular vesicles and are capable of transferring mitochondria.

Genflow Biosciences is interested in age-related diseases, and in particular in a variant of the gene encoding sirtuin 6 (SIRT6c), identified only in a population of centenarians. This SIRT6 gene is involved in regulating mitochondrial function, a function impaired in sarcopenia.

The idea was therefore to combine these data to develop an innovative drug therapy using modified mdMCSs expressing the SIRT6c variant to improve the function of deficient muscle cells. Cells will be transfected with the gene encoding SIRT6c, potentially in combination with other sirtuin family genes. This drug will target mitochondrial dysfunction, which plays a major role in the pathophysiology of sarcopenia.

"We're particularly delighted to have the opportunity to benefit from this initiative of the Walloon Region, highlighting the importance of the ecosystem that has formed around the innovative technologies associated with ATMP products. As the Health Cluster of Wallonia, BioWin has once again demonstrated its responsiveness in helping and supporting companies wishing to be part of this ambitious project. We are very proud to be part of this initiative."

- Justine Ceusters, *CSO/COO,* Revatis

WORK PACKAGE 8: PDC*neo+

Company | PDC*Line Pharma
Coordinator | Laurent Levy, *Co-founder & COO/CFO* | l.levy@pdc-line-pharma.com | pdc-line-pharma.com
Partners | OncoDNA, salamanderU, UCLouvain, ULB
Areas of activity | Personalised cancer immunotherapy targeting individual neoantigens and molecular diagnostic based on circulating tumour DNA

Project description

The PDC*neo+ project aims to develop PDC*neo+, a personalised therapeutic vaccine for colorectal cancer (CRC), using PDC*LINE PHARMA's innovative PDC*line technology. Targeting unique neoantigens in each CRC patient, PDC*neo+ represents a groundbreaking approach in cancer immunotherapy.

CRC is among the most prevalent and deadly cancers globally, with a high recurrence rate post-surgery and chemotherapy. PDC*neo+ is designed as an adjuvant treatment to prevent relapses in high-risk patients with stages II, III, and certain stage IV CRC. This aligns with chemotherapy, potentially making it a pioneering treatment in CRC.

This project is a collaborative effort involving several key partners. OncoDNA contributes with its expertise in personalised medicine, focusing on neoantigen identification and circulating tumour DNA analysis. salamanderU is developing a compact isolator for decentralised vaccine production. Academic centers UCLouvain – IREC/MIRO and ULB-BCTL offer vital support in translational research and clinical trial execution.

The main goal is to confirm the clinical feasibility and safety of PDC*neo+ in a Phase I trial. This initiative is expected to have a significant impact on CRC patient care, alongside broader economic and societal benefits. The project is estimated to create or maintain around 34 full-time jobs across all partners.

"Wallonia benefits from an ATMP ecosystem with high potential thanks to its dense network of biotechnology players, big pharma company headquarters, international CDMOs, and other partners providing valuable tools and competencies required to be competitive in the field. This success can be explained by the availability of private and government grants/ funding for R&D ATMP projects, and by the precious support that the BioWin competitiveness cluster provides to the regional consortium of partners for growth and financing, communication, and talent development."

- Laurent Levy, *Co-founder & COO/CFO,* PDC*Line Pharma

WORK PACKAGE 9: SOLIT

Company | Novadip
Coordinator | Hara Episkopou, *Head of Discovery* | hara.episkopou@novadip.com | novadip.com
Partner | CER Groupe
Areas of activity | Allogenic therapeutics targeting solid tumours

Project description

Cancer is a critical public health concern and the world's leading cause of death, with annual rates significantly increasing. The most common cancer treatments are surgery, chemotherapy, radiation, and immunotherapy, but they cause adverse effects, drug resistance, and long-term consequences.

Based on the knowledge of its 3-dimensional tissue-engineered platform (derived from adipose stem cells) for local tissue healing in the regenerative medicine field, Novadip demonstrated the key role of the extracellular matrix to improve the capacity of adipose stem cells to secrete highly specific growth factors and miRNA involved in the control of the cellular proliferation and differentiation.

Although this approach was firstly applied in the field of regenerative medicine for bone reconstruction with an autologous tissue-engineered product (for large defect reconstruction to avoid amputation), and an allogenic cell-derived matrix (to improve the capacity of bone healing in a large population of patients with co-morbidities), strong scientific evidence showed that the 3-dimensional platform could propose a new alternative in the oncology field.

In this context, the aim of SOLIT project is the development of a flexible technology "Matrisome" platform to generate unique, allogeneic, and "ready to use" therapeutics which will target solid tumours through the local delivery of highly specific biomolecules with tumour suppressive properties. This project will consolidate the business models of the CER and Novadip through the development of (i) a complete platform of preclinical testing and (ii) a commercial, large-scale adipose stem cell manufacturing for allogenic cell-derived Matrisome products as a new therapeutic class of anti-cancer drugs for the IT delivery.

"Within the vibrant ATMP ecosystem of Wallonia and Belgium, BioWin stands as a catalyst, providing unwavering support and fostering innovation to promote the full development of promising therapeutic candidates that would give rise to innovative therapies for a healthier future."

- Hara Episkopou, *Head of Discovery,* Novadip

WORK PACKAGE 10: UROPHAGE

Companies | Vesale Bioscience
Coordinator | Johan Quintens, *CSO* | johan.quintens@phage.health | phage.health
Partners | OncoDNA, UCLouvain
Areas of activity | Personalised phage therapy against chronic urinary tract infections

Project description

The ambition of this work package is to give a proof of concept for the treatment of complicated Urinary Tract Infections (cUTI) due to *Escherichia coli (E.coli)* and *Klebsiella pneumoniae (K.pneumoniae)* with a personalised phage therapy model.

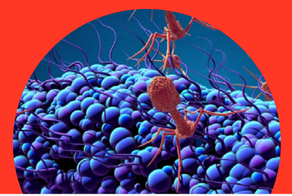
UTIs (Urinary Tract Infections) are the most frequent infections seen on consultations. They are mainly caused by bacilli bacteria (amongst whom *E.coli* and *K. pneumoniae*). UTIs become long-term, or chronic, when bacteria in the urine embed themselves into the lining of the bladder wall where antibiotics and immune cells cannot easily reach them.

They can cause constant inflammation in the bladder, but they do not always show in current urine tests. Over time, changes to the tissue in the bladder wall and the appearance of biofilms make the infection even harder to treat since they became hidden for antibiotics and immune cells. Phages are particularly well equipped to penetrate through biofilms by removing the physical barrier of phage access to bacterial cells, but this activity varies from one phage to another. This project will build from the foundation provided by the successful "Inteliphages" project utilising the characterised phages and bacterial collections to jumpstart the current project. It will also continue to build on the experience obtained with the phagogram, as an automated susceptibility test for phage activity, in the projects "Phagediag" and the EIC Accelerator.

This project will be run together with the Laboratory of Food and Environmental Microbiology (MIAE) of UCLouvain in Wavre, which has the necessary expertise as one of the leading phage laboratories in Wallonia.

"BioWin has a long history in supporting the development of the personalised phage therapy model of Vesale Bioscience. Starting with the "Inteliphage" project, where the foundations of the personalised phage therapy model were tested for the first time and later the "Vetphage" project, BioWin is an important partner for Vesale Bioscience. With the Urophage project BioWin continues this engagement to support Vesale Bioscience in this important indication of complex UTIs. "

- **Johan Quintens**, *CSO,* Vesale Bioscience



WORK PACKAGE 11: GTRP_DIAT

Company | UCB
Coordinator | Jiri Keirsse, *Head of Innovation Strategy and Public Private Partnerships* | Jiri.Keirsse@ucb.com | ucb.com
Partner | ThermoFisher Scientific
Areas of activity | Development of analytical technologies in gene therapy research

Project description

The goal of this gene therapy research partnership is to discover and apply innovative analytical technologies to advance the characterisation of recombinant adeno-associated viral vectors (rAAVs), the safest and most effective vehicles for delivering genes into cells and driving their long-term expression. Investigation of the vectors' quality and efficacy is critical to treating genetic diseases affecting millions of people worldwide: we need to progress our fundamental understanding of the impact of complex vector structures on its properties, to establish label-free non-invasive analytical approaches to determine bio- and virological activity of the vectors, to invent novel methods to reveal their structural complexity, genome integrity and impurity, and finally to understand the impact of impurities on the final drug structure and its function.

ThermoFisher Scientific (represented by Henogen S.R.L.) and UCB have the ambition to discover novel analytical technologies to address these challenges and to translate rAAV-based gene therapy research into safe and effective therapeutic solutions for millions of patients worldwide. In addition, a digital data platform, supported by statistical and advanced data analytics, will be put in place to discover the link between pre-clinical and clinical outcomes and drug quality attributes, with that feedback loop enabling more informed decision-making and overall higher success rates for future projects.

The project will further strengthen the ATMP ecosystem in Wallonia by deepening the knowledge and expertise of the region's scientific talent and reinforce Wallonia's and Belgium's position as the 'Health and Biotech Valley of Tomorrow'.

"Driven by the ambition to improve patient lives through ground-breaking solutions, UCB applauds the strategic foresight and dedication to the biopharma and life sciences exhibited at both the Belgium federal and Walloon regional levels. For ATMP specifically, the Walloon Region with the support of BioWin is actively strengthening and promoting the local ecosystem through relevant and focused incentives impacting different stakeholders across the value chain and driving transversal collaboration."

- Jiri Keirsse, *Head of Innovation Strategy and Public Private Partnerships,* UCB

WORK PACKAGE 12: Hybrid-Tx

Company | Univercells
Coordinator | José Castillo, *Quantoom CEO and Univercells co-founder* | j.castillo@univercells.com | univercells.com
Partners | CER Groupe, ULiège
Areas of activity | Vaccination development; Cancer treatment solution

Project description

Development of a hybrid approach comprising a recombinant viral vector (Newcastle Disease Vector, NDV) and an mRNA vector for the development of a) a vaccination solution and b) a personalised cancer treatment solution. In the context of a regional ATMP Hub based in Belgium (Jumet), Univercells' objective would be to offer the fastest, safest, and most cost-effective solutions across the entire value chain for the manufacture of new hybrid approaches to vaccination and new anti-cancer therapies, from discovery through to clinical and commercial phases.

This project proposes an innovative approach to achieving this, combining cutting-edge innovation, first published preclinical and clinical proofs of concept, and a vision of manufacturing from the smallest to the largest scale, meeting the needs of personalised medicine for high-precision cancer treatment, and mass production of prophylactic vaccines.

Univercells aims to develop two hybrid approaches.

1. A hybrid therapy for the treatment of cancer, combining a bulk-produced Newcastle vector (the same vector for all patients, specific to the type of cancer) and an mRNA encoding a series of neoantigens, designed specifically for each patient and manufactured in very small, milligram quantities. The aim of the approach is to combine an oncolytic effect, destroying cancer cells, and to engage the patient's immune system by administering the personalised mRNA vaccine.

2. A hybrid approach for prophylactic vaccination, combining a Newcastle vector to be produced in large quantities (specific to the type of viral infection) and an mRNA coding for the antigen specific to said viral infection, and produced in large quantities, on the order of kilograms. The aim of the approach is to capitalise on an effect recently demonstrated with COVID, showing, in the case of an adenovirus, that the RNA-virus vector combination results in better protection than the conventional approach. Given the characteristics of the Newcastle vector, which allows intranasal administration in the form of a live vector, there is a high probability that this synergy will be even greater.

Rooted in Wallonia, Belgium, our dynamic ATMP ecosystem is a beacon of innovation and collaboration. With steadfast support from BioWin, we lead the way in pioneering breakthroughs, turning visionary ideas into advanced therapies that reshape the landscape of healthcare for the future.

- José Castillo, *Quantoom CEO and Univercells co-founder*

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ATMP-PIT (*Partenariat d'Innovation Technologique*) is a collaborative project specific to the field of Advanced Therapy Medicinal Products, initiated and funded by the Walloon Government in collaboration with BioWin and the SPW-EER (*Service Public de Wallonie Économie, Emploi, Recherche*). The project brings together 26 different partners.

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