

Mallinckrodt Announces 2022 Advancing Extracorporeal Photopheresis Immunomodulation Investigator Award

-- Winning project hopes to unlock invaluable insights on how ECP could improve quality of life and clinical outcomes in chronic lung allograft dysfunction --

DUBLIN, Nov. 16, 2022 -- Mallinckrodt plc (NYSE American: MNK), a global specialty pharmaceutical company, today announced the recipient of 2022's Advancing Extracorporeal Photopheresis (ECP) Immunomodulation Investigator Award. Andrew Fisher, the project's principal investigator won this year's award for a project to help address significant unmet medical need by evaluating responses to extracorporeal photopheresis therapy (ECP) in chronic lung allograft dysfunction (CLAD).

The study hopes to identify potential novel biomarkers that could guide a precision-medicine approach to ECP treatment, and help people avoid the disability and mortality associated with CLAD – a devastating complication that affects more than half of lung transplant recipients within five years.

Lung transplantation is the only treatment offering a meaningful improvement in survival and quality of life to selected patients with life-threatening chronic lung disease. However, long-term survival is significantly poorer than that in other organ transplants, mainly due to the development of progressive immune mediated damage to the lung allograft.

More than 50%¹ of lung transplant recipients will develop CLAD within five years. This can progress rapidly, leading to lung function decline, respiratory failure, and death. As such, there is an urgent need to identify new treatments that can arrest the alloimmune mechanisms that drive CLAD as early as possible, preserving longevity and quality of life while also reducing the risk of repeat lung transplantation.

“There is an urgent need for treatments to stop CLAD early to protect lung function, help preserve quality of life, and hopefully prolong survival in lung transplant patients,” said the award-winning project's principal investigator, Andrew Fisher, Professor of Respiratory Transplant Medicine at Newcastle University, and Honorary Consultant Respiratory and Transplant Physician at The Newcastle upon Tyne Hospitals NHS Foundation Trust's Institute of Transplantation.

The E-CLAD UK study is a clinical trial funded by the National Institute for Health and Social Care Research (NIHR) Efficacy and Mechanism Evaluation (EME) program. It is aimed at assessing if the addition of ECP to current treatment is more effective at stabilizing the function of transplanted lungs compared to standard treatments for CLAD.

The Mallinckrodt 2022 Investigator Award winning project, 'Predicting Response to ECP in the Treatment of CLAD after Lung Transplantation', is an in-depth mechanistic evaluation of participants' immune responses. It is hoped it will address a currently unmet clinical need and provide powerful insights into how ECP treatment is working at immunological level.

Professor Fisher was presented with the €50,000 prize at a Therakos Institute-supported Workshop on Solid Organ Transplantation and Extracorporeal Photopheresis in Monte Carlo, in September.



The award, now in its fifth year, is part of Mallinckrodt's ongoing commitment to the science of immunomodulation through ECP across therapeutic applications. It was designed to recognize individuals and institutions whose innovative research contributes to the advancement of knowledge in this broad area of medicine.

Entries were invited from clinicians and scientists working on translational or outcomes-based research, as well as collaborative projects. Submissions were assessed on a range of criteria, including scientific merit, originality, and feasibility.

"Every year, the investigator award showcases the huge array of cutting-edge, innovative, and ambitious research being conducted in the use of ECP across a broad spectrum of disease settings – and 2022 was no exception," said Steven Romano, M.D., Executive Vice President and Chief Scientific Officer of Mallinckrodt. "As a pioneer in ECP immunomodulation, Mallinckrodt is proud to support those who continue to investigate this exciting field of medicine. Congratulations to Professor Fisher and his team on winning this extremely competitive award. We're looking forward to seeing the results in the fullness of time."

The 2023 Advancing ECP Immunomodulation Investigator Award will be open for entries during the first quarter of 2023

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ABOUT THERAKOS

Mallinckrodt's Therakos therapeutic platforms, including the latest generation THERAKOS™ CELLEX™ Photopheresis System, are used by academic medical centres, hospitals, and treatment centres in more than 30 countries and have delivered more than 1 million treatments globally. For more information, please visit www.therakos.eu.

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Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The Company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

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¹ Verleden G, Verleden S, Vos R. Freedom from chronic lung allograft dysfunction (CLAD) or CLAD-free survival: What's in a name? *J Heart Lung Transplant* 2019;38:1-2. [doi: 10.1016/j.healun.2018.11.005](https://doi.org/10.1016/j.healun.2018.11.005).

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