New Consortium aims to Standardize and Accelerate Development of Advanced Therapy Medicinal Products in €25.5 million project

*The Accelerating Research and Innovation for Advanced Therapies (ARDAT) consortium, **led by Pfizer and the University of Sheffield, UK** and supported by Europe's Innovative Medicines Initiative (IMI), aims to help standardize and accelerate development of Advanced Therapy Medicinal Products (ATMPs), allowing potentially transformative treatments to reach patients sooner*

The consortium brings together the leading expertise of 34 academic, nonprofit and private organizations

BRUSSELS, November 23, 2020 – Accelerating Research and Innovation for Advanced Therapies (ARDAT), a new, five-year European consortium supported by the Innovative Medicines Initiative (IMI), today announces its launch. The precompetitive consortium brings together the leading expertise of 34 academic, nonprofit and private organizations, led by Pfizer (ARDAT Project Lead: Dr Gregory LaRosa) and the University Of Sheffield (ARDAT Coordinator: Professor Mimoun Azzouz), and experts from across Europe and the US with the shared goal of helping to standardize and accelerate development of Advanced Therapy Medicinal Products (ATMPs) and potentially helping to bring these transformative treatments to patients sooner.

The field of ATMP research, which includes gene and cell therapies, is expected to grow exponentially in the coming years, with potentially up to 10-20 new drug applications submitted per year to the FDA by 2025. The ARDAT consortium will aim to bring together researchers from public and private organizations to help fill the knowledge gaps in how these therapies could potentially work, and to develop appropriate standards to aid researchers, developers and regulators in accelerating effective and safe gene and cell therapies to benefit patients.

"While still an emerging field, ATMP research has largely been fragmented and siloed within organizations with little opportunity to share best practices and information," said Dr Greg LaRosa, Head of Scientific Research, Rare Disease Research Unit, Pfizer. "As Gene and Cell therapies research grows and more potential ATMPs move into later-stage clinical trials, it is in the interest of the industry and of patients to further our collective understanding of their mechanisms by sharing data and regulatory expertise."

The consortium aims to develop standardized models for predicting ATMP immunogenicity in humans; build understanding of ATMP drug metabolism within a host; identify adaptive immune responses that could affect ATMP safety, efficacy and persistence; and engage regulators to help support filings that address standardized regulatory, safety and efficacy concerns.

“We are very excited to bring together world leading experts to accelerate delivery of advanced therapies to patients suffering from rare diseases”, said Professor Mimoun Azzouz, Chair of Translational Neuroscience, Director of Research and Innovation at the University of Sheffield’s Institute of Translational Neuroscience (SITraN) and ARDAT Coordinator. “This is a significant development expected to change the landscape of research, innovation and regulatory activities for cell and gene therapies”

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About ARDAT

The ARDAT project is a precompetitive €25.5M, 5 year consortium that brings together the leading expertise of 34 academic, nonprofit, and private organizations, with the shared goal of helping to standardize and accelerate development of Advanced Therapy Medicinal Products (ATMPs) and potentially helping to bring these transformative treatments to patients sooner.

For more information on ARDAT, visit www.ardat.org

About the IMI

The IMI is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of patients, industrial and academic experts in order to boost pharmaceutical innovation in Europe. IMI is a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

For further details please visit: http://imi.europa.eu/

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