



Media Statement

Innovative Medicines Initiative launches translational safety biomarker pipeline project to enable development and implementation of novel safety biomarkers

Mönchengladbach, April 15, 2019 - The Innovative Medicines Initiative (IMI) today announced the launch of the Translational Safety Biomarker Pipeline (TransBioLine) Project, a five-year program to generate exploratory and confirmatory data supporting regulatory qualification and acceptance of novel safety biomarkers for five target organ systems, i.e. kidney, liver, pancreas, vascular, and central nervous system, for application in drug development.

The TransBioLine Project is a consortium of 27 partners including pharmaceutical companies like Pfizer, Merck Sharp & Dohme, Eli Lilly, Novartis, Roche, Janssen and Sanofi, as well as small and medium-sized enterprises, and academic institutions from 10 European countries. It is coordinated by the University of Zurich with Pfizer as the industry lead. TransBioLine is funded by the IMI Joint Undertaking as a public-private partnership, with a budget of 28M€ and will be active through 2024.

“One of the major gaps in drug development is the lack of qualified safety biomarkers with acceptable precision and accuracy for safety monitoring during clinical development,” says Shashi Ramaiah, Executive Director, Pfizer Drug Safety Research & Development and TransBioLine Lead Scientist. “MLM Medical Labs will be one of three laboratories, among Signatope from Reutlingen, Germany and TaMiRna from Vienna, Austria, which will analyze various novel safety markers from samples collected by the consortium and thereby hopefully validating them for future application in drug development. I am very proud that we can leverage our broad portfolio of validated assays and our expertise in clinical trials for this exciting project.” states Stephan Wnendt, CEO of MLM Medical Labs.

Michael Merz, Consortium Coordinator, University of Zurich, adds, “This is one of the largest public-private partnerships of European and American scientists that focuses on the development and regulatory qualification of new safety biomarkers. These new markers are ultimately expected to not only improve safety of new and approved drugs, but also to contribute to better diagnosis and management of acute and chronic diseases.”

When the project ends in 2024, the consortium will have established an infrastructure and processes to continue biomarker research across a comprehensive network of industry, academic institutions, and small and medium-sized enterprises. TransBioLine will be able to provide the scientific community, industry and regulators with detailed data and information about a large spectrum of novel safety markers.

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About the Innovative Medicines Initiative

The Innovative Medicines Initiative is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). It is working to improve health by speeding up the development of the next generation of medicines, particularly in areas where there is an unmet medical or social need.

More info on IMI: www.imi.europa.eu

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About MLM Medical Labs GmbH

MLM Medical Labs is an internationally active, GLP-certified, and CLIA-, CAP- and DIN EN ISO15189-accredited central laboratory dedicated exclusively to clinical trials. Over 75 employees support between 140 and 150 Phase I–IV clinical studies at any given time. MLM's global customer base includes renowned pharmaceutical companies, CROs and biotech companies .

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