



Launch of DIRECT An Innovative Medicines Initiative Project for Personalized Medicine in Diabetes

Academia and the pharmaceutical industry working together in the
fight against diabetes

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DIRECT (“Diabetes REsearchCh for patient strATification”), a consortium funded by the Innovative Medicines Initiative (IMI), announced today the launch of a 45 million Euro project focusing on a stratification of patients with diabetes. Scientists and clinicians working in academia have joined forces with the pharmaceutical industry to tackle the current bottlenecks in diabetes drug development and to develop a personalized medicines approach to treatment of ‘type 2 diabetes’ (T2D) with either existing or novel therapies.

Leading European experts from 21 academic institutions and four pharmaceutical research organizations officially launched the DIRECT project on February 1st. The project is supported by the Innovative Medicines Initiative (IMI), a unique Public Private Partnership (PPP) between European Union and the pharmaceutical industry (represented by the European Federation of Pharmaceutical Industries and Associations / EFPIA). The EU contributes to this PPP a total of one billion Euro over ten years, which is matched in-kind by the EFPIA member companies.

Type 2 diabetes is a pandemic disease which currently affects 285 million people worldwide and which is anticipated to affect 439 million people worldwide by 2030. Whilst Type 2 diabetes is usually assumed to be one condition, the DIRECT consortium believes that it can be stratified into different subtypes that may progress differently or be treated differently to other subtypes. The aim of the consortium is the discovery, development and application of biomarkers, or tests, that predict who gets diabetes, whose diabetes deteriorates rapidly after diagnosis and who responds well or poorly to diabetes therapy. This will result in the development of new drugs and the better targeting of existing drugs in order to improve outcomes of patients with diabetes.

DIRECT is a unique collaboration of leading European academic groups and pharmaceutical companies in the diabetes field in Europe. Around 150 researchers operating in nine different scientific work packages will collect phenotypic and genomic data from pre-diabetic and diabetic patients, diabetic patients treated with anti-diabetic drugs and by bariatric surgery. More than 100.000 samples of well-characterized T2D patients will be provided by the consortium partners to apply novel methods in systems biology and pathway analysis with the goal of identifying biomarkers that predict the incidence of diabetes, the rapid deterioration of glycaemia or the response/non-response to therapy. The identified biomarker candidates will then be validated in prospective clinical trials for later use as new diagnostics or prognostics as well as in the development of novel therapeutics.

“It has been fascinating to see how quickly a strong consortium has been formed, building bridges between the very different worlds of academic and the pharmaceutical industry research organizations,” said Hartmut Ruetten from Sanofi. Ewan Pearson from University of Dundee and Veikko Koivisto from Eli Lilly, the coordinators of DIRECT, agree: “There is no doubt that strong collaboration between diabetes clinicians and scientists in academia, and the experts in biomarker and drug discovery, and drug trials, in the pharmaceutical industry will result in improvements in patient care, and that’s what DIRECT is all about – better, personalized treatment for patients with diabetes.”

About DIRECT:

The DIRECT team, coordinated by Sanofi, Eli Lilly and the University of Dundee is working on the identification and validation of biomarkers to improve treatment of Type 2 Diabetes with either existing or novel therapies.

The seven year scientific program will deliver:

- Prospective studies, and large scale retrospective data analysis, to define and intensively study groups of people with different rates of deterioration of glycaemia (both pre-diabetes and with diabetes) and different response to diabetes therapies
- A high quality European database to store relevant genomic and phenotypic data sets.
- A Systems Biology Platform: Integrating clinical data, biological data, genomics, metabolomics, proteomic and other relevant data.
- Application and development of novel data mining tools and algorithms to generate stratification and response biomarker candidates (i) describing patients at risk of diabetes and at risk for disease progression, (ii) to derive a personalized treatment strategy and (iii) potentially identify new drug development targets.

- Development of biomarker assays: “Industrialized” confirmation and qualification of new or already known biomarkers for personalized therapy in well defined sub-populations.
- Validation of biomarker candidates in prospective clinical trials.

DIRECT participants are *Sanofi-Aventis Deutschland GmbH, University of Dundee, University of Bath, Consiglio Nazionale delle Ricerche, Technical University of Denmark, Eberhard Karls Universitaet Tuebingen, Helmholtz Zentrum München – Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH, Consorci Institut D'Investigacions Biomediques August Pi i Sunyer, Imperial College London, Kungliga Tekniska Högskolan, University of Lille-CNRS, Leiden University Medical Center, University of Copenhagen, University of Eastern Finland, Lunds Universitet, University of Newcastle upon Tyne, University of Exeter, Université de Genève, University of Oxford, Universitaet Ulm, Vereniging voor christelijk hoger onderwijs, wetenschappelijk onderzoek en patiëntenzorg, Novo Nordisk A/S, Eli Lilly and Company Ltd, Laboratoires Servier, Centre Hospitalier Regional et Universitaire de Lille.*

The close collaboration of academic teams and pharmaceutical companies is providing unique levels of expertise and is forming a strong basis to reach the DIRECT project goals.

For further details – please visit: <http://www.direct-diabetes.org>

About IMI:

The Innovative Medicines Initiative is a unique Public Private Partnership (PPP) between the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Union represented by the European Commission. IMI's overall goal is to make Europe again the world leader in pharmaceutical research for the benefit of the economy and society, by removing research bottlenecks in the current drug development process.

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



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