

## **"Innovative Medicines Initiative" (IMI): €246 million to support public-private research cooperation for a fast development of better medicines**

*Today, 15 new research projects aimed at bringing innovative medicines more quickly to the market have been selected to receive €246 million from the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The projects will foster understanding of health issues such as diabetes, pain, severe asthma and psychiatric disorders while increasing drug safety. They will also help improve the training of researchers and clinicians involved in medicines development. The projects were chosen following the first call for proposals launched within the Innovative Medicines Initiative (IMI), a public-private partnership – so called Joint Technology Initiative- between the European Commission and the pharmaceutical industry. With this selection, IMI has reached a key milestone. This initiative marks the first time that pharmaceutical competitors are pooling their resources, together with research organisations, patient groups and other stakeholders in large consortia, in order to develop generic, pre-competitive knowledge. The Commission's contribution of €110 million is backed up with €136 million provided in-kind from the pharmaceutical industry. The successful projects will now enter into the final negotiation phase.*

"I'm happy to see that this unique public-private partnership is bearing fruit. Our objective is for Europe to become a champion's league for biopharmaceutical research. In times of crisis, such a model of cooperation is proving well suited to answering both EU competitiveness objectives and public health needs", said Janez Potočnik, the EU Commissioner for Science and Research.

Arthur Higgins, CEO of Bayer Healthcare and president of the EFPIA, stated, "I am delighted to see that this pioneering model of collaboration between industry and the Commission has been taken up so positively all across Europe. The IMI will set new standards in data sharing and knowledge exchange."

### **Better medicines reaching patients faster**

The projects selected will address the main causes of delay, or "bottlenecks", in the pharmaceutical research and development (R&D) process. The overall objective is to encourage the more rapid discovery and development of better medicines for patients while improving the competitiveness of the European pharmaceutical industry. The projects will help to increase predicted safety and efficacy of medicines, enhance data exchange between researchers and improve education and training in the sector.

### **The selection process: a substantial interest from stakeholders**

Around 150 applications were received. The best consortia, consisting of research organisations, Small and Medium Enterprises (SMEs), academia, patient organisations, and regulatory bodies, were selected in the first peer review to form joint project teams with the corresponding EFPIA consortia. On the basis of stringent scientific criteria and their potential impact on the identified "bottlenecks", 15 projects from these teams have been selected.

### **European funding to boost the R&D capabilities of the public sector and SMEs**

Pharmaceutical companies within EFPIA will fully fund their own participation by providing R&D resources including staff, laboratory facilities, materials and clinical research. European Community's funds will be allocated exclusively to other participants (public sector, SMEs, patient groups, academics).

### **Further steps**

Contract negotiations for the 15 projects should be finished by November 2009. A second Call for Proposals is to be launched in autumn 2009. It is planned to seek proposals for projects in oncology, diagnosis of infectious diseases, chronic inflammatory diseases and knowledge management.

### **Background**

Launched in 2007, the Innovative Medicines Initiative was one of the first Joint Technology Initiatives (JTI) to be created. The total IMI budget for the period 2008-2013 is €2 billion (1 billion from the European Community and 1 billion from the industry).

Created in 2007, the Innovative Medicines Initiative Joint Undertaking (IMI JU), representing both the European Community and the industry, implements IMI and is responsible for the launch of Calls for Proposals and the award of grants.

To find out more about IMI: <http://imi.europa.eu> and <http://www.imi-europe.org> and also [IP/08/662](#)

To find out more about Joint Technology Initiatives: <http://cordis.europa.eu/fp7/jtis/>

See the list of the 15 research projects as well as the name of 5 joint technology initiatives in the annex attached.

### **Full list of selected projects with their expected outcome**

#### 1. Non-genotoxic carcinogenesis

Expected outcome: proven reliable role of early biomarkers in the prediction of cancer development.

#### 2. Expert systems for in silico toxicity prediction

Expected outcome: in silico prediction and expert systems for secondary pharmacology prediction and for pure chemistry-related toxicity.

#### 3. Qualification of translational safety biomarkers

Expected outcome: new specific and sensitive safety biomarkers and their respective assays for human sample for improved predictivity between non-clinical and early clinical studies.

#### 4. Strengthening the monitoring of the benefit/risk of medicines

Expected outcome: new methodologies in pharmacovigilance and pharmacoepidemiology

#### 5. Islet cell research

Expected outcome: better understanding of  $\beta$ -cell proliferation, differentiation and apoptosis permitting the identification of approaches to preserve  $\beta$  cell function aiding the development of preventive and curative treatments for diabetes types 1 and 2.

#### 6. Surrogate markers for vascular endpoints

Expected outcome: biomarkers/surrogate endpoints for micro- and macrovascular hard endpoints in diabetes clinical research and new in vitro or in silico tools to test novel therapies.

#### 7. Pain research

Expected outcome: improved understanding of the pathways and mechanisms mediating different kinds of pain, and markers for patient stratification and quantitative pain assessment for efficient testing of new analgesics.

#### 8. New tools for the development of novel therapies in psychiatric disorders

Expected outcome: blood/CSF markers, imaging and/or electrophysiological measures suitable for clinical assessments to be used for preclinical models with sensitive pharmacodynamic markers that are closely linked with psychiatric disorders

#### 9. Neurodegenerative disorders

Expected outcome: translatable animal and human volunteer models for better prediction of clinical efficacy of new therapies in patients with Alzheimer's disease, Parkinson's disease and multiple sclerosis.

#### 10. Understanding severe asthma

Expected outcome: a large longitudinal patient cohort enabling validation of novel biomarkers and development of diagnostic criteria for mechanistic and therapeutic trials.

#### 11. COPD patient recorded outcomes

Expected outcome: a framework for better understanding of patients' experience of chronic obstructive pulmonary disease (COPD) leading to better strategies for measuring clinical trials outcomes

#### 12. European Medicines Research Training Network

Expected outcome: a European biopharmaceutical research training platform providing a sustainable academia-industry cross-disciplinary approach to efficient organisation of training courses on emerging science and technologies across Europe.

#### 13. Safety sciences for medicines training programme

Expected outcome: training programme integrating all safety-relevant disciplines linking animal and human/patient safety data thereby facilitating a more holistic evaluation of new medicines

#### 14. Pharmaceutical medicine training programme

Expected outcome: establish a network of academic centres that delivers postgraduate training programmes in pharmaceutical medicine including quality management of the processes and outcomes.

#### 15. Pharmacovigilance training programme

Expected outcome: customised training programmes for professionals in pharmacovigilance from industry and regulatory agencies to support proactive pharmacovigilance and risk management of medicines.

### **On Joint Technology Initiatives**

JTI's are a major new element of the EU's 7<sup>th</sup> Research Framework Programme. They provide a way of creating new partnerships between publicly and privately-funded organisations involved in research, focussing on areas where research and technological development can contribute to European competitiveness and quality of life.

5 JTI's have been developed so far: Innovative Medicines Initiative (IMI), Embedded Computing Systems (ARTEMIS), Aeronautics and Air Transport (Clean Sky), Nanoelectronics Technologies 2020 (ENIAC), Hydrogen and Fuel Cells Initiative (FCH).