Public-private partnership tackles major challenges in the care of pain patients

June 04, 2018 – To improve the care of patients with acute or chronic pain, a consortium from academia, small and medium-sized enterprises (SMEs), pain societies, patient organizations and pharmaceutical industry launched the research project "IMI-PainCare – Improving the care of patients suffering from acute or chronic pain" on April 01, 2018. The consortium strives to develop a toolbox that can streamline the research and development process for novel analgesic drugs and improve treatment quality in clinical practice. The project comprises three sub-projects across all phases of the pharmaceutical value chain – from early research to clinical practice – addressing major challenges in the care of patients suffering from acute or chronic pain in a complementary manner. It is anticipated that tools will be validated that will allow patient stratification and enrichment as recommended by the recent EMA/CHMP/970057/2011 guideline on pain treatment.

IMI-PainCare is set within the framework of the Innovative Medicine Initiative (IMI), the largest public-private partnership for health research worldwide. The project is driven by a consortium of 40 partners from 14 countries, while the lead is shared by Rolf-Detlef Treede, University of Heidelberg, and Petra Bloms-Funke, Grünenthal. IMI-PainCare is supported by the IMI 2 Joint Undertaking with € 11.2 million provided by the European Union. The industrial partners will provide € 12.0 million through direct and in-kind contributions, e.g. employees working on the project in partnerships with the consortium. The project runs over four years and will end on March 31, 2022.

Pain management is essential for all medical conditions, as it is one of the major dimensions of Quality-of-life scores that patients report. Additionally, chronic pain may outlast the normal healing process (e.g. after surgery). It can be a symptom of a chronic disease (e.g. endometriosis, bladder pain syndrome, diabetic neuropathy) or may occur without any signs of an underlying disease. The treatment of both acute and chronic pain is often inadequate, which underlines the high need for innovative solutions to improve pain management. This is partly due to a poor translation of results from preclinical models into clinical trials, and partly due to a lack of sophistication in outcome reporting and accurate division of patients into subgroups in clinical trials.

"Acute and persistent pain of different origins represent a common medical, social, and economic burden, and improvement of its management is still a major challenge for all health care systems. I look forward to working towards innovative solutions to these unmet medical needs together with my partners of IMI-PainCare which represents an unprecedented close cooperation between academia, SMEs, patient organizations, pain societies and pharmaceutical companies," Rolf-Detlef Treede, University of Heidelberg, explained. "I am delighted that we were able to bring together the expertise of 40 partners to drive innovative solutions in pain management. The joint work of these best-in-class experts may enable us to provide pain patients with the appropriate prevention or treatment for their condition at the right time", Petra Bloms-Funke, Grünenthal, stated.

"Providing standardized consented patient-reported outcome measures" (PROMPT) is the first sub-project, led by Winfried Meissner, University of Jena, and Hiltrud Liedgens, Grünenthal. It is located in a key area of both clinical research and clinical practice and has the patient's perspective in its focus. "We aim to improve the management of pain by defining a consented set of patient-reported outcome measures which is suitable to assess acute and chronic pain in controlled trials as well as real world conditions. It would be beneficial for patients if success is documented routinely after pain treatment, and the tools we aim to identify can help with this", Winfried Meissner stated. "A defined set of patient-reported outcome measures in clinical trials of novel analgesics could become a discussion basis in our exchange with regulatory authorities, especially when defining claims in submission documents, and with Health Technology Assessment Agencies (HTAs) when we have to discuss relevant clinical benefits to gain reimbursement", Hiltrud Liedgens, Grünenthal, added.

"Functional pain biomarkers" (BioPain) – the second subproject – is led by Rolf-Detlef Treede, University of Heidelberg, and Keith Phillips, Eli Lilly and Company. It is located in the transition stage from pre-clinical to early clinical development and aims to establish pharmacokinetic / pharmacodynamic models in healthy humans and rodents. "Functional electrophysiological and imaging tests validated in experimental pain models could be a basis for the creation of purposeful clinical endpoints, also in patients", Rolf-Detlef Treede, University of Heidelberg explains. "If these clinical markers prove their reliability, we could aim to carry them into preclinical models as well. This could improve our candidate selection and may increase the chance of a successful translation from preclinical to clinical development", Keith Phillips, Eli Lilly and Company, added.

The subproject "Translational research in pelvic pain" (TRiPP) is led by Katy Vincent, University of Oxford, and Jens Nagel, Bayer. It has a special focus on pain related to endometriosis and interstitial cystitis / bladder pain syndrome and is located in clinical practice as well as the early stage of disease understanding to provide a robust pre-clinical environment for drug development. "We aim to determine subgroups within these diseases and identify biomarkers of these clinical phenotypes. Ultimately, we hope this strategy will move towards more personalised treatments for these distressing conditions", Katy Vincent stated. "It is of key importance to understand better the molecular pathways leading to inflammation and chronic pelvic pain both in endometriosis and bladder pain syndrome and to assure that these are reflected in pre-clinical models to improve their translational value for clinical research", Jens Nagel added.

About the Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) 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, and patient access to, the next generation of medicines, particularly in areas where there is an unmet medical or social need. It does this by facilitating collaboration between the key players involved in healthcare research, including universities, pharmaceutical companies, and other companies active in healthcare research, small and medium-sized enterprises (SMEs), patient organizations, and medicines regulators. This approach has proven highly successful, and IMI projects are delivering exciting results that are helping to advance the development of urgently-needed new treatments in diverse areas.

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

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Please visit our website for more information on the IMI-PainCare project

www.imi-paincare.eu

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