

Press release

Pan-European APPROACH project receives 15 million Euro research funding to find the right osteoarthritis medicine for the right patient

Brussels, Belgium and Eindhoven/Leiden, The Netherlands, September 16, 2015

In a bid to stimulate the development of much needed treatments for osteoarthritis, a consortium of 24 partners comprising pharmaceutical companies, biotech companies, academic institutions, notfor-profit organizations, small and medium enterprises (SMEs) and public bodies have joined forces in the pan-European APPROACH (Applied Public-Private Research enabling OsteoArthritis Clinical Headway) project, with total research funding of 15 million Euros. Of this amount, 7.5 million Euros will come from the European Innovative Medicines Initiative (IMI) and 7.5 million Euros in the form of 'in kind' contributions from participating members of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

It is estimated that worldwide around 9.6% of men and 18% of women over the age of 60 years experience the debilitating symptoms of osteoarthritis¹, yet drug development for the disease has so far been disappointing due, in part, to complexities around identifying the right patients to treat. The APPROACH consortium will combine biomedical data for >10,000 patients and controls from nine existing cohorts into a unified bioinformatics platform. It will use this platform to generate several well-defined targetable patient subsets based on existing and newly developed biomarkers. Validation and qualification of the diagnostic tools will be performed in a 500-patient longitudinal study. The results of this 5.5 year program will be used to support the selection of patient cohorts for new disease modifying osteoarthritis drug (DMOAD) clinical trials. Ultimately, the identification of patients who are most likely to respond to a given treatment, should lead to improved drug development and diagnostic / prognostic tools that allow osteoarthritis patients to receive highly personalized treatment.

GSK will be the coordinator of the consortium, the University Medical Center Utrecht (UMCU, The Netherlands) will be the co-coordinator, and CTMM-TI Pharma (a merger of the Dutch CTMM and TI Pharma Top Institutes) was chosen as the independent managing organization because of its unique experience in coordinating large-scale public-private partnership translational medical research in the Netherlands over the last nine years.

"In addition to a unique and comprehensive set of OA patient data, the APPROACH consortium brings together a diverse set of highly regarded experts in the field to develop, validate and link biomarkers with biological processes and clinical endpoints. Ultimately, this will increase efficiency in clinical trial design and interpretation leading to regulatory qualification and personalised medicines to treat this serious disease", said Dr. Jonathan Larkin, APPROACH Coordinator and Senior Scientific Investigator at GSK.

¹ Wolf AD, Pfleger B. Burden of Major Musculoskeletal Conditions. Policy and Practice. Special Theme-Bone and Joint Decade 2000-2010. Bulletin of the World Health Organization 2003, 81 (9): 646-656.



Harrie Weinans, professor of Tissue Biomechanics and Implants, at the Dutch University Medical Center Utrecht, and APPROACH Co-coordinator, says "this consortium blends clinical centre expertise on patient care and cohort studies and provides cutting edge imaging technology, biochemical assays, omics platforms and human motion analysis expertise. In addition, state-of-the-art facilities are available within our industrial partners and the clinical hospitals, including GLP certified labs, enabling a unique approach that allows us to make a big leap forward in this field".

Scientific Director of CTMM-TI Pharma, Professor Peter Luijten, said, "By bringing together European expertise in drug development, medical imaging and biomarker discovery, the APPROACH project will develop the companion diagnostics that will be needed for targeted osteoarthritis drugs to be used most effectively."

Note for the editors:

Project Partners:

The APPROACH program has a budget of 15 MEuro distributed across a total of 24 partners from the private and academic sectors:

GSK	United Kingdom
University Medical Centre Utrecht	The Netherlands
CTMM-TI Pharma	The Netherlands
Medical University of Vienna	Austria
Artialis SA	Belgium
Nordic Bioscience A/S	Denmark
Assistance Publique - Hôpitaux de Paris	France
Centre National de la Recherche Scientifique	France
Institut de Recherches Internationales Servier	France
Friedrich Alexander University Erlangen	Germany
Nuremberg	
Merck Serono	Germany
Universitaetsklinikum Erlangen	Germany
Diakonhjemmet Hospital AS	Norway
Servizo Galego de Saúde	Spain
Lund University	Sweden
Academisch Ziekenhuis Leiden h.o.d.n. Leids	The Netherlands
Universitair Medisch Centrum	
Dutch Arthritis Foundation	The Netherlands
Hemics B.V.	The Netherlands
Arthritis Research UK	United Kingdom
European Technology for Business Ltd	United Kingdom
Immunodiagnostic Systems Limited	United Kingdom
Newcastle University	United Kingdom
University of Leeds	United Kingdom
University of Surrey	United Kingdom



About GSK

One of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

For further information please visit www.gsk.com

About UMCU

University Medical Center Utrecht (UMC Utrecht) belongs to the largest public healthcare institutions in the Netherlands. It was created in 2000 through the merger of Utrecht Academic Hospital, Wilhelmina Children's Hospital and the Medical Faculty of Utrecht University. UMC Utrecht has the ambition to be a leading international healthcare provider, medical school and research institute that is exciting for its people, attractive to talent and embodies a culture of teamwork, innovation, sustainability and high performance. As a patient-centered organization, its 11,000 employees are dedicated to prevent disease, improve healthcare, develop new treatment methods and refine existing ones, with patient safety and quality as cornerstones. Strategic research programs are Brain, Child Health, Circulatory Health, Infection & Immunity, Personalized Cancer Care and Regenerative Medicine & Stem Cells. UMC Utrecht is embedded in a vibrant and entrepreneurial science community where knowledge about health, disease and healthcare is generated, validated, shared and applied.

For more information, visit www.umcutrecht.nl

About CTMM-TI Pharma

CTMM-TI Pharma is a Dutch not-for-profit organization that catalyzes the development of new medical solutions for patients by driving public-private collaboration between academia, industry and society. We focus on solutions that involve or combine medical technology and pharmacotherapy, and increase health, wealth and social responsibility. CTMM - TI Pharma will be named Lygature as of January 1st, 2016.

More information can be found at <u>www.ctmm.nl</u>, <u>www.tipharma.com</u>

About IMI

The Innovative Medicines Initiative (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 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.

More information can be found at www.imi.europe.eu



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Disclaimer

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