

NEW U.S.-IRELAND R&D PARTNERSHIP PROJECT TO RESEARCH CONTINUOUS MANUFACTURING FOR NANO-BASED PHARMACEUTICAL DRUGS

WASHINGTON, U.S., 16th March 2016: A tri-partite US-Ireland R&D partnership has been announced at an event hosted in Washington D.C. by Science Foundation Ireland to celebrate scientific collaboration between Ireland and the United States as part of the St Patrick's Day. The "Centre-to-Centre" collaboration project is titled 'Partnership in continuous manufacturing for nano-based drug products.'

This project links together three of the world's significant research centres in pharmaceutical manufacturing; The Science Foundation Ireland Research Centre, Synthesis and Solid State Pharmaceutical Centre (SSPC) located at University of Limerick, Ireland; The Center for Structured Organic Particulate Systems (C-SOPS) at Purdue University and Rutgers University, USA; and The Centre for Pharmaceutical Sciences (CPS) at Queens University Belfast, Northern Ireland. The alliance builds on the combination of expertise of these three centres: SSPC for upstream continuous processing for drug synthesis and crystallisation; CSOPS for continuous drug product manufacture; and MPRI for polymers for drug delivery.

The project will be funded by; Science Foundation Ireland in Ireland, the National Science Foundation (NSF) in the US; and the Department of Employment and Learning Northern Ireland (DEL/NI) in the UK.

Prof. Kieran Hodnett, SSPC Scientific Director said: *"At present the manufacture of nano-particles of medicines on a commercial scale remains a major challenge. The Irish American Partnership Programme offers an exciting opportunity to work towards the development of continuous manufacturing to address this challenge. The combined expertise of this collaboration should result in new solutions to increase operating efficiency in the manufacturing of new medicines."*

The overarching goal of this "Centre-to-Centre" collaboration is to establish and deliver new end-to-end continuous manufacturing capabilities for poorly soluble micron and Nano sized drugs. The objective of this project is to transform the global supply chain for medicines by developing techniques capable of making nano-particulate active pharmaceutical ingredients and retaining their desirable nano properties throughout the entire manufacturing process. This will increase the

number of available medicines, improve production efficiency and minimize the quantities of dangerous chemicals in production.

Professor Mark Ferguson, Director General, Science Foundation Ireland and Chief Scientific Adviser to the Government of Ireland, said: "I welcome the partnership between these three research Centres and encourage the growth and collaboration of scientific links between our countries. These partnerships are not only advancing scientific research but are also delivering important economic, societal and reputational benefits for Ireland."

Prof. Gavin Walker, Bernal Chair of Pharmaceutical Powder Engineering, University of Limerick said: *"The Centre-to-Centre research will be integral to the Bernal Project, a €52 million strategic investment focused on physical sciences and engineering at University of Limerick. The Centre-to-Centre project aims to catalyse research between SSPC and our partner institutions in the US and NI. Moreover, the research project is aligned to Science Foundation Ireland and SSPC goals of maximising impact and supporting Ireland's pharmaceutical manufacturing excellence."*

Prof. Gavin P. Andrews, Chair of Pharmaceutical Engineering at Queen's University, Belfast added: *"The Centre of Pharmaceutical Sciences at Queen's University Belfast has significant interest in emerging pharmaceutical technologies and are delighted to be an integral member of a large tripartite research consortium that brings together internationally leading research centres from across the US, Ireland and the UK. This unique collaboration has the potential to be evolutionary in its impact and represents a wonderful opportunity to develop novel and innovative continuous processes that ensure manufacturing keeps pace with rapid changes within the global pharmaceutical R&D environment."*

Continuous manufacturing is a major step towards improved process reliability, product quality and the reduction of development and manufacturing cost. Advances in manufacturing will help deliver higher quality and affordable medicines in both developed and developing nations.

Dr. Rohit Ramachandran, Assistant Professor, Dept. of Chemical & Biochemical Engineering, Rutgers University said: *"The Centre for Structured Organic Particulate Systems (C-SOPS) develops programmes that foster academic-industrial interactions. The newly formed Centre-to-Centre collaboration project will not only promote this but will also set the basis to aid better product consistency and process capabilities."*

The collaboration will promote inter-disciplinary research among research centres, bring together experts in process engineering, material science and pharmaceutical science and promote job creation in the Pharmaceutical sector in Ireland, USA, and NI. The young researchers involved will develop as global scientists and engineers with improved cultural awareness, technical, leadership and communications skills.

Zoltan Nagy, Professor of Chemical Engineering, Purdue University said: *“In an ever changing global pharmaceutical market, many conditions drive the need to introduce new processes on a regular basis. The promotion of inter-disciplinary research among centres across the globe, will help improve future process reliability and product quality.”*

Each researcher (graduate student or postdoctoral fellow) will spend three to six months at a partner international institution as part of the collaboration. Senior researchers (faculty) will undertake shorter visits, to present seminars and training courses. Where possible, the international experience will be linked to an industry placement.

-End-

For further media information contact

Synthesis and Solid State Pharmaceutical Centre

Louise O’Neill, Communications Officer

+353 (0)61 234675

louise.oneill@ul.ie

Science Foundation Ireland

Niamh Bradley or Alva O’Cleirigh

+353 1-6073228/+353 86-0271744 or +353 1 607 3249/+353 87-9152553

niamh.bradley@sfi.ie or alva.ocleirigh@sfi.ie

For Science Foundation Ireland

Sarah O’Connor or Jessica Devenney

+353 01 260 5000 / +353 87 222 5995 or +353 1 260 5000 / +353 86 077 8353

sarah.oconnor@drurypn.ie or jessica.devenney@drurypn.ie

Notes to the Editor:

About the Synthesis and Solid State Pharmaceutical Centre (SSPC)

The Synthesis and Solid State Pharmaceutical Centre (SSPC) is a Global Hub of Pharmaceutical Process Innovation and Advanced Manufacturing, funded by Science Foundation Ireland through its Research Centres programme and the Pharmaceutical industry. It is a unique collaboration between 22 industry partners, 9 research performing organisations and 12 international academic collaborators. The SSPC comprises over 150 active researchers and has funding of over 40 Million Euro for 6 years from mid-2013. This large research collaboration has particular skills in active pharmaceutical ingredient (API) synthesis, purification and crystallization.

The Centre for Structured Organic Particulate Systems (C-SOPS) is a major Engineering Research Centre sponsored by the US National Science Foundation. The centre consists of four university sites (Rutgers, Purdue, NJIT, UPRM) and has 40 industry partners. C-SOPS comprises over 80 active researchers and has had over USD30 million from the NSF (2006-2016) with additional substantial funding from industry member fees and sponsored projects. The core expertise of the centre is in continuous manufacture of oral solid dosage medicines via traditional and novel platforms.

The Drug Delivery and Material Science Group at The School of Pharmacy at Queen's University Belfast is part of the interdisciplinary Medical Polymers Research Institute (MPRI). MPRI is a partnership between the Drug Delivery and Biomaterials Research Group in the School of Pharmacy and the Polymer Processing Research Centre in the School of Mechanical and Aerospace Engineering. The group has extensive experience in the fundamental science, manufacture and characterisation of a wide range of drug delivery systems with EU and industrial funding support.

About Science Foundation Ireland

Science Foundation Ireland funds oriented basic and applied research in the areas of science, technology, engineering, and mathematics (STEM) which promotes and assists the development and competitiveness of industry, enterprise and employment in Ireland. The Foundation also promotes and supports the study of, education in and engagement with, STEM and promotes an awareness

and understanding of the value of STEM to society and in particular to the growth of the economy.

For more information, visit www.sfi.ie.