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DUBLIN, IRELAND, October 5th 2017 - The National Institute for Bioprocessing Research and Training (NIBRT) and Pfizer today announced a new collaboration focused on the development and application of advanced process and analytical methods for in-line monitoring and continuous characterisation of bio-pharmaceutical manufacturing processes. The collaboration, which is funded through Enterprise Ireland's Innovation Partnership scheme, aims to reduce the requirement for

offline analytical testing by integrating automated sampling and analytical characterisation using high resolution liquid chromatography mass spectrometry directly with the bioreactor systems. The system will generate both process and product quality data in near real time, to provide process and analytical scientists with key information to guide development of their bio-pharmaceutical processes.

Bio-pharmaceuticals are protein molecules produced by genetically engineered living cells using large scale industrial bioprocessing. Bio-pharmaceuticals are large complicated molecules which often exist in a distribution of forms resulting from varying degrees of processing and modification by the biosynthetic machinery within the cell. The distribution of these forms can be affected by the process conditions within the bioreactor. To ensure that bio-pharmaceuticals are produced to the highest possible quality, advanced analytical characterisation strategies are required.

Speaking on behalf of Pfizer, Brian Fitzpatrick, Senior Director, Bio Aseptic Sciences group explained, "Pfizer are excited to collaborate with Dr. Jonathan Bones, Dr. Colin Clarke and their teams at NIBRT to develop and apply more automated process and analytical characterisation platforms for the near real time analysis of bio-pharmaceuticals during the manufacturing process. The range of information we can get from such integrated systems will be a real step forward and can really help us to develop a much greater understanding of our manufacturing processes and their influence on the characteristics of our products."

Dr Jonathan Bones, Principal Investigator of the NIBRT Characterisation and Comparability Laboratory, said, "It is great to work with Pfizer on this exciting project. This collaboration allows us to bring our analytical and process technology platforms to the next stage. By combining these platforms with automation and data analytics, we can generate highly informative data that will assist the team in Pfizer in the development of new bioprocesses through advanced understanding of process behaviour in near real time."

Speaking at the launch of the collaboration, Mr. Dominic Carolan, NIBRT CEO, added, "We are delighted to be working with Pfizer on this exciting project, which blends Pfizer Pharmaceuticals Ireland expertise in the development, manufacture and delivery of bio-pharmaceuticals with NIBRT's excellence in analytical characterisation, automation and data analytics. Impactful collaborations, such as this interaction between Dr. Jonathan Bones and Dr. Colin Clarke of NIBRT and Pfizer are testament to Ireland's emergence as a global centre of excellence in all aspects of bio-pharmaceutical manufacture."

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About**NIBRT**

The National Institute for Bioprocessing Research and Training (NIBRT) is a global centre of excellence for training and research in biopharmaceutical manufacturing. NIBRT is located in a world class facility in Dublin, Ireland. NIBRT's mission is to support the growth and development of all aspects of the biopharmaceutical industry by becoming a global leader in biopharmaceutical manufacturing research, education and training. For further information, please visit www.nibr.ie.

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