Philadelphia, PA – 30 October, 2017 Leading outsourcing provider PCI Pharma Services is excited to announce further market leading investment in fully contained Xcelodose® 600S technology at its center of excellence for contained manufacturing, Tredegar, UK.

This investment delivers another important capability for the award-winning facility in the development and manufacturing of highly potent molecules. The pharmaceutical landscape continues to evolve with more and more products in development being deemed potent. As the biological activity and specificity of Active Pharmaceutical Ingredients (API) increases, dosage strengths are decreasing which has led to molecules becoming more potent in nature.

The pharmaceutical industry's on-going demand to shorten drug development times, saving both time and money, is driving technological advances. The traditional product development route of formulating a solid dosage form for Phase I studies typically involves a range of complex activities including analytical method development, prototype development, short-term stability, process/formulation refinement, validation and finally clinical manufacture.

Manufacturing drug in capsule (DIC) is a way to significantly reduce both the time and financial investment at the early stage of the drug development process, providing faster delivery for first-time-in-man. This approach minimizes the use of costly API, and reduces the amount of formulation and analytical development necessary to support an Investigation New Drug (IND) application or Investigational Medicinal Product Dossier (IMPD).

Xcelodose® technology delivers this drug in capsule process, removing the need for initial formulation/analytical development and the associated stability testing, enabling PCI to achieve faster times to first-in-man studies on behalf of its clients. In 2010 PCI invested in Xcelodose® 120S technology, a semi-automated system to provide early stage clinical supplies. This additional investment in fully automated Xcelodose® 600S technology delivers a programmable system providing exceptional levels of accuracy and precision.

This state-of-the-art technology has the capability to fill amounts as low as 100 micrograms at speeds of more than 600 capsules per hour. Waste of API is minimized and batch documentation allows traceability of individual capsules that meet GMP requirements. The Xcelodose® 600S technology is further enhanced by a PCI-designed, custom-built Xceloprotect™ containment system providing an early stage development solution for the

management of highly potent molecules. The high levels of containment provide Occupational Exposure Limits (OEL) as low as 0.1µg/m^3 over an eight-hour time weighted average, meeting Safebridge 3 and 4 categorization, preventing operator exposure and adhering to the very latest regulatory requirements.

PCI is a trusted partner for the management of clinical programs, from the initial early stage development and manufacturing using technologies such as Xcelodose®, through clinical trial supply services including packaging, labeling, storage and distribution. Most recently PCI launched its FastTrack™ service offering a demand-led approach to the delivery of secondary packaging, labeling, release and distribution of clinical supplies based on patient and site requirements. This service provides compliant clinical supplies for time-critical studies and, depending on availability of materials, delivers projects in less than ten working days.

Commenting on the new technology, David O'Connell, Director of Pharmaceutical Development at PCI said: "This is a very exciting time as we add this important technology to our capabilities. Being able to offer this service for early stage development programs will deliver both time and cost efficiencies for our customers."

O'Connell continued: "As molecules increase in potency, API is often very expensive and in short supply. By being able to fill drug directly into capsules and accelerate first-time-in-man studies, customers will be able to assess very quickly whether the project will progress to the next stage or 'fail and fail' fast – thereby minimizing costs, and enabling informed decisions to be made."

To find out more about PCI and its clinical services, please visit www.pciservices.com.

About PCI

The global healthcare industry trusts PCI for the drug development solutions that increase their products' speed to market and opportunities for commercial success. Only PCI brings the proven experience that comes with more than 50 successful product launches a year and over four decades in the healthcare business. Leading technology and continued investment enables us to address global development needs throughout the product life cycle — from Phase I clinical trials through commercialization and ongoing supply. Our clients view us as an extension of their business and a collaborative partner, with the shared goal of improving patients' lives. For more information, please visit www.pciservices.com or follow us on Twitter at @PCI_Social.

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