Puridify and GSK extend evaluation of FibroSelect purification technology

Platform technology set to transform purification in bioprocess manufacturing

London, UK - 5 December 2016 - Puridify Limited ("Puridify"), developers of novel bioprocessing purification technologies for industrial biomolecule manufacture, today announced the signing of an 18 month collaboration with GlaxoSmithKline ("GSK") to extend the evaluation of Puridify's FibroSelect purification technology with a view to building a package to support potential use of nanofibres in toxicology and clinical manufacture. This signing follows a previous 18 month collaboration which has seen successful demonstration of proof of concept studies at the 50L scale, with potential calculated economic benefits based on the technology's use.

Venture backed Puridify has been on a rapid path of development and commercialisation to deliver an industry-ready technology that will allow a step-change to current downstream processing of industrial biotherapeutic manufacture. The unique high capacity (Dynamic Binding Capacities equivalent to packed beds) combined with high flowrate properties (1 second residence times) of FibroSelect enable the replacement of columns that are more than fifty times larger. The ready-to-operate units reduce validation burden, improve process robustness and increase facility flexibility.

FibroSelect simplifies chromatography to rapid and robust adsorptive depth filter type operations. This is further supported by the use of well understood materials: the cellulosic matrix can support any functionality, with evaluations focused on costly product-capture applications. Protein A FibroSelect achieved mAb purification with equivalent product Critical Quality Attributes (CQAs) at a productivity fifty times greater than Protein A resins (>500 g/L/h) using a single cartridge on standard chromatography equipment.

Using a 'multi-cycle, single batch' mode of operation FibroSelect units have demonstrated an ability to match process CQAs when cycled over 190 times with three minute run times. This purification throughput also offers rapid process development opportunities.

"The development of FibroSelect has focused on generating industry relevant end-user data. At the same time, we have been establishing a manufacturing basis for GMP-compliant products that are delivered pre-packed and ready-to-operate," commented Dr Oliver Hardick, Chief Executive Officer of Puridify.

"Our single-use purification units will enable this technology to service very effectively the wider Life Sciences industry. Specifically, collaborations with biotherapeutic drug manufacturers are already proving the benefit of FibroSelect as a single-use high productivity product capture platform, suitable for existing and emergent biologic therapies.

"We are delighted that GSK are continuing to support us in such a significant manner, particularly as we approach commercial manufacture of the FibroSelect technology. This kind of industrial collaboration is critical for shaping the technology and generating data to support its market adoption."

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About Puridify Ltd

Puridify Limited is a UK-based bioprocessing company formed in 2013 as a spin-out from University College London. Puridify's platform purification technology, *FibroSelect*, aims to enable new processing strategies. The technology was developed during a collaborative research project between the Advanced Centre for Biochemical Engineering, UCL and the Science & Technology Facilities Council.

The company is privately funded by leading venture capital investors Imperial Innovations and SR One. Puridify's head office and research & development facilities are based at the Stevenage Bioscience Catalyst, 20 minutes north of London. The company works closely with bioprocessing research experts at University College London and leading industrial collaborators around the world, to drive the rapid development of its platform technologies.

Puridify has secured a number of prestigious awards, including the SR-One funded OneStart Competition and Innovate UK Proof of Concept Bid to Smart Award in 2013; Innovate UK's Feasibility Studies and Collaborative R&D Awards in 2014; and this year received an Innovate UK Industrial Biotechnology Catalyst Project award, co-funded by the Engineering and Physical Sciences Research Council (EPSRC) and the Biotechnology and Biological Sciences Research Council (BBSRC).

For more information, visit www.puridify.com

Biotherapeutic Industry Context

Global demand for cheaper biotherapeutics and growth of biosimilars, which represent many of the new tools in the fight against diseases such as cancer, inflammation and neurodegenerative conditions, is driving the need for increased efficiency in biomolecule manufacturing. A significant proportion of current costs arise from the purification technologies now used to ensure the safety and efficacy of these treatments. Recent rapid evolution of the global biopharmaceutical market has drawn focus to the limitations of current purification operations, demanding a step-change improvement in processes. The rapid development of "Next Generation" biotherapeutics of increased complexity and size in addition to a focus on process efficiency, flexibility and convenience during manufacturing is driving the need for innovative but robust technologies that enable new platform processing strategies.

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