Polyplus-transfection® further expands transfection reagent portfolio for Cell and Gene therapy GMP production

New reagent, PEIpro-GMP, designed to support clinical phase and commercialization stages of production

Strasbourg, France – December 13, 2018 – Polyplus-transfection® SA, a biotechnology company that develops and sells innovative solutions for the delivery of nucleic acids in research, bioproduction and therapeutics, today announces the launch of PEIpro®-GMP, a transfection reagent designed for the clinical and commercial lentivirus and adeno-associated virus (AAV) production of cell & gene therapies.

Polyplus-transfection has released PEIpro-GMP to provide a solution for the cell and gene therapy industry faced with tightening regulations. The increase in regulatory requirements include the use of reagents as raw material in the production of viruses for clinical trials, specifically mandating higher levels of quality compliance at earlier stages of clinical development.

As a result, industrial viral vector production for cell & gene therapy has to increase in quality, with the essential use of cGMP compliant raw materials such as plasmids. Polyplus-transfection's latest product, PEIpro-GMP, has been designed as the highest quality grade transfection reagent available on the market that is compliant with all cGMP viral vector manufacturing requirements.

Transfection reagents are used in lentivirus viral vector production, critical for cell therapies such as CAR-T, and AAV for gene therapy, especially for inherited genetic disorders. The viral vectors are produced using reagents to transiently transfect DNA plasmids into virus producing cell lines such as HEK-293 cells. Following the few days that the virus production process takes, and followed by purification, the viruses are used to infect cells *ex vivo* for cell therapy or directly injected into humans for gene therapy. The highest grade of Polyplus-transfection's, PEIpro-GMP will enable compliant transfection throughout the clinical and commercialization processes.

"An increasing numbers of cell and gene therapies now progress towards commercialization. This has resulted in tighter regulatory controls across all production processes. In addition, therapeutic developers are targeting an increasing range of diseases, including rare genetic disorders," said Karsten Wilking, CEO, Polyplus-transfection. "Whilst compliant development risks have continued to increase, Polyplus-transfection has built over 17 years expertise in developing transfection reagents that can be applied directly to the cell and gene therapy

industries. We have built a full portfolio of reagents with three different product grades to support the different stages of development. This includes PEIpro for process development, PEIpro-HQ for preclinical studies and PEIpro-GMP for clinical phases and commercialization. Moreover, we will continue to develop reagents to support the exponential growth and development of the cell and gene therapy industries."

Details of the product can be reached here: www.polyplus-transfection.com/products/peipro-gmp.

About Polyplus-transfection SA

Polyplus-transfection SA is a biotechnology company specializing in nucleic acid delivery solutions located close to the University of Strasbourg in Eastern France and a market leader for transfection reagents for cell & gene therapy. Polyplus-transfection's vast portfolio of delivery solutions can be used for all types of applications, from research and process development, all the way to clinical trials.. For more information, please visit the Polyplus-transfection web site at: www.polyplus-transfection.com

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