PL BioScience Wins Regulatory Certification from Japan's PMDA

- Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has issued a Material Qualification Certificate for ELAREM™ Ultimate-FD PLUS (GMP Grade) cell culture media.
- The PMDA Certification is the first regulatory approval of ELAREM™ for clinical applications in Japan.
- Provides the product credibility necessary to accelerate adoption with Japanese sponsors and CDMOs while serving as a springboard for broader Asia expansion.
- ELAREM™ Ultimate-FD PLUS is PL BioScience's gamma-irradiated Human Platelet Lysate (HPL) cell culture for viral inactivation—a process for which PL BioScience is the only company with a global patent.

Aachen, Germany, 11 February 2026 – PL BioScience GmbH, a German life science company specializing in the production and development of Human Platelet Lysate (HPL), today announced that Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has issued a Material Qualification Certificate for ELAREM™ Ultimate-FD PLUS (GMP Grade), the company's processed cell culture media based on human platelets designed to support the efficient and safe *in vitro* expansion of primary cells and cell lines.

"The PMDA material qualification is an important step for PL BioScience as it allows us to support developers in Japan who are advancing regenerative medicine and other clinical programs that require certainty in raw material quality and safety compliance," said Dr. Hatim Hemeda, CEO, PL BioScience. "We believe ELAREM™ can help teams move faster with confidence as they design and manufacture investigational products."

"By having a GMP-grade, platelet-derived cell culture media formally qualified for clinical use in Japan, developers can de-risk their CMC packages, streamline supplier qualification work, and potentially shorten the path from process development to first-in-human production," said Jungsoo Park, VP of Marketing and Sales, PL BioScience. "Especially in cell and regenerative medicine programs where media choice can materially affect consistency and scalability."

About ELAREM™ Ultimate-FD PLUS (GMP Grade):

ELAREM™ Ultimate-FD PLUS is a gamma irradiated, fibrinogen-depleted and anticoagulant-free Human Platelet Lysate of EU origin. As a xeno-free cell culture supplement, the product supports the efficient and safe in vitro expansion of primary cells and cell lines. The product is especially suited to cell manufacturing applications requiring proven viral reduction, e.g. for potential use in clinical trials. It is manufactured, tested and released in compliance with the relevant GMP guidelines. The manufacturing process for the product is patented.

About PL BioScience:

PL BioScience GmbH, a life science company located in Aachen, Germany, specializes in the production and development of Human Platelet Lysate (HPL). The company has pioneered proprietary technology to produce fully artificial HPL, allowing for a fully lab-made, scalable supply of HPL. PL BioScience currently offers a comprehensive portfolio of donor-derived, natural HPL products tailored for a range of applications – the ELAREM™ platform. From academic and preclinical research to cell therapy and biopharmaceutical manufacturing, ELAREM™ ensures

seamless translations of regenerative medicine breakthroughs – from the lab to patients in need. PL BioScience is the only company worldwide holding a patent for the gamma-irradiation of HPL, covering the manufacturing process for ELAREM™ Ultimate-FD PLUS.

For more information on PL BioScience and the ELAREM™ platform, visit: https://www.pl-bioscience.com/

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