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Recipharm Advanced Bio to deliver series of seminar to U.S. FDA showcasing novel PAT and digital infrastructure to enable real-time testing and continuous biomanufacturing

- *Mobilised "lab on wheels" Process Analytical Testing (PAT) platform highlights the future of real-time, digital biologics manufacturing*
- *Invitation by CBER's Advanced Technologies Program at U.S. FDA to deliver an educational seminar series on PAT and digital manufacturing Seminar series builds on previously federally supported work in continuous manufacturing of LNP-encapsulated xRNA therapeutics and infectious disease prevention*

Recipharm Advanced Bio, Recipharm's segment specializing in advanced therapy medicinal products (ATMPs), today announced it will deliver a multi-part educational seminar series to scientific staff at the U.S. Food and Drug Administration (FDA). The program focuses on next-generation testing enabled by Process Analytical Technology (PAT), digital manufacturing, and advanced analytics.

At the center of the series is Recipharm Advanced Bio's innovative PAT framework, a mobilized, modular 'lab on wheels' concept designed to bring advanced analytical capabilities directly into the manufacturing environment. By integrated in-line and at-line analytics, real-time data modeling and digital control strategies, this approach has the potential to fundamentally change how biologics manufacturing is monitored, controlled and validated.

Rather than relying solely on traditional off-line testing performed after production steps are complete, advanced PAT systems enable continuous process verification, real-time release potential and enhanced process understanding. The series highlights how these tools could reshape regulatory testing paradigms for complex biologics and advanced therapies.

"Showcasing modern analytics ultimately supports better, more reliable access to critical therapies," said Aaron B. Cowley, PhD, Chief Scientific Officer, Recipharm Advanced Bio. "We view this seminar series as an opportunity to contribute to open, technical dialogue around emerging analytical and digital approaches that can strengthen process robustness and product quality across the industry."

Delivered as part of the CBER Advanced Manufacturing Seminar Series, the PAT seminars reflect Recipharm Advanced Bio's commitment to open, science-based dialogue and knowledge sharing on advanced manufacturing technologies. The content draws on its experience supporting the development and manufacture of complex biologics using modern analytical, computational, and digital approaches.

The seminars are designed to provide an educational overview of current and emerging approaches to process monitoring, control strategies, and digital enablement. Planned topics include foundational PAT concepts, validation and bridging strategies between off-line and in-process analytical methods, the use of digital twins and models for real-time process monitoring, and considerations for modular and mobilized analytical systems in biologics production environments.

Background on prior federally supported work

The PAT seminar series builds on a 2023-FDA contract supporting work led by MIT and conducted by Recipharm Advanced Bio in collaboration with academic partners. The project enabled the

development of a continuous, integrated manufacturing platform for LNP-encapsulated xRNA production including inline PAT and novel control software.

Insights from this work have helped inform Recipharm Advanced Bio's advanced manufacturing framework, Recimagine™ solutions for continuous production, PAT, and digital process development.

Participation in the seminar series does not constitute FDA endorsement of any specific technology, product, or manufacturing approach.

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For more information

About CBER Advanced Manufacturing Seminar Series

The CBER Advanced Manufacturing Seminars focus on innovative manufacturing technologies, systems, and approaches with the potential to improve manufacturing of CBER-regulated products. Presentations cover topics including advanced manufacturing modalities (e.g., continuous), smart manufacturing, artificial intelligence/machine learning, and novel process analytical technologies and analytical methods. Speakers include past and present recipients of CBER extramural research funds, as well as leading experts from academia, industry, and government sectors.

About Recipharm Advanced Bio

Recipharm Advanced Bio, a division of Recipharm, is a contract development and manufacturing organization (CDMO) specifically established to focus on serving companies seeking to develop and commercialize advanced therapy medicinal products (ATMPs). Recipharm Advanced Bio's specialized CDMO capabilities include pre-clinical to clinical development and manufacturing and commercial production of novel biological modalities encompassing live viruses and viral vectors, live-biotherapeutic products, nucleic acid-based mRNA and plasmid DNA. Led by an agile management team and robust technical experts with a proven track record in both process development and contract manufacturing, Recipharm Advanced Bio offers the knowledge and resources necessary to help customers deliver promising new therapies to critical patient needs across the world and to advance the future of global health.

For more information, please visit http://www.recipharm-ab.com.

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