Kudo Biotechnology Opens New Process Science Center of Excellence in Needham, MA and Appt of Additional Leadership Team

Kudo Biotechnology, a leading global CDMO announces they have opened a New Process Center of Excellence in Needham, Massachusetts for mRNA-LNP companies.

NEEDHAM, MASSACHUSETTS, UNITED STATES, December 19, 2023 /EINPresswire.com/ -- Kudo Biotechnology Opens New Process Science Center of Excellence in Needham, Massachusetts and Appointment of Additional Leadership Team

Kudo Biotechnology, a leading global CDMO dedicated to providing a complete suite of solutions from pre-clinical to commercial GMP for mRNA-LNP companies, today announced that they have recently opened a brand-new facility in Needham, Massachusetts, USA, focused on providing process and analytical development, MSAT services, and GMP productions to better meet its growing demands in US and European markets.

> The opening of Kudo's Process Science Center of Excellence in Needham, MA is an important milestone towards our growth and expansion in the US market"
>
> *CEO Molly S. McGlaughlin*

The new office – a Process Science Center of Excellence – includes a 5,500 sqft lab space with industry-leading expertise in pDNA, mRNA, lipid nanoparticle (LNP) and drug product process development along with a broad range of analytical testing capabilities. This new Center is also a business development hub for the US and EU and is designed to provide access to industry-leading Chemistry, Manufacturing and Controls (CMC) advancements and cutting-edge Process Science. The facility accommodates

research scale to pilot scale productions.

In addition, Kudo Biotechnology today announced the appointment of three additional leaders to the team:

Dr Marieke Zhao, Vice President of Process Sciences. Dr Zhao is an industry leader who brings in over 20 years of experience in bio-therapeutic development, including drug substance process development, technology transfer, process scale-up, CMO selection and management, CMC strategy, and regulatory filings. She comes with a strong track record of ushering novel Biologics from pre-development to first-in-human clinical trials with aggressive timelines. Most recently, Dr Zhao worked as a senior director, drug substance at Greenlight Biosciences. She led both upstream and downstream process development teams, as well as managed internal and external manufacturing. Prior to Greenlight Biosciences, Dr Zhao worked as a Director in Biologics Development, CMC, at Mersana Therapeutics, where she managed internal and external teams in the development and manufacturing of Antibody-Drug Conjugates (ADC) for clinical oncology programs. Prior to Mersana Therapeutics, Dr Zhao worked as an independent consultant, as well as a principal scientist at ImmunoGen and Pfizer. Dr Zhao received her Ph.D. in molecular biology from University of Zurich in Switzerland.

Dr Atsuko Sangria, Director of DS Process Development. Dr Sangria has 16 years of research experience in molecular biology and vaccine development. Prior to joining Kudo Bio, Dr Sangria led the mRNA DS process development, scale-up, and tech transfer at RVAC Medicines, a mRNA product company. Before that, Dr Sangria was an expert scientist at GSK Vaccines, where she played a vital role in mRNA vaccine platform development. She also has preclinical and process development experience in biological products from her past role at VLP Therapeutics and postdoctoral training in the National Institute of Health. Dr Sangria obtained her Ph.D. in Pharmaceutical Sciences from Kitasato University in Japan.

Dr Jim Stout, Director of Drug Product Process Development. Dr Stout has more than two decades of experience in process development and manufacturing for antibodies and other recombinant proteins, with demonstrated success in clinical and commercial biomanufacturing. Dr Stout was most recently Vice President, CMC/ Manufacturing Operations and Facilities at Shattuck Labs, where he led CMC and Manufacturing Operations (external CDMOs for drug substance and drug product) and Supply Chain for GMP materials and Clinical Trials. Dr Stout previously held leadership roles in process development and manufacturing at BioVectra, Natrix Separations which was purchased by Merck/ Millipore-Sigma during his tenure, Amgen, and Abbott Bioresearch Center. He has significant experience in authoring CMC sections/INDs to support regulatory filings and amendments, including QP reviews and Regulatory Authority Q&A. Dr Stout received his PhD in Chemistry (Biochemistry/Analytical Chemistry) from the University of Cincinnati.

“The opening of Kudo’s Process Science Center of Excellence in Needham, MA is an important

milestone towards our growth and expansion in the US market," said Molly S. McGlaughlin, CEO of Kudo Biotechnology. "By having our Center of Excellence right here in Needham, we can better serve our US, EU and global clients, and fulfil complete CMC needs across process development, analytical development, and GMP manufacturing. I am excited to welcome onboard Dr Marieke Zhao, Dr Atsuko Sangria and Dr Jim Stout, and I look forward to our Process Sciences team's continuous growth under their leadership."

About Kudo Biotechnology

Kudo Biotechnology is a leading global mRNA CDMO, providing world-class, end-to-end mRNA manufacturing solutions, all under one roof. Kudo has a state-of-the-art clinical GMP manufacturing facility and MSAT laboratories in Shanghai, a Process Science Center of Excellence in Needham, MA, and with additional presence in Singapore. Offering a complete suite of services in pDNA, mRNA, LNP and Fill-Finish, our GMP manufacturing facility spans over 57,000 sqf and is designed in accordance with cGMP and global regulatory guidelines. Kudo's facility features two plasmid lines, three mRNA lines, two LNP bulk lines, and one drug product fill & finish line. It can cater to manufacturing needs for preclinical through Phase 2 clinical trials, with capacity to manufacture up to 40 million vials/year for Phase 3 and commercial manufacturing. Our cutting-edge equipment is customized for mRNA and LNP drug development, and we offer a range of additional services, including Process and Analytical Development, Technology Transfer, Testing & Release, and Supply Chain Management. Kudo provides comprehensive solutions for our clients' drug development needs and has a robust quality management system to ensure the highest quality and to comply with global regulations. For more information, please visit www.kudobio.com, follow us on LinkedIn @KudoBio, or search KudoBio on WeChat.

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