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Kilo Scale Synthesis Laboratory at Chembiotek, TCG Lifesciences, Kolkata

TCG Lifesciences Limited has commissioned its cGMP kilo scale synthesis laboratory in Kolkata at 'Chembiotek,' its discovery research services business unit. This represents a significant new step in establishing its fully integrated drug discovery and development research services offerings to the global pharmaceutical and biotechnology industries. With the aim to support its clients' developmental needs by supplying material required for 'First-in-human' clinical studies, this facility has been designed with reactor capacity ranging up to 200L and reaction capabilities ranging from -80 to +200 degree Celsius. High end equipment, such as Differential Scanning Calorimeter and Reaction Calorimeter, have been installed with matching equipment like centrifuges, jet mills, vacuum tray dryers, sifters, etc.

Following 'safety through quality' principle, the whole facility is integrated with a full scale Effluent Treatment Plant and due care has been taken to comply with stringent Health, Safety and Environmental ("HSE") norms. A strong quality control team has been put in place to monitor achievement of the cGMP norms for the release of the material synthesized.

"Chembiotek is an established global leader in providing high end chemistry and allied discovery research solutions to its customers. The addition of this cGMP compliant kilo lab will allow us to offer developmental chemistry services which would enable us to speedily and seamlessly transfer technology from our current chemistry labs to the kilo lab for scale-up, process development and optimization.

This kilo lab will also serve as a robust platform for technology transfer to pilot plant scale. Consistent with our fundamental value proposition, the kilo lab operations will inculcate state-of-the-art science, strictly adhere to delivery time and quality, and observe the highest ethical standards", said Swapan Bhattacharya, Managing Director, TCG Lifesciences Limited.

"Our kilo lab would operate on a 24x7 basis with particular emphasis on efficiency, time optimization, innovative analytical techniques and highest quality control standards. We have taken great care in designing the labs and used the best-in-class equipment. Keeping in mind the spectrum of reaction handling capabilities, I am sure the lab will serve the varying needs of our existing and prospective customers. It will support all Investigative New Drugs ("IND") enabling activities and the manufacture of clinical trial materials under GMP conditions.

Other capabilities would include analytical method development, synthesis of impurities, metabolites and degradation products and stability studies, as per the international guidelines. Our in-house chemistry knowledge and experience generated over the years will help us develop and optimize safe, eco-friendly and cost effective processes," said Jagdish Sastry, President, Custom Synthesis and Large Scale Manufacturing.