Syngene

Press Release

Syngene biologics manufacturing facility to be operational for US and European customers from mid-year

New facility includes 20KL of single use drug substance capacity coupled with drug product filling capacity of up to one million vials per day

Bangalore, March 14, 2024: At DCAT 2024 global bio/pharmaceutical manufacturing forum, Syngene International, a global contract research, development and manufacturing organization (CRDMO), announced that its newly upgraded biologics facility - Unit 3 - would be operational for clinical and commercial supply in the second half of 2024.

The facility will be available for biotech and pharma customers seeking drug substance and drug product contract manufacturing. The drug substance capacity includes two production suites with five 2KL single use bioreactors each, for a total capacity of 20KL. The facility also includes two high-speed vial filling lines capable of producing up to 1 million vials per day ranging from 1 to 100mL fill volumes. In addition to the production capacity, the site has a development suite for clinical supply of drug substance equipped with a 500L single use bioreactor.

The facility triples Syngene's bio manufacturing capacity and adds to its existing commercial manufacturing site in Bangalore, India, – BMP 1 - which has been approved by the US FDA (with no 483 observations) and EMA, as well as a PROTAC research site in Hyderabad, India.

Syngene has further expansion plans for two additional vial filling isolator lines with capacity for 600 vials/minute and 100 vials/minute respectively and drug substance expansion into perfusion cell culture processing.

"We see interest not only from existing partners looking to move innovative biologics into clinical and commercial manufacturing, but also from new biotechs and big pharma companies. In particular, there is demand from commercial clients looking for immediately available capacity. With US FDA and EMA approvals in place, Unit 3 is a very attractive option, so we are preparing for a busy week at DCAT," commented Jonathan Hunt, MD & CEO, Syngene International Ltd.

The $98m[1] manufacturing site is integrated with other biologics capabilities in the city including around 170 R&D scientists located nearby offering clients a seamless transition from discovery biology services into clinical and commercial manufacturing. The Company also has a microbial

[1] https://cdn.syngeneintl.com/2023/07/05033142/PR-final-04072023.pdf

cGMP facility and a mammalian cell manufacturing facility to extend end-to-end Chemistry, Manufacturing and Control (CMC) development solutions for its global clients.

Alex Del Priore, Senior Vice President – Manufacturing Services, Syngene International Ltd. added: *"Unit 3 provides the capacity to support our customers' growth and will become our flagship location for both our core business and the emerging growth areas in ADCs or cell and gene therapy. The site is integrated with nearby R&D, drug substance and drug product capabilities to improve our time to clinical trials and reduce cost per gram."*

Downstream processing is supported by chromatography systems with capacity of 600 to 2000 LPH enabling the purification and isolation of target molecules from complex mixtures. The integration of chromatography systems streamlines the purification processes and enhances the overall efficiency of biologics manufacturing. Additionally, to meet the growing demand for protein concentration and diafiltration, Syngene has invested in automated tangential flow filtration (TFF) systems to facilitate the concentration and diafiltration of biologics, maximizing the yield and quality of final products, as well supporting perfusion manufacturing.

In total Unit 3 will have around 100 staff for Quality Assurance and Manufacturing, part of Syngene's 600-strong team across its biologics manufacturing services and supporting specialist functions.

-ENDS-

Notes to editors

About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 6000 scientists offer both skills and the capacity to deliver great science, robust data security, and world class manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA. For more details, visit www.syngeneintl.com. For the Company's latest Environmental, Social, and Governance (ESG)report, visit https://esgreport.syngeneintl.com/.

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