Tanvex BioPharma Accelerates CDMO Layout to Expand Business Opportunities

June 28, 2023

Tanvex BioPharma, Inc., Chairman Yen Yun emphasized that the company is actively building a comprehensive CDMO service platform. Combined Tanvex Taiwan's long-established upstream process development capability with the experience of Tanvex USA in passing the US Food and Drug Administration's (FDA) strict facility inspections and their good manufacturing practices (GMP) for local production, Tanvex aims to use this one-stop service model to become the best strategic partner for the development and manufacturing of biopharmaceuticals in Taiwan and abroad.

Tanvex BioPharma, Inc., held its 2023 general meeting of shareholders on June 28. During the meeting, Chairman Yen Yun stated that the joint effort between the US, Tanvex BioPharma USA, and Taiwan, Tanvex Biologics Corp., as part of its CDMO and cooperative service model will become a unique competitive advantage for the company.

Tanvex Biologics Corp. specializes in non-GMP pre-clinical pilot production development. It has accumulated strong R&D capabilities and extensive experience in cell line development, process development, bioassay development, and pilot production, providing a seamless transition toward to GMP process. In addition, it was ranked as one of CDMO service providers by Taiwan's Industrial Development Bureau, Ministry of Economic Affairs in January officially.

With the establishment of a CDMO service infrastructure, Tanvex BioPharma USA has declared its intent to enter the CDMO business. In February this year, it brought on John R. Mosack as COO. Mosack has 30 years of CDMO experience in the US biopharmaceutical industry.

Mosack expects Tanvex BioPharma USA will become the best strategic partner for Taiwan-based companies looking to enter the international market. He pointed out that the GMP facility has three big advantages. First, TX01 and TX05 have already

submitted biologics license applications (BLA) and passed the FDA's facility inspections twice. Second, its San Diego plant is one of a few GMP factories that have both large-scale microbial and mammalian cell production lines—it also has the experience to fulfill the diverse needs of customers. Third, TX01 has already obtained a drug license in Canada and is expected to begin sales at the end of this year. Tanvex is also stepping up efforts on drug licenses for TX01 and TX05 in the US.

Chairman Yen Yun expects that the new CDMO service platform can be ready in August and will bring new business opportunities to both Tanvex subsidiaries in US and Taiwan.

About Tanvex

Tanvex BioPharma, Inc. (TWSE: 6541) is a biopharmaceutical company focused on the biosimilar market. The Company is vertically integrated with end-to-end in-house development, manufacturing and commercialization capabilities. Tanvex BioPharma, Inc. is registered in Cayman Islands and has operations and facilities in Irvine, CA, San Diego, CA, and Taipei, Taiwan. Tanvex is publicly traded on the Taiwan Stock Exchange.