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EirGenix's comprehensive CDMO services strengthening Taiwan’s position in the global biopharmaceutical landscape

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"To meet the growing demands of Biopharmaceutical, EirGenix launched a new Xizhi and Zhubei facilities house state-of-the-art cGMP-compliant pilot plants, each equipped with massive bioreactors that support large-scale biologics manufacturing" explains Dr. Chih-Jung Chang, CEO of Biomanufacturing at EirGenix

EirGenix (HQ: Taipei, Taiwan), an established Taiwanese Contract Development and Manufacturing Organization (CDMO), specializes in high-quality, cost-effective CDMO services and biologics to ensure affordable biopharmaceuticals capable of meeting global biopharma demands through its dual-product development and CDMO business models. With its two business units, EirGenix is achieving its goal of making biopharmaceutical drugs accessible to all patients. A contract development and manufacturing operation unit assists clients in manufacturing their biologics; a product development unit

focuses on developing biologics, including biosimilars, biobetters, and new drugs.

EirGenix is further expanding its contract development and manufacturing services globally by accelerating biosimilar drug development pipeline. EirGenix's latest breast cancer biosimilar is making strides in the international markets. EirGenix actively pursues international partnerships, alliances, mergers, and acquisitions as part of its strategy to establish itself as a global biopharmaceutical development and manufacturing center.

Recently, EirGenix held an exclusive exhibition and interactive session at **BIO Asia-Taiwan 2024,** jointly organized by the global Biotechnology Innovation Organization (BIO) and the Taiwan Bio Industry Organization (Taiwan BIO) in July 24th to 28th at the Taipei Nangang Exhibition Center (TaiNEX) showcasing its capabilities and global reach. **Dr. Chih-Jung Chang, CEO of Biomanufacturing at EirGenix, discussed** the company's global growth strategies and recent ventures more extensively with Biospectrum Asia, *(the official media partner for BIO Asia-Taiwan 2024).*

- **What are EirGenix's strengths in contract development and operations in the biologics manufacturing industry?**

EirGenix offers comprehensive CDMO services, from cell line development to commercial manufacturing, excelling in biologics production, especially antibodies (monoclonal or polyclonal or ADC) and biosimilars. Our key strengths lie in advanced technology, extensive experience, and flexibility to meet diverse client needs. Additionally, we maintain rigorous quality standards that align with global benchmarks, ensuring products and services meet world-class requirements. This combination of technical expertise and commitment to quality enables us to deliver scalable, cost-effective solutions that consistently meet regulatory and industry expectations on an international level.

- **How does EirGenix contribute to Taiwan's biotechnology sector as a key player in CDMO and gene technology platforms? Could you describe the key milestone contributions?**

EirGenix has played a pivotal role in advancing Taiwan's biotechnology sector by offering high-quality CDMO services and leading innovations in biologics manufacturing. Notably, we are the first CDMO in Taiwan to secure PMDA approvals for biologics, a testament to our commitment to quality and regulatory excellence. This achievement not only underscores our expertise but also strengthens Taiwan’s position in the global biopharmaceutical landscape. EirGenix has consistently delivered milestone contributions, such as the successful development of biosimilars like our HER2-targeting biosimilar, which launched for the Taiwan market and will also get the FDA approval, further highlighting our leadership and dedication to quality-driven biologics production.

- **How would you describe EirGenix's mission to provide high-quality, cost-effective CDMO services and biologics to strengthen the healthcare ecosystem?**

EirGenix is committed to delivering top-tier, cost-effective CDMO services to enhance the global healthcare ecosystem. Our mission focuses on improving accessibility to biologics by offering efficient, reliable, and innovative solutions that help accelerate drug development while maintaining the highest quality standards. We strive to work closely with our clients to address their needs while ensuring affordable treatments reach patients faster.

- **What are the core focus and production capabilities of massive bioreactors at Xizhi and Zhubei facilities? How are these two cGMP pilot plants bioreactors designed to meet the demands for quality and affordable biopharmaceuticals?**

To meet the growing demands of Biopharmaceutical, EirGenix launched a new GMP plant in the Zhubei Biomedical Park in 2019. In the first stage, one production line was established at Zhubei GMP with two 1,000-liter and six 2,000-liter single-use bioreactors. With further expansion, an additional production line is operating since mid-2023, elevating our capacity to the maximum twelve 2000-liter single use bioreactors, and the maximum annual production capacity of antibody can reach 1,000 kg.

The Xizhi and Zhubei facilities house state-of-the-art cGMP-compliant pilot plants, each equipped with massive bioreactors that support large-scale biologics manufacturing. Our Xizhi site focuses on early-stage development and pilot production, while the Zhubei facility is optimized for commercial-scale manufacturing. The bioreactors are designed to meet stringent quality and regulatory standards, ensuring reliable production of affordable biopharmaceuticals. This allows us to support global demand while maintaining cost-efficiency.

- **How does EirGenix optimize its plasmid DNA platform to produce broadspectrum viral vectors? How is EirGenix handling sustainability risks and operational stability?**

To cater to the diverse demands of cell and gene therapy development, EirGenix provides a comprehensive suite of plasmid DNA manufacturing services, supporting everything from preclinical research to clinical development and commercial supply. Clients can either supply an existing plasmid for production or rely on us to generate a custom plasmid tailored to their specific requirements. Our team offers end-to-end scientific support, including both upstream and downstream process development for each plasmid DNA production program, ensuring optimal results and scalability. Through continuous process optimization, we ensure efficient and reliable production while addressing sustainability and operational stability for long-term success.

We are also actively addressing sustainability and operational risks through efficient resource utilization, waste minimization, and stringent process control, ensuring long-term operational stability.

- **How is EirGenix making strides on the international biopharma sphere under its robust drug development strategies and scalability? How is the momentum in gaining access to international markets?**

EirGenix has made significant strides in the international biopharma space by adopting robust drug development strategies that focus on scalability and flexibility. Our partnerships with global pharmaceutical companies have expanded our market access, especially in regions like the US, Europe, and Japan. We continue to gain momentum by forming strategic alliances and leveraging our biosimilar developments, enhancing our global footprint.

EirGenix currently has seven products undergoing development mainly focused on the biosimilar products. Four antibody products are for treating HER2 gene variance; one antibody biosimilar is for inhibiting angiogenesis, and one carrier protein is for vaccination use.

- **Are there any expansion plans to enhance the capacity and potentials of late-stage Drug development programs? How have stakeholder and investment relations been to benefit this development process?**

To support late-stage drug development, EirGenix is expanding its manufacturing capacity, with plans for additional bioreactor installations and new production lines. These initiatives are supported by strong stakeholder engagement and investment relations.

Regarding Expansion Plans and Investment Relations, in addition to our current production capacity being the largest in Taiwan, EirGenix is preparing to further scale up to meet increasing demands for large-scale commercial manufacturing. Although we already have significant capacity, we recognize the need for even more robust facilities to handle the anticipated

surge in biopharmaceutical production.

To address this, we are planning to build a new facility in Kaohsiung Qiaotou, which will house 10 bioreactors, each with a 15,000-liter capacity. This expansion will enable us to accommodate higher production volumes, positioning us to meet global demands for large-scale commercial production. By further expanding our bioreactor capacity, we aim to solidify our leadership in biologics manufacturing while maintaining our commitment to cost-efficiency and quality.

This strategic expansion is supported by strong investment relations, with investors confident in our vision to enhance Taiwan's biotechnology infrastructure and grow our capabilities in the global biopharmaceutical market.

- **Is EirGenix actively screening M&A endeavors to expand reach and network? Are there any notable co-development alliances in the recent fiscal? How does the company intend to expand its investment in the biotechnology landscape and collaborate with active investors?**

EirGenix is actively exploring M&A opportunities to expand our reach and strengthen our CDMO network. In recent fiscal periods, we have established notable co-development alliances with international partners to co-create innovative therapeutics. We are also working closely with investors to expand our investment portfolio in the biotechnology space, fostering collaboration and growth in cutting-edge biologics and gene therapy solutions with our strategic alliance.