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To All Members of the Press

To All Concerned Parties

OrganTech Inc.

OrganTech Inc. Partners with U.S. Company for FDA Application of Next-Generation Bio-Implant

**— Aiming to Accelerate Market Launch
with a Track Record of 100% FDA Approval Success —**

OrganTech Inc. (Head Office: Chuo-ku, Tokyo; CEO: Yoshio Shimo; hereinafter “OrganTech”), engaged in the world’s first application of organ regeneration technology* to the medical field, has entered into a consulting agreement with QNova LifeSciences (hereinafter “QNova”), a Maryland-based U.S. CRO (Contract Research Organization) and consulting company specializing in the life sciences field. Under this agreement, the two companies will jointly advance preparations for regulatory approval applications to the U.S. Food and Drug Administration (FDA) for OrganTech’s next-generation bio-implant.

QNova provides comprehensive support from the development of pharmaceuticals and medical devices to FDA approval and commercialization. QNova has been involved in over 250 Class I and II medical device applications, boasting a 100% success rate for approvals. In addition, the company has obtained more than 30 special FDA designations and participated in over 500 pharmaceutical-related projects, accumulating extensive experience across a broad spectrum of pharmaceutical and medical device fields.

The next-generation bio-implant is an “organ regeneration treatment for tooth loss” that, unlike current bone integration-based implant treatments, connects the implant to the alveolar bone via the periodontal ligament, similar to natural teeth. This approach preserves biological functions—such as sensory perception for bite comfort and infection defense—that are typically lost with conventional bone-integrated implants. The underlying technology was developed through fundamental research conducted at the RIKEN (National Institute of Physical and Chemical Research) by a research group led by OrganTech’s Founder and Chairman, Dr. Takashi Tsuji.

Since February 2025, the next-generation bio-implant has been undergoing a world-first specified clinical trial to verify its safety and efficacy in humans. Participating institutions include the Dental and Maxillofacial Implant Center at Minami Tohoku Medical Clinic



(Koriyama, Fukushima; Center Director: Dr. Shohei Kasugai, Institute of Science Tokyo Honorary Professor and former Professor, Department of Oral Implantology and Regenerative Dental Medicine, Graduate School, Tokyo Medical and Dental University), part of the Minami Tohoku General Hospital group.

Through this partnership, OrganTech will combine its research and product development capabilities with QNova's expertise in international pharmaceutical and medical device regulatory affairs. Leveraging the combined track records and know-how of both companies, we aim to shorten the development timeline and accelerate the market launch of the next-generation bio-implant through close communication with regulatory authorities. OrganTech targets entry into the U.S. market for the next-generation bio-implant in 2027.

OrganTech is committed to contributing to the realization of a healthy, long-lived society and improving quality of life by creating new high-value-added industries in Japan through the research and development of medical devices and regenerative medicine.

*(Note) Almost all organs develop only once during the fetal stage from an organ germ composed of epithelial stem cells and mesenchymal stem cells. The process by which a fully functional organ forms involves complex molecular signaling between these two cell populations.

In 2007, the Tsuji Laboratory pioneered a method to recreate organ germs by isolating epithelial and mesenchymal stem cells from an organ germ and then reaggregating them at high density in a compartmentalized manner (Nature Methods, 2007).

This technique, known as the "organ germ method," has since been used to functionally regenerate organs such as teeth, hair follicles, salivary glands, and lacrimal glands, thereby establishing the foundation of organ regeneration technology.

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