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Promotion of Proprietary Brand Business in the Medtech Segment

FDA 510(k) Clearance for Accelagen™ Plus Surgical Matrix

(Note) This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the Japanese original shall prevail.

GNI Group Ltd. (the "Company") has been undertaking a fundamental review of its Medtech business with the aim of addressing the segment's current relatively low profitability and transforming it into a higher-margin business. As part of these efforts, Berkeley Advanced Biomaterials ("BAB"), a consolidated subsidiary of the Company, has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for Accelagen™ Plus Surgical Matrix ("Accelagen™ Plus"), BAB's first proprietary branded product. The 510(k) clearance is required to market medical devices in the United States.

Accelagen™ Plus is a biomaterial-based product containing collagen and other materials that supports tissue formation and natural wound healing across a broad range of wounds, including those resulting from surgical procedures, burns and pressure ulcers.

BAB has historically focused on the development and manufacture of biomaterials, primarily bone graft substitutes, as well as the supply of products marketed under third party brands. Accelagen™ Plus expands BAB's biomaterials technologies and capabilities beyond its traditional bone graft portfolio into wound management and represents BAB's first proprietary branded product.

Danielle Kelley, CEO of BAB, commented:
"FDA clearance of Accelagen™ Plus represents an important milestone for our Medtech business and for Berkeley Advanced Biomaterials. It demonstrates our ability to leverage BAB's expertise in collagen and biomaterials to develop innovative products beyond our traditional bone graft portfolio. As we prepare for the U.S. commercial launch in Q1 2027, Accelagen™ Plus represents an important first step in building a broader portfolio of proprietary, higher value products to support the long-term growth of the business."

BAB is currently completing preparations for the U.S. commercial launch of Accelagen™ Plus, targeted for Q1 2027. With the receipt of FDA clearance, BAB will continue to expand its proprietary product portfolio, including Accelagen™ Plus, as it advances its transition toward a proprietary branded product business model, with the aim of improving profitability and achieving sustainable growth in the Medtech segment.
The impact of this matter on the Company's consolidated financial results for the fiscal year ending December 31, 2026 is expected to be immaterial.

About Accelagen™ Plus
Accelagen™ Plus is a sterile, 100% resorbable wound matrix composed of Type I/III bovine collagen, 45S5 bioactive glass and sodium hyaluronate. The product acts as a scaffold for cellular migration and tissue growth and maintains a moist wound environment to support natural wound healing.
Accelagen™ Plus is cleared for the management of a broad range of wounds, including partial and full-thickness wounds, pressure ulcers, venous and diabetic ulcers, surgical and trauma wounds, draining wounds, and certain burns.