

## Mochida Pharmaceutical Obtains 510(k) Clearance for "ReFeel<sup>®</sup>", a Material that Supports Nerve Regeneration, in the United States

---

This material is an English translation of the press release to be issued on July 2, 2024 in Japanese, and the Japanese release is given priority regarding content and interpretation.

July 2, 2024

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that it has obtained 510(k) clearance from the US Food and Drug Administration (FDA) for "ReFeel<sup>®</sup>" (regulation name: Nerve Cuff), a material that supports nerve regeneration designed for repairing and regenerating damaged peripheral nerves. The product will be launched in the United States soon.

"ReFeel<sup>®</sup>" is a medical device, a sheet material composed of sodium alginate\* and polyglycolic acid nonwoven fabric. Sodium alginate creates an environment favorable to nerve regeneration in the damaged nerve site, supporting the repair and regeneration of nerves. The polyglycolic acid nonwoven fabric ensures the flexibility and strength of the sheet material during use. In Japan, development of "dMD-002", a sheet material with the same composition as "ReFeel<sup>®</sup>", is underway for the treatment of cavernous nerve injury.

In order to achieve the "vision for 2031", announced two years ago, Mochida Pharmaceutical Group is working to position the biomaterials business as one of the pillars of the next generation in addition to the current mainstay pharmaceutical and healthcare businesses. The biomaterials business promotes several projects based on alginate, which is expected to have various medical applications, and will also expand globally. "ReFeel<sup>®</sup>" is the first product to receive regulatory clearance in the biomaterials business.

\* Sodium alginate, a polysaccharide derived from seaweed, is a biocompatible biomaterial widely used for neural regeneration. Furthermore, it holds great promise for use in tissue engineering, such as cartilage repair and cell transplantation. Sodium alginate is manufactured by KIMICA Corporation (Head office: Tokyo, Japan, President and CEO: Fumiyoshi Kasahara), which is a leading manufacturer of alginate with a proven track record in pharmaceutical grade alginate production.

