FOR IMMEDIATE RELEASE

Lynch Regenerative Medicine Acquires REGRANEX® Gel and Exclusive Rights to Use Recombinant Pure PDGF for Soft Tissue Rejuvenation and Regeneration

Franklin, Tenn – March 31, 2025 – Lynch Regenerative Medicine, LLC., (LRM) announced today that it has acquired exclusive rights to REGRANEX® gel and recombinant purified platelet-derived growth factor (PDGF) from Smith & Nephew, Inc., for use in skin rejuvenation and regeneration as well as other soft tissue wound healing and tissue regeneration applications. PDGF is the first and only pure recombinant growth factor to have received approval from the U.S. Food and Drug Administration (FDA) for the treatment of wounds in the lower extremities of diabetic patients. The terms of the transaction were not disclosed.

The prevalence of diabetes is rising, with an estimated 38.4 million people in the United States, or 11.6% of the population, suffering from diabetes in 2021. Of those patients, 15% are likely to experience a diabetic foot ulcer (DFU). Approximately 85% of diabetes-related lower extremity amputations are preceded by a DFU, and most of these amputations are preventable. REGRANEX is a proven first-line treatment for DFUs when used as an adjunct to good ulcer care. It has been demonstrated in Phase III randomized double-blind placebo-controlled clinical trials to significantly increase healing of DFUs, as compared to a standard good ulcer care. Under the terms of the transaction, Smith & Nephew will continue to distribute REGRANEX through August 2025, after which LRM will become the exclusive manufacturer and seller of REGRANEX.

LRM is working with leading universities and skin care centers in the United States to identify and develop new formulations of recombinant pure PDGF for additional wound healing and skin rejuvenation and regeneration indications beyond DFUs.

“We are excited to acquire the exclusive rights to use recombinant cGMP pure PDGF for soft tissue and wound healing indications. These rights complement our existing broad patent portfolio covering the composition and use of PDGF for skin rejuvenation and regeneration and hair restoration. I have led the development of five pure PDGF products for tissue regeneration and rejuvenation and am confident that we can successfully develop pure PDGF for additional indications in skin and other soft tissue applications,” said Dr. Samuel Lynch, founder and CEO of LRM and inventor on more than 150 patents worldwide and author of more than 100 peer-reviewed articles on PDGF and regenerative medicine.

“PDGF is the most powerful, most important growth factor so far discovered for stimulating healing, tissue regeneration and rejuvenation. Our mission at LRM is to harness the power of PDGF to help patients heal skin and other soft tissue wounds faster and with less scarring, and to rejuvenate the skin

to achieve optimum aesthetic results. Our vision is that it becomes best practice for every surgical incision and every injury to skin to be treated with pure PDGF to accelerate healing, reduce inflammation and pain, and decrease the opportunity for wounds to become infected," added Dr. Lynch.

Recombinant pure PDGF has a strong record of regulatory approval in numerous clinical indications. PDGF has been through multiple phase I – IV clinical trials and has received FDA approval four times – twice as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, posttraumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material; once for promoting periodontal regeneration including regeneration of bone and soft tissues lost due to periodontal disease; and once for promoting healing of chronic skin wounds in the lower extremities of diabetic patients.

In addition, LRM, through its wholly owned LRM Aesthetics company, has recently introduced its first commercial product, Ariessence™ pure PDGF+, to the aesthetics market, where it is rapidly gaining adoption as the go-to topical product for skin rejuvenation and improved aesthetic results following laser therapy, microneedling and other skin rejuvenation procedures.

About Lynch Regenerative Medicine, LLC

Lynch Regenerative Medicine, LLC., is a commercial stage biotech company pioneering innovative treatments that aim to revolutionize aesthetics and wound care through skin rejuvenation and regeneration, so that patients can rediscover the joy of healthy skin and natural beauty. LRM is advancing the $100 billion aesthetics and wound-care markets by leveraging our regenerative medicine heritage, and our decades-long commitment to safe and effective regenerative products of the highest quality. LRM's first solution to come to the market, Ariessence™ Pure PDGF+ (www.ariessence.com), is on the market today and can be found in leading innovative med/spa clinics, and other aesthetic focused offices including dermatology and plastic surgery practices. The company was founded in 2023 by Dr. Samuel Lynch and is based in Franklin, Tennessee.

Select Safety Information for REGRANEX® Gel

REGRANEX is the only FDA-approved PDGF indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. REGRANEX is indicated as an adjunct to, and not a substitute for, good ulcer care practices. Limitations of use:

- The efficacy of REGRANEX has not been established for the treatment of pressure ulcers and venous stasis ulcers.
- The effects of REGRANEX gel on exposed joints, tendons, ligaments, and bone have not been established in humans.
- REGRANEX gel is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention.

Contraindication: REGRANEX is contraindicated in patients with known neoplasm(s) at the site(s) of application.

Warnings and Precautions: The benefits and risks of treatment should be carefully evaluated before prescribing in patients with known malignancy.

If application site reactions occur, consider the possibility of sensitization or irritation caused by parabens or mcresol. Interrupt treatment and evaluate (e.g. patch testing) as appropriate.

For complete product information, please see the REGRANEX Full Prescribing Information.

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