



To Whom It May Concern

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NANO MRNA Co., Ltd.
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(C o d e N o . 4 5 7 1)

RUNX1 mRNA, a disease modifier for knee osteoarthritis
Study plan submitted for initiation of Phase 1 clinical trial

NANO MRNA is pleased to announce that PrimRNA AU Pty Ltd, an Australian subsidiary of its subsidiary PrimRNA Inc., has submitted the Phase 1 trial plan of RUNX1 mRNA, an mRNA-based knee osteoarthritis (OA) drug to the Human Research Ethics Committees (HREC) for the initiation of the trial

The Therapeutic Goods Administration (TGA), Australia's regulatory authority, delegates scientific and ethical review of research involving human subjects, such as clinical trials, to the HREC. Once the HREC approves the Phase I clinical trial plan, the trial can begin with the electronic registration with the TGA. We expect to obtain HREC approval in about six weeks and then proceed smoothly with patient registration.

Phase 1 clinical trial

Target patients:	Knee OA patients scheduled for arthroplasty*
Endpoints:	Safety and Tolerability
Exploratory evaluation:	Biomarker analysis including expression of genes related to cartilage regeneration
Study design:	Single dose, dose escalation study (intra-articular administration)

* RUNX1 mRNA is intended for patients with mild to moderate knee osteoarthritis. However, in this trial, the expression of RUNX1 protein and genes related to cartilage regeneration will be observed following the administration of RUNX1 mRNA, in addition to safety and tolerability evaluation. Therefore, the trial will target severe knee OA patients who are scheduled to undergo joint replacement surgery.

RUNX1 mRNA

A DDS formulation of mRNA encoding RUNX1, a transcription factor that promotes cartilage regeneration.

It is a new type of osteoarthritis treatment for knee joints that is administered directly into the knee joint to promote the repair of damaged cartilage tissue.

Osteoarthritis of the knee

Osteoarthritis is a disease in which the cartilage in the knee wears away due to ageing and obesity, causing severe pain in the knee and making walking difficult. Currently, the only treatment available is a coping drug that aims to reduce pain, so the creation of disease-modifying drugs with cartilage-repairing properties is anticipated. The number of patients is increasing worldwide. The global market size is estimated at approximately USD 9.5 billion in 2024 and is expected to grow to USD 24.3 billion by 2034 (source: Towards HEALTHCARE). The emergence of disease-modifying drugs such as RUNX1 mRNA preparations is expected to further expand the market.

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