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Novo Nordisk
Zurich, Switzerland

cc. European Medical Agencies, EMA, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

30.7.2026

Re.: Nedosiran

Dear Yuen,

NovoNordisk has finally informed the community of physicians involved in pivotal studies about the discontinuation of the nedosiran program. For many of us, this came as a surprise; for some, it had been on the horizon after no real progress had been noticeable for quite some time.
We, the undersigned and our colleagues are aware that we have no influence over corporate decisions; nevertheless, we urgently want to express our dissatisfaction with the timing as well as the decision itself.
The majority of patients in the pivotal studies were from Europe, not the U.S., yet an application for approval was submitted only in the U.S. to the FDA. European patients—as well as patients from other countries—were thus „used“ for studies but will finally not receive benefit from their participation in the trials. Not only that, but the promise of continuing with the medication was suddenly withdrawn, even though it had initially been granted to all trial participants after end of study.
It should also be noted here that nedosiran certainly plays an important role in the treatment of PH1 patients. The therapeutic effect of lumasiran is not sufficient in all patients; cases of patients who showed no response at all have also been described in the literature. Not to mention patients with infantile oxalosis, where dual RNAi therapy clearly had a dramatic effect, and these young patients required only a kidney transplant!
Lumarisan is not fully reimbursed in every EU country (in Spain is not approved for patients with an eGFR below 45 or transplant patients), so that means that stopping the development of nedosiran would impact very negatively in many patients who will then be untreated.
Novo's main argument is primarily strategic. But, this decision of cessation of the nedosiran program outside the US is an unfair and unethical decision for patients suffering a very severe rare disease and mostly for those participating in the pivotal trials. It will be associated with lack of therapeutic alternatives in many cases.

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So, we have no choice but to voice our displeasure (loudly). This whole situation has not left a good impression. You can only regain your reputation here if you make it possible for someone else to take over the program as quickly as possible. That is why we must urge you to do so.

With our kind regards,

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