

Nogra Pharma announces out-licensing agreement with Torii Pharmaceutical for Japan for New Chemical Entity topical acne treatment

- *NAC-GED-0507 is a Phase III-ready New Chemical Entity (NCE), potential first-in-class treatment, selective PPAR γ modulator for topical treatment of acne*
- *Phase IIb trial demonstrated a superior safety and efficacy profile compared to standard of care. Results were published in the British Journal of Dermatology in October 2022*

Dublin, Ireland, 26 January 2023, Nogra Pharma (“Nogra” or “the Company”), a clinical stage biotechnology company developing innovative therapeutics for immune-inflammatory-mediated diseases, today announces it has entered into an out-licensing agreement with Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551), to further develop and commercialise NAC-GED-0507 in Japan for the treatment of acne vulgaris.

Under the agreement, [for which financial terms are not being disclosed], Torii Pharmaceuticals will gain exclusive development and commercialisation rights for NAC-GED-0507 in Japan.

NAC-GED-0507 is an IP protected, Phase III-ready, small molecule selective modulator of the peroxisome proliferation-activated receptor γ (PPAR γ), which has been developed by Nogra Pharma in a gel formulation, ideal for topical treatment of acne vulgaris. NAC-GED-0507 has a novel mechanism of action, which acts on the primary pathogenetic factors of acne, with demonstrated: anti-inflammatory activity in both sebocytes and keratinocytes, sebogenesis-modulating activity in sebocytes, capability to “normalize” keratinocytes proliferation/differentiation process, altered by pro-inflammatory cytokines, and effect of induction of sebocytes differentiation.

The late-stage clinical development plan has been agreed with the US Food & Drug Administration (FDA) and the European Medicines Agency (EMA).

Acne vulgaris is a skin condition that affects 85% of the adolescent and young adult population and is one of the most common skin diseases, with an estimated global prevalence (for all ages) of nearly 10% of the population¹. Despite its high prevalence, innovation in the space has been limited in recent years with NAC-GED-0507 being the first innovative treatment, based on its pharmacological properties, developed in the last 25 years.

Leopoldo Zambelletti, Director of Nogra Pharma Ltd, commented: *“The agreement with Torii Pharmaceuticals is a testament to the high quality of our scientific network and our development and formulation expertise. At Nogra Pharma, we are committed to using this expertise to develop novel therapeutics agents for the treatment of immune-inflammatory-mediated diseases with high unmet medical need and this agreement is a good step towards this goal.*

“We’re particularly excited to be exploring innovative pathways in acne, a significant unmet need. If approved, NAC-GED-0507 will be the first new drug for acne in decades, which acts via a novel mechanism of action and has the potential to be the first “disease-modifying agent” for millions of patients affected by the condition worldwide. We’re delighted to be working with Torii, which has a leading position and reputation in dermatology, and look forward to progressing this molecule into development.”

Goichi Matsuda, Representative Director, President and Chief Executive Officer of Torii, commented: *“We are excited to partner with Nogra and add NAC-GED-0507 to Torii’s growing portfolio of products to treat dermatologic skin diseases with significant unmet need.*

The development of NAC-GED-0507 for the treatment of acne is a unique and new approach. Given the promising clinical data, we are confident that NAC-GED-0507 will provide a new treatment option for acne patients. We look forward to collaborating with Nogra and developing NAC-GED-0507 for the Japanese market.”



A double-blinded, randomised, vehicle-controlled, multi-centre Phase IIb study conducted on 450 patients with moderate-to-severe acne (registered on EudraCT [2018-003307-19](#)) demonstrated statistically superior efficacy of NAC-GED-0507 5% gel over placebo ($p < 0.0001$) in terms of IGA success rate and total lesion count and was well tolerated. Results of the study, which were published in the British Journal of Dermatology in October 2022, can be found [here](#).

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References

1.J.K.L. Tan, K. Bhate: A global perspective on the epidemiology of acne.
British Journal of Dermatology (2015)172(Suppl. 1), pp 3-12

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About Nogra Pharma

Nogra Pharma is a private, clinical stage biotechnology company developing innovative therapeutics for immune-inflammatory-mediated diseases. Led by a highly experienced team with expertise in drug development, Nogra Pharma in collaboration with its subsidiary PPM Services, identifies high-value targets and develops innovative medicines through partnerships with world-leading academic partners.

Through a deep understanding of immuno-inflammation, combined with formulation and manufacturing expertise the Company has generated a promising, diversified, commercial pipeline comprising three highly differentiated technology platforms, which can yield multiple assets in a range of indications with high unmet medical need.

The oligonucleotide platform has yielded the first oral formulation in the drug class for the treatment of inflammatory bowel disease (an antisense oligonucleotide to Smad7 mRNA which will re-enter clinical development under Nogra's lead), while the small molecule platforms AhR and SPARMM have yielded promising candidates for the treatment of immune-inflammatory conditions and fibrosis, in skin, gastrointestinal and pulmonary disease.

Headquartered in Dublin, Ireland, the Company operates a lean business model of early drug development, up to Phase IIb, before outsourcing assets to pharma partners.





About Torii Pharmaceutical

Torii Pharmaceutical Co., Ltd. operate business from day to day in line with Torii Pharmaceutical's Purpose: "We are committed to sincerely serving patients, their families, and those involved in medical care.

We contribute to the healthy recovery of patients, as well as to a happy, enriched life free from fear of illness. We will flexibly change and adapt to meet the needs of the times and the environment, while retaining the trust we have earned over our long history, and we will continue to take on the challenge of contributing to healthcare that only we can make."

Torii focuses on Renal diseases, Hemodialysis, Allergy and Skin diseases as its therapeutic areas of importance. Torii is a member of Japan Tobacco Inc. (JT) group. Collaboration with JT takes the form of functional focus, with JT undertaking R&D on new compounds and Torii integrating manufacture and marketing.

In addition to Torii's independent activities, Torii's partnership with JT includes in-licensing of high-quality pharmaceuticals.

