
SLCTR/2025/040: Notification of Study Termination

Registry Remediumone <registry@remediumone.com>

Tue, Aug 18, 2026 at 2:26 PM

To: SLCTR Sri Lanka <srilankactr@gmail.com>

Cc: Sonali liyanagamage <sonali@remediumone.com>, Dinushi Dias <dinushi@remediumone.com>

18 Aug 2026

Sri Lanka Clinical Trials Registry
Sri Lanka Medical Association
[6, Wijerama Mawatha](#)
Colombo 07

Dear Sir/ Madam,

Protocol Title A Phase III, 52-week, Prospective, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center study, with a primary efficacy endpoint at 12 weeks, to determine the efficacy, safety, and tolerability of fixed doses of 15 mg bid and 30 mg bid of Evenamide as add-on in patients with documented Treatment-Resistant Schizophrenia, which is not adequately controlled by a stable therapeutic dose of the patient's current antipsychotic medication(s)

Subject Notification of Study Termination

The referenced study registered in Sri Lanka Clinical Trials Registry on 03 Oct 2026 (Registration No:SLCTR/2025/040).

The Sponsor has informed us that all required regulatory and ethics approvals and making every effort to initiate the study in Sri Lanka, the investigational medicinal product (IMP) could not be imported due to regulatory requirements related to the Certificate of Analysis and shelf-life verification. Despite extensive discussions with the relevant authorities to identify a suitable regulatory pathway, the required import clearance for the IMP could not be obtained.

Consequently, the Sponsor has decided to discontinue the study in Sri Lanka due to the inability to obtain the required import clearance for the IMP. As the study did not commence at the site, no participants were screened, enrolled, or treated. Furthermore, no investigational medicinal product was imported or dispensed, and no study-related procedures or activities involving participants were conducted.

We sincerely apologize for any inconvenience caused and greatly appreciate the time, effort, and support extended by the Committee throughout the review and study start-up process.

Please find enclosed the Sponsor's letter confirming the withdrawal of the study in Sri Lanka & the ERC Acknowledgment letter for your reference.

This is for your information and notification.

Please acknowledge the receipt of this notification.

Thank you!

Kind Regards,
Regulatory team
Dinushi Dias

2 attachments

 **Sri Lanka Termination Letter_Signed.pdf**
77K

 **TRS(023)_REG_23 - Notification of Study termination_EC_ACK.pdf**
939K

Sponsor: Newron Pharmaceuticals S.p.A.
Protocol number: NW-3509/023/III/2024
Study Name: Study 023
Study Title: A Phase III, 52-week, prospective, randomized, double-blind, placebo-controlled, parallel-group, multi-center study, with a primary efficacy endpoint at 12 weeks, to determine the efficacy, safety, and tolerability of a fixed dose of 15 mg *bid* and 30 mg *bid* of evenamide as add-on in patients with documented treatment-resistant schizophrenia, which is not adequately controlled by a stable therapeutic dose of the patient's current antipsychotic medication(s)
Product: Evenamide

27 July 2026

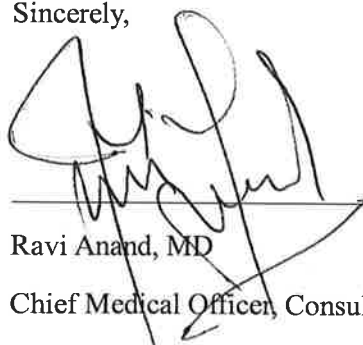
Subject: Withdrawal of Study NW-3509/023/III/2024 in Sri Lanka

Study NW-3509/023/III/2024 (Study 023) was formally discontinued in Sri Lanka on 27 July 2026 as the Investigational Medicinal Product (IMP) could not be imported due to unresolved regulatory requirements related to the Certificate of Analysis (CoA) and IMP shelf-life assessment. Although the study received ERC approval from the University of Kelaniya on 11 June 2025 and NMRA approval on 28 August 2025, and nine NMRA import licences were issued on 30 September 2025 (valid until 17 September 2026), the required import clearance was not obtained for the IMP.

The Import Control Agency required the CoA to clearly indicate the manufacturing date and expiry date of the drug substance to verify the remaining shelf life at the time of importation. The Sponsor clarified that the CoA reflected the retest date for the bulk packaging, while the final IMP expiry date was assigned based on available stability data for the final clinical trial packaging. However, the absence of a CoA meeting the Import Control requirements prevented completion of the import approval process. As a result, the IMP was not imported into Sri Lanka, and no patients were enrolled in the study.

The Sponsor therefore decided to discontinue the trial in Sri Lanka despite obtaining regulatory approvals and the commitment of investigators and study staff. The Sponsor plans a future manufacturing campaign for evenamide, and Sri Lanka is expected to participate in future clinical studies. The Sponsor expressed appreciation to the NMRA, ERC, investigators, and site staff for their support during the study start-up process.

Sincerely,



Ravi Anand, MD
Chief Medical Officer, Consultant
Newron Pharmaceuticals SpA

Prof. Shehan Williams

MBBS (Jaffna), MD (Psychiatry) (Colombo), MPhil (Kelaniya), FRCPsych (UK)

Consultant Psychiatrist

Colombo North Teaching Hospital

Ragama

03 Aug 2025

Chairperson
Ethics Review Committee
Faculty of Medicine
University of Kelaniya
Ragama, 11010

Dear Sir,

Protocol number NW-3509/023/III/2024

Protocol Title A Phase III, 52-week, Prospective, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center study, with a primary efficacy endpoint at 12 weeks, to determine the efficacy, safety, and tolerability of fixed doses of 15 mg bid and 30 mg bid of Evenamide as add-on in patients with documented Treatment-Resistant Schizophrenia, which is not adequately controlled by a stable therapeutic dose of the patient's current antipsychotic medication(s)

Subject Notification of study termination

The referenced study received approval from Ethics Review Committee, Faculty of Medicine, University of Kelaniya on 11 Jun 2025.

The Sponsor has informed us that all required regulatory and ethics approvals and making every effort to initiate the study in Sri Lanka, the investigational medicinal product (IMP) could not be imported due to regulatory requirements related to the Certificate of Analysis and shelf-life verification. Despite extensive discussions with the relevant authorities to identify a suitable regulatory pathway, the required import clearance for the IMP could not be obtained.

Consequently, the Sponsor has decided to discontinue the study in Sri Lanka due to the inability to obtain the required import clearance for the IMP. As the study did not commence at the site, no participants were screened, enrolled, or treated. Furthermore, no investigational medicinal product was imported or dispensed, and no study-related procedures or activities involving participants were conducted.

We sincerely apologize for any inconvenience caused and greatly appreciate the time, effort, and support extended by the Committee throughout the review and study start-up process.

Please consider this letter as the formal notification of study termination and withdrawal/closure of the ERC submission pertaining to the above-mentioned study.

Prof. Shehan Williams
MBBS (Jaffna), MD (Psychiatry) (Colombo), MPhil (Kelaniya), FRCPsych (UK)
Consultant Psychiatrist
Colombo North Teaching Hospital
Ragama

Please find enclosed the Sponsor's letter confirming the withdrawal of the study in Sri Lanka for your reference.

This is for your information and notification.

Yours Faithfully,



Prof. Shehan Williams
Coordinating Principal Investigator

CC:

Dr. Gayani Punchihewa
Prof. Sambasivamoorthy Sivayokan

Enclosed:

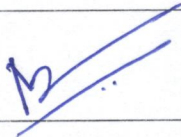
Document	Version details
Study withdrawal letter	N/A

Please be kind enough to acknowledge receipt of this document.

ERC Acknowledgement

Name : Dr. K. M. N. Perera

Designation : _____

Signature : 

Date : 11/08/2026

SECRETARY
Ethics Review Committee
Faculty of Medicine
University of Kelaniya