

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2023/021

Scientific title of trial: A Phase 2b/3, Multi-part, Randomized, Double-Blinded, Placebo-Controlled study to Evaluate the Efficacy and Safety of Atacicept in Subjects with IgA Nephropathy (IgAN)

Date of commencement (enrolment of first participant): 01 Jul 2024

Progression: 6 months 1 year 2 years 3 years
At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruiting

Number assessed for eligibility: 15

Number recruited and allocated/**randomized**: 07

Number allocated/randomized to each intervention/arm (please edit as relevant): Not applicable as this is a double blinded study.

Arm 1:

Arm 2:

Losses/exclusions after allocation/randomization (please edit as relevant): Not applicable as this is a double blinded study.

Arm 1:

Arm 2:

3. Trial output

Date of trial completion ("last patient, last visit"): N/A

Final sample size:

Summary of Interim/Final data (if available):

--

Abstract presentations of results at scientific meetings

Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
Long-term Results from the ORIGIN Phase 2b Study of Atacicept for the Treatment of IgAN	Jonathan Barratt, ¹ Sean Barbour, ² Robert Brenner, ³ Kerry Cooper, ³ Xuelian Wei, ³ Necmi Eren, ⁴ Jürgen Floege, ⁵ Vivekanand Jha, ⁶ Sung Gyun Kim, ⁷ Bart Maes, ⁸ Richard Phoon, ⁹ Harmeet Singh, ¹⁰ Vladimir Tesar, ¹¹ Richard Lafayette ¹² Kidney Week 2024, 26 Oct 2024 Journal of the American Society of Nephrology
Impact of Atacicept on Hematuria in IgA Nephropathy: Post-Hoc Analysis of The Phase 2b ORIGIN Study	Jürgen Floege ¹ , Jonathan Barratt ² , Bart D. Maes ³ , Celia J.F. Lin ⁴ , Xuelian Wei ⁴ , Sean Barbour ⁵ , Richard K. Phoon ⁶ , Sung Gyun Kim ⁷ , Vladimir Tesar ⁸ , Vivekanand Jha ⁹ , Shikha Wadhvani ¹⁰ , Richard A. Lafayette ¹¹ 61 st ERA Congress – Stockholm and Virtual 23 rd – 26 th May 2024
ORIGIN 3: Pivotal Phase 3 Study Evaluating Effect of Atacicept vs Placebo on Proteinuria and Renal Function Preservation in IgAN	Jonathan Barratt ¹ , Bart D. Maes ² , Rubeen K. Israni ³ , Xuelian Wei ³ , Jürgen Floege ⁴ , Vivekanand Jha ⁵ , Vladimir Tesar ⁶ , Hong Zhang ⁷ , Sean Barbour ⁸ , Hitoshi Suzuki ⁹ , Hernan Trimarchi ¹⁰ , Celia J.F. Lin ³ , Richard A. Lafayette ¹¹ World Congress of Nephrology 2024, Abstract 1414 13 th – 16 th April 2024, Buenos Aires - Argentina

Atacicept Reduces Hematuria and Serum Gd-IgA1, Both Associated with Long-term Renal Outcomes in IgAN: 36 Week Results from the Phase 2b ORIGIN Study	Jonathan Barratt ¹ , Bart D. Maes ² , Celia J.F. Lin ³ , Xuelian Wei ³ , Sean Barbour ⁴ , Richard K. Phoon ⁵ , Sung Gyun Kim ⁶ , Vladimir Tesar ⁷ , Jürgen Floege ⁸ , Vivekanand Jha ⁹ , Richard A. Lafayette ¹⁰ World Congress of Nephrology 2024, Abstract 1294 13 th – 16 th April 2024, Buenos Aires - Argentina
Atacicept Reduces Hematuria and Serum Gd-IgA1, Both Associated with Long-term Renal Outcomes in IgAN: 36 Week Results from the Phase 2b ORIGIN Study	Jonathan Barratt ¹ , Bart D. Maes ² , Celia J.F. Lin ³ , Xuelian Wei ³ , Sean Barbour ⁴ , Richard K. Phoon ⁵ , Sung Gyun Kim ⁶ , Vladimir Tesar ⁷ , Jürgen Floege ⁸ , Vivekanand Jha ⁹ , Richard A. Lafayette ¹⁰ American Society of Nephrology SA-PO887
ORIGIN 3: Pivotal Phase 3 Study Evaluating Effect of Atacicept vs Placebo on Proteinuria and Renal Function Preservation in IgAN	Jonathan Barratt ¹ , Bart D. Maes ² , Rubeen K. Israni ³ , Xuelian Wei ³ , Jürgen Floege ⁴ , Vivekanand Jha ⁵ , Vladimir Tesar ⁶ , Hong Zhang ⁷ , Sean Barbour ⁸ , Hitoshi Suzuki ⁹ , Hernan Trimarchi ¹⁰ , Celia J.F. Lin ³ , Richard A. Lafayette ¹¹ American Society of Nephrology INFO17-TH

Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
A phase 2b, randomized, double-blind, placebo-controlled, clinical trial of atacicept for treatment of IgA nephropathy	Richard Lafayette ¹ , Sean Barbour ² , Rubeen Israni ³ , Xuelian Wei ⁴ , Necmi Eren ⁵ , Jürgen Floege ⁶ , Vivekanand Jha ^{7,8,9} , Sung Gyun Kim ¹⁰ , Bart Maes ¹¹ , Richard K.S. Phoon ¹² , Harmeet Singh ¹³ , Vladimir Tesar ¹⁴ , Celia J.F. Lin ¹⁵ and Jonathan Barratt ¹⁶ DOI - 10.1016/j.kint.2024.03.012 Kidney International (2024) Volume 105, Issue 6 p1306-1315, June 2024



.....
Name and signature of Responsible Registrant/
Principal Investigator: Dr. A.L.M. Nazar

Date: 12 Dec 2024