UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

November 2026

Commission File Number: 001-38723

Tiziana Life Sciences LTD
(Exact Name of Registrant as Specified in Its Charter)

9th Floor
107 Cheapside
London
EC2V 6DN
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On November 9, 2026, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing, additional context on the positive topline results from its Phase 2a INFORM-MS trial, building on the highly engaged Key Opinion Leader (KOL) investor call held on Monday, November 9, 2026. The November 9 call, featuring principal investigator, Tanuja Chitnis, M.D., Tarun Singhal, MBBS, M.D., M.B.A., and Howard L. Weiner, M.D., reviewed the dual primary endpoint success of INFORM-MS and generated strong participation from the investment and scientific communities.

The Announcement and presentation is furnished herewith as Exhibit 99.1 and 99.2 to this Report on Form 6-K. The information in the attached Exhibits 99.1 and 99.2 are being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TIZIANA LIFE SCIENCES LTD

Date: November 9, 2026

By: /s/ Keeren Shah
Name: Keeren Shah
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Tiziana Life Sciences LTD Press Release, dated November 9, 2026
99.2	Tiziana Life Sciences LTD Presentation, dated November 9, 2026

Exhibit 99.1

Tiziana KOL Call Highlights Consistency Between Positive Phase 2a INFORM-MS Topline Results and Longer-Term Clinical Benefits Observed in Expanded Access Program for Patients with Non-Active Secondary Progressive Multiple Sclerosis Treated with Intranasal Foralumab

BOSTON, MA, November 9, 2026 – Tiziana Life Sciences, Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies with its lead development candidate, intranasal foralumab, a fully human anti-CD3 monoclonal antibody, today provided additional context on the positive topline results from its Phase 2a INFORM-MS trial, building on the Key Opinion Leader (KOL) investor call held on Monday, November 9, 2026.

The November 9 call, featuring principal investigator, Tanuja Chitnis, M.D., Tarun Singhal, MBBS, M.D., M.B.A., and Howard L. Weiner, M.D., reviewed the dual primary endpoint success of INFORM-MS with the investment and scientific communities.

Key points emphasized during the discussion included:

- INFORM-MS placebo-controlled 12-week findings confirmed longer-term real-world data trends seen in patients treated for up to 3 years in the foralumab expanded access (EA) program, including EDSS stabilization and improvement in patients with treatment-refractory na-SPMS progressing via PIRA.
- Statistically significant reduction in microglial activation on [^{18}F]PBR06 TSPO PET imaging with the 50 µg dose versus placebo (p=0.0168)—the dose for which this arm was powered for statistical significance.
- The positive signals in the 50 µg dose (n=19) supporting a potential effect on the chronic neuroinflammation underlying progression independent of relapse activity (PIRA).
- 100 µg dose was exploratory to assess immunomodulatory effects as previous Phase 1 observations showed that higher doses (e.g., 250 µg) had less immunomodulatory effects relative to 50 µg. Fewer patients (n=11) were enrolled in this arm to meet study timelines.

- Favorable safety and tolerability profile of intranasal foralumab as the first non-invasive anti-CD3 therapy at both doses studied.

- Clinically meaningful and statistically significant improvements in Modified Fatigue Impact Scale (MFIS) scores from baseline in both dose arms after only 12 weeks (50 μg: –6.17 points, p=0.035; 100 μg: –7.18 points, p=0.040), an endpoint for which the study was not powered, yet which exceeded the threshold for clinical relevance.

These early signals closely mirror the biological and clinical effects previously observed in the Company's open-label expanded access program. In the peer-reviewed paper "Nasal Foralumab for the Treatment of Progression Independent of Relapses in Patients With Nonactive Secondary Progressive Multiple Sclerosis" (Chitnis et al., Neurol Neuroimmunol Neuroinflamm 2026;13:e200543), ten patients with treatment-refractory na-SPMS who continued to progress despite B-cell therapy received nasal foralumab for a minimum of six months.

Key findings in the expanded access program included:

- All 10 patients stabilized on Expanded Disability Status Scale (EDSS) scores.

- Three of four patients treated continuously for 12 months demonstrated improvement on EDSS.

- Seven of ten patients showed improvement in fatigue on the MFIS scale after 6 months of foralumab treatment.

- No study drug related serious adverse events have been seen in more than 37.4 patient-years of cumulative exposure.

- Reduction in TSPO-PET signal over six months ($p < 0.05$), consistent with dampened microglial activation.

- Induction of regulatory immune responses, including increased TGFβ expression across multiple cell subsets.

- No anti-drug antibodies (ADAs) were detected in any serum samples evaluated from patients at multiple time points (baseline through 15–17 months for the longest-treated patients, and through 6 months for others).

Updated data from the ongoing intermediate-size EA program (now encompassing 14 patients, with some treated for up to three years) continues to show favorable tolerability over extended treatment durations, with trends toward disability stabilization and clinically meaningful fatigue improvements, further reinforcing the absence of immunogenicity concerns.

“The primary imaging endpoint on TSPO PET in the 50 µg nasal foralumab treatment arm from the INFORM-MS study closely mirrors the reductions in microglial activation we previously published in our expanded access program, providing important corroboration in a placebo-controlled study,” said Tanuja Chitnis, M.D., Principal Investigator of INFORM-MS and Professor of Neurology at Harvard Medical School and Brigham and Women’s Hospital. “Equally encouraging is the clinically significant improvement in fatigue as measured by MFIS, despite the short 12-week treatment duration in the Phase 2 trial. These findings, together with the complete absence of anti-drug antibodies even with prolonged dosing, the longer-duration clinical stabilization and improvement seen in the expanded access patients, underscore the therapeutic potential of nasal foralumab in a population with no FDA-approved therapies specifically indicated for na-SPMS.”

Ivor Elrifi, Chief Executive Officer of Tiziana Life Sciences, commented: “The industry and scientific community interest in our November 9 KOL call underscores the significance of these data. The consistency between the placebo-controlled 12-week Phase 2a results and the real-world, longer-term experience in our expanded access program strengthens our conviction in intranasal foralumab. Early biological activity on PET and clinically meaningful fatigue improvements after only three months align with the clinical benefits, including EDSS stabilization and improvement, observed with sustained dosing beyond six and twelve months. We look forward to completing the full analysis of the INFORM-MS dataset, discussing next steps with the FDA, and advancing this program for patients who currently have limited options.”

Non-active secondary progressive multiple sclerosis (na-SPMS) is defined by the gradual accumulation of disability independent of clinical relapses or new inflammatory MRI activity—a process known as progression independent of relapse activity (PIRA).

PIRA is now recognized as the predominant driver of long-term disability accumulation across the MS spectrum. In treated relapsing-remitting MS, PIRA accounts for the large majority (approximately 70–90%) of confirmed disability worsening events, even when relapses and new lesions are effectively controlled by high-efficacy disease-modifying therapies. In the progressive phase, PIRA becomes the defining clinical feature.

Unlike relapse-associated worsening, which is driven by focal inflammatory demyelination, PIRA is thought to reflect chronic, compartmentalized (“smoldering”) neuroinflammation within the central nervous system, involving persistent microglial activation, gradual axonal injury, and loss of neural reserve. Current disease-modifying therapies, which primarily target peripheral adaptive immunity and acute inflammatory activity, have shown limited ability to halt or reverse PIRA. As a result, many patients continue to experience irreversible disability progression, worsening fatigue, and functional decline despite optimal control of relapses and MRI activity.

There are currently no FDA-approved therapies specifically indicated for na-SPMS or for the treatment of PIRA. This represents one of the most significant remaining unmet needs in multiple sclerosis. Patients with non-active secondary progressive disease have limited therapeutic options once they transition beyond the relapsing phase, and existing agents approved for progressive MS have demonstrated only modest benefits, primarily in patients with residual inflammatory activity.

Tiziana plans to present detailed findings from INFORM-MS at an upcoming scientific meeting and continues to evaluate the broader development path for intranasal foralumab in progressive MS and other neurodegenerative indications.

About Foralumab

Foralumab, a fully human anti-CD3 monoclonal antibody, is a biological drug candidate that has been shown to stimulate T regulatory cells when dosed intranasally. At present, 14 patients with Non-Active Secondary Progressive Multiple Sclerosis (na-SPMS) have been dosed in an open-label intermediate sized Expanded Access (EA) Program (NCT06802328) with either an improvement or stability of disease seen within 6 months in all patients. Intranasal foralumab is also currently being studied in additional Phase 2 trials in AD, ALS, and MSA.

Intranasal foralumab is the only fully human anti-CD3 monoclonal antibody (mAb) currently in clinical development. Immunomodulation by intranasal foralumab represents a novel avenue for the treatment of neuroinflammatory and neurodegenerative human diseases.[1],[2]

About Tiziana Life Sciences

Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. Tiziana's innovative intranasal approach has the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's lead candidate, intranasal foralumab, which is the only fully human anti-CD3 mAb currently in clinical development, has demonstrated a favorable safety profile and clinical response in patients in studies to date. Tiziana's technology for alternative routes of immunotherapy has been patented with several applications pending and is expected to allow for broad pipeline applications.

For more information about Tiziana Life Sciences and its innovative pipeline of therapies, please visit www.tizianalifesciences.com.

[1] https://www.pnas.org/doi/10.1073/pnas.2220272120

[2] https://www.pnas.org/doi/10.1073/pnas.2309221120

Forward-Looking Statements

Statements in this press release may be "forward-looking statements" within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry; its beliefs; and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These forward-looking statements reflect the current beliefs and expectations of Tiziana's management and statements regarding completion of the INFORM-MS data analysis, presentation of detailed results, engagement with the FDA and potential further clinical development of intranasal foralumab. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this announcement. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled 'Risk Factors' in Tiziana's Annual Report on Form 20-F for the year ended December 31, 2025, and other periodic reports filed with the SEC from time to time. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

For further inquiries:

Tiziana Life Sciences Ltd
Paul Spencer, Business Development, and Investor Relations
+44 (0) 207 495 2379
email: info@tizianalifesciences.com

INFORMS-MS
A Phase 2 Placebo Controlled, Double Blind Trial of Intranasal Foralumab

Non-active Secondary Progressive Multiple Sclerosis (na-SPMS)

KOL Call
November 9th 2026



Nasdaq: TLSA

INFORM-MS KOL Call: Forward-Looking Statements and Important Information

Forward-Looking Statements. This presentation may contain forward-looking statements within the meaning of applicable U.S. federal securities laws, including Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These include statements regarding the interpretation and potential implications of INFORM-MS findings, the therapeutic potential of intranasal foralumab, completion and presentation of additional analyses, dose selection, future trial designs, development timelines and planned regulatory discussions.

Forward-looking statements reflect current expectations and assumptions, are not guarantees of future performance and involve risks and uncertainties that could cause actual results to differ materially. These include unsuccessful or inconclusive clinical results; differences between preliminary and final analyses; unexpected safety findings; delays in trial initiation, enrollment or completion; regulatory requirements or decisions; inability to obtain sufficient financing; manufacturing and supply constraints; reliance on third parties; intellectual-property risks; and competition. These risks are not exhaustive, and new risks may emerge. The Company cannot predict all risks or assess the impact of every factor, or combination of factors, on its business. Additional risks are described under “Risk Factors” in the Company’s most recent Annual Report on Form 20-F and subsequent SEC filings. You should not place undue reliance on forward-looking statements.

All forward-looking statements are qualified by these cautionary statements and speak only as of the date of this presentation. Except as required by applicable law, the Company undertakes no obligation to publicly update or revise them, whether as a result of new information, future events or otherwise. Continued availability of this presentation on the Company’s website does not mean that its contents remain current.

Intranasal foralumab is investigational and is not approved for commercial use. Preliminary, early-stage and expanded-access findings may not predict results in larger or later-stage controlled trials. Any topline findings remain subject to completion of the full analysis. Open-label, uncontrolled and individual-patient observations do not establish efficacy. Cross-trial comparisons are subject to differences in study design, populations, endpoints and follow-up and do not establish comparative safety or efficacy. No assurance can be given that any product candidate will receive regulatory approval.

Other Information. Market and industry estimates are subject to assumptions and limitations and do not represent projected Company revenue. This presentation is for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities, or investment or medical advice. It should be read together with the Company’s SEC filings.

Purpose and Speaker Disclosures. This Company-sponsored presentation is for investor information and scientific discussion, not treatment guidance or an offer or solicitation involving securities. Scientific opinions expressed by individual speakers are their own; institutional affiliations do not imply institutional endorsement.

INFORM-MS Virtual KOL Call: Meet the Presenters



Tanuja Chitnis, M.D.

Principal Investigator of the INFORM-MS trial

Professor of Neurology, Harvard Medical School / Brigham and Women's Hospital



Tarun Singhal, M.B.B.S, M.D., M.B.A.

Founding Director, NeuroPET Program

Ann Romney Center for Neurologic Diseases, Brigham and Women's Hospital, Mass General Brigham

Associate Professor of Neurology, Harvard Medical School



Howard L. Weiner, M.D.

Chairman of Tiziana's Scientific Advisory Board

Robert L. Kroc Professor of Neurology, Harvard Medical School

Co-Director, Ann Romney Center for Neurologic Diseases, BWH



Ivor Elrifi, Ph.D.

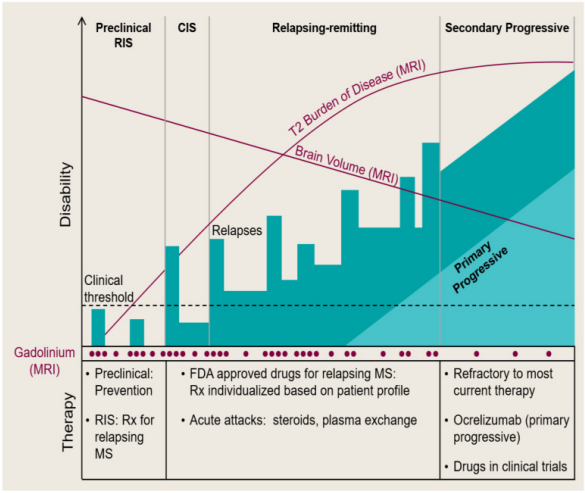
Chief Executive Officer & Executive Director

Tiziana Life Sciences

INFORM-MS: Major Unmet Need in Non-Active SPMS

- No FDA-approved therapies specifically indicated for non-active SPMS
- Patients with progression independent of relapses (PIRA) remain in need of effective therapy
- ~25% of RRMS patients progress to SPMS; substantial portion become non-active
- Fatigue is a major symptom impacting quality of life and daily function
- Current treatments primarily target active/relapsing disease (e.g., ocrelizumab)
- Intranasal foralumab uniquely targets microglial-driven neuroinflammation

Stages of Multiple Sclerosis



tiziana LIFE SCIENCES

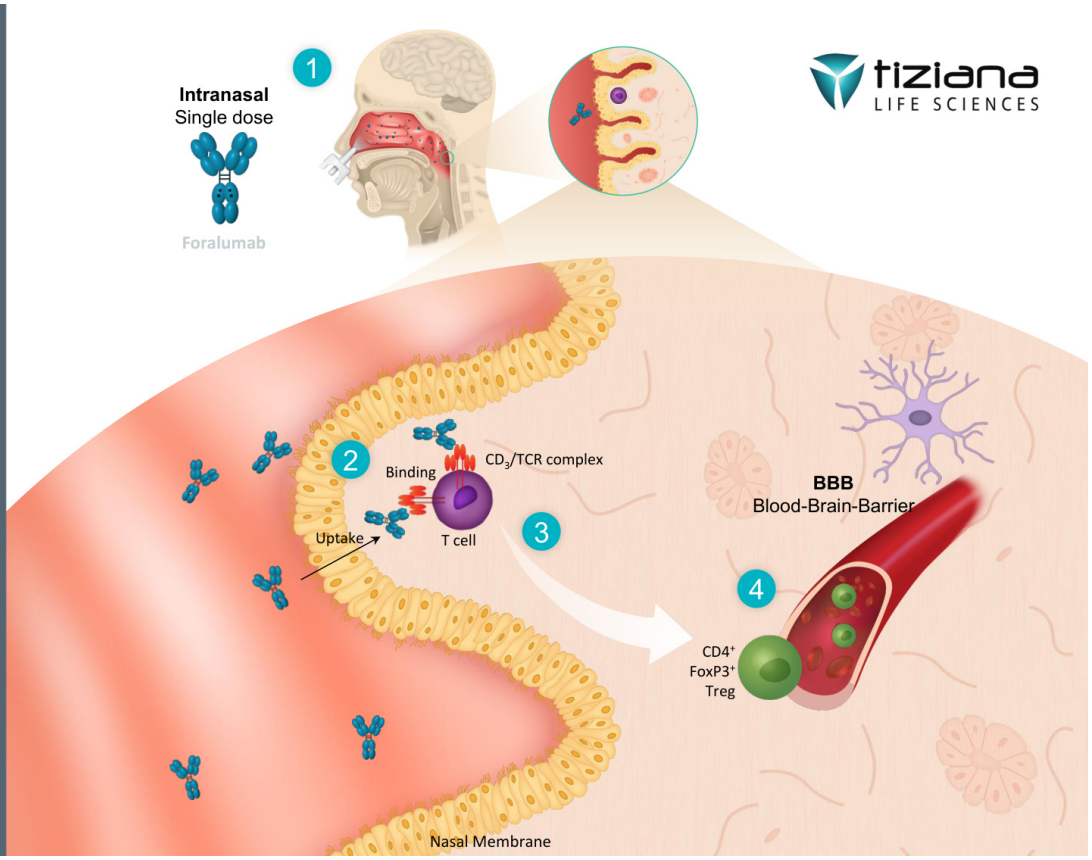
Foralumab: Mechanism of Action[1,2]

Patient inhales the antibody intranasally

Binding of foralumab to the T-cell receptor complex in cervical lymph node

Tregs are then created and activated

These created Tregs then cross the blood brain barrier and regulate the activated innate immune system (microglia).



[1] https://www.pnas.org/doi/10.1073/pnas.2220272120
[2] https://www.pnas.org/doi/10.1073/pnas.2309221120

EXPANDED ACCESS TRIAL

Intranasal Foralumab

Non-active Secondary Progressive Multiple Sclerosis (na-SPMS)



Positive Results With Nasal Foralumab in Expanded Access Program

No Toxicities

No treatment-related toxicities observed
No anti-drug antibodies detected in serum

TSPO PET

8 / 10

Patients Showed Reduced Neuroinflammation After 3 Months Treatment

Fatigue

7 / 10

Patients Improved After 6 Months Treatment

EDSS

10 / 10 Patients Stabilized After 6 Months Treatment

3 / 4 Patients Improved After 12 Months Treatment



RESEARCH ARTICLE OPEN ACCESS

Nasal Foralumab for the Treatment of Progression Independent of Relapses in Patients With Nonactive Secondary Progressive Multiple Sclerosis

Tanuja Chitnis,[1,2,3,*] Tarun Singhal,[1,2,3,4,*] Jonathan Zurawski,[1,2,3] Taylor J. Saraceno,[1] Nivedtha Gopalakrishnan,[1] Lauren Cain,[1] Brenna LaBarre,[1,2] Devin King,[1,2] Regan W. Bergmark,[1,5] Alice Z. Maxfield,[1,2] Steven Cicero,[1] Hong Pan,[1] Shipra Dubey,[1,6] Steven Vaquerano,[1] Caleb Hansel,[1] Brian C. Healy,[1,2] Shrishti Saxena,[1] Hrishikesh A. Lokhande,[1] Mosgeh Baharnoori,[1,2,3] Evan Samuel Madill,[1,2,3] Manali S. Sheth,[1,2,3] Rachel Rodin,[1,2,3] Jessica Ye,[1,2,3] Nancy Clement,[6] William A. Clements,[7] and Howard L. Weiner[1,2,3]

Correspondence
Dr. Chitnis
tchitnis@bwh.harvard.edu

Neurol Neuroimmunol Neuroinflamm 2026;13:e200543. doi:10.1212/NXI.0000000000200543

Abstract

Background and Objectives
Progression independent of relapses (PIRA) is a major therapeutic challenge in multiple sclerosis (MS). Nasal anti-CD3 treats animal models of progressive MS by inducing regulatory T cells (Tregs) that suppress CNS inflammation and lessen clinical disease.

Methods
Ten patients with nonactive secondary progressive MS (naSPMS) that continued to progress on B-cell therapy were treated with nasal anti-CD3 (foralumab) for a minimum of 6 months in an open-label study. Safety monitoring included otolaryngology evaluation and neurologic assessments including Expanded Disability Status Scale (EDSS), MS Functional Composite, Modified Fatigue Impact Scale (MFIS), California Verbal Learning Test, and Low Contrast Visual Acuity. MRI and microglial translocator protein (TSPO)-PET imaging with [F-18] PBR06 were conducted. Serum and CSF proteomic biomarkers and single-cell RNA sequencing of blood were performed to evaluate foralumab-induced immunomodulation. The end points of our study were safety, clinical effects, microglial signal, and immune measures.

Results
Our clinical observations were that all patients stabilized on EDSS scores and 3 of 4 patients treated continuously for 12 months had improvement on EDSS. Six of 10 patients had improvement in fatigue on the MFIS scale. There were no treatment-related serious adverse events or severe AEs, and no new T2 lesions were observed on MRI. There was a reduction in TSPO-PET signal over 6 months ($p < 0.05$). Changes in peripheral blood gene expression occurred as early as 3 months and affected antigen presentation, interferon responses, and regulatory pathways in multiple cell types including FoxP3+ Tregs, $CD4^+$ Tcm cells, $CD8^+$ Tem cells, $CD14^+$ and $CD16^+$ monocytes, and B cells. TGFβ expression was increased across multiple cell subsets.

Discussion
These findings identify a novel, nontoxic immune based therapy for the treatment for PIRA that acts by the induction of a regulatory immune responses and dampens microglial inflammation. Double-blind placebo-controlled trials are warranted to explore nasal foralumab for the treatment of naSPMS.

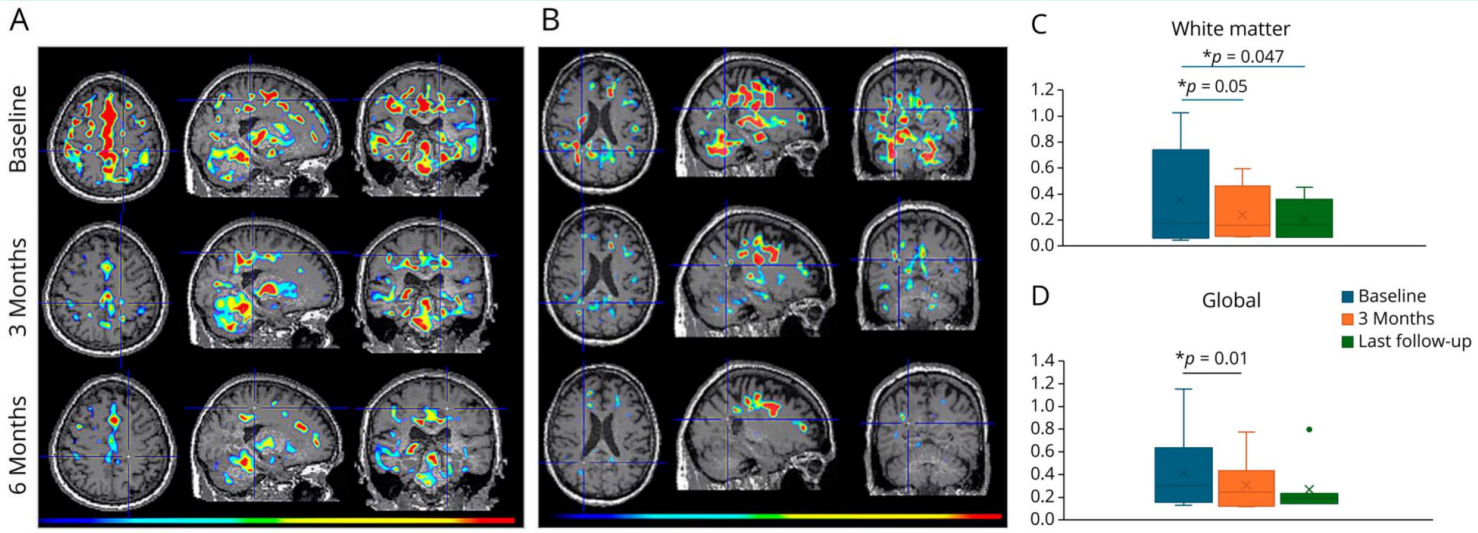
MORE ONLINE
Class of Evidence
Criteria for rating therapeutic and diagnostic studies
NPub.org/coe
Supplementary Material

*These authors contributed equally to this work as co-first authors.
[1]Harvard Medical School, Boston, MA; [2]Ann Romney Center for Neurologic Diseases, Brigham and Women's Hospital, Mass General Brigham, Boston, MA; [3]Brigham Multiple Sclerosis Center, Department of Neurology, Brigham and Women's Hospital, Mass General Brigham, Boston, MA; [4]Division of Nuclear Medicine, Department of Radiology, Brigham and Women's Hospital, Mass General Brigham, Boston, MA; [5]Department of Otolaryngology, Brigham and Women's Hospital, Mass General Brigham, Boston, MA; [6]Clement Associates, Bryn Mawr, PA; and [7]Tiziana Life Sciences, New York.

The Article Processing Charge was funded by the authors.

This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CC BY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Nasal Foralumab Reduced Neuroinflammation in Expanded Access Program



Reduced TSPO-PET signal after nasal foralumab treatment. Individualized pGALP z-score maps for patients EA6
(A) and EA1 (B) superimposed on respective patient's T1-weighted MRI demonstrate decreased PET signal after treatment at 3 months (middle row) and 6 months (bottom row) as compared with baseline (top row). Hotter colors represent a higher z-score value and cooler colors represent a lower z-score value as determined by the GALP 2.0 pipeline.
(C and D) White matter and global PET scores at baseline and on treatment. Decreased voxel-wise average [F-18] PBR06-PET mGALP z-scores (GALP 3.0) in white matter (C) and global (D) regions of interest after nasal foralumab treatment for 3 months and 7.5 months (mean duration of treatment at last available PET follow-up visit). GALP = Glial activity load on PET.

Neurol Neuroimmunol Neuroinflamm 2026;13:e200543. doi:10.1212/NXI.0000000000200543

Nasal Foralumab Modulates Immune Function

Molecular & Cellular Effects in Blood & CSF of na-SPMS Patients Treated with Nasal Foralumab

Results after 6 months nasal foralumab treatment
Increase in regulatory T cells (T_{regs})
Decrease in cytotoxic T cells
Reduced inflammation in spinal fluid

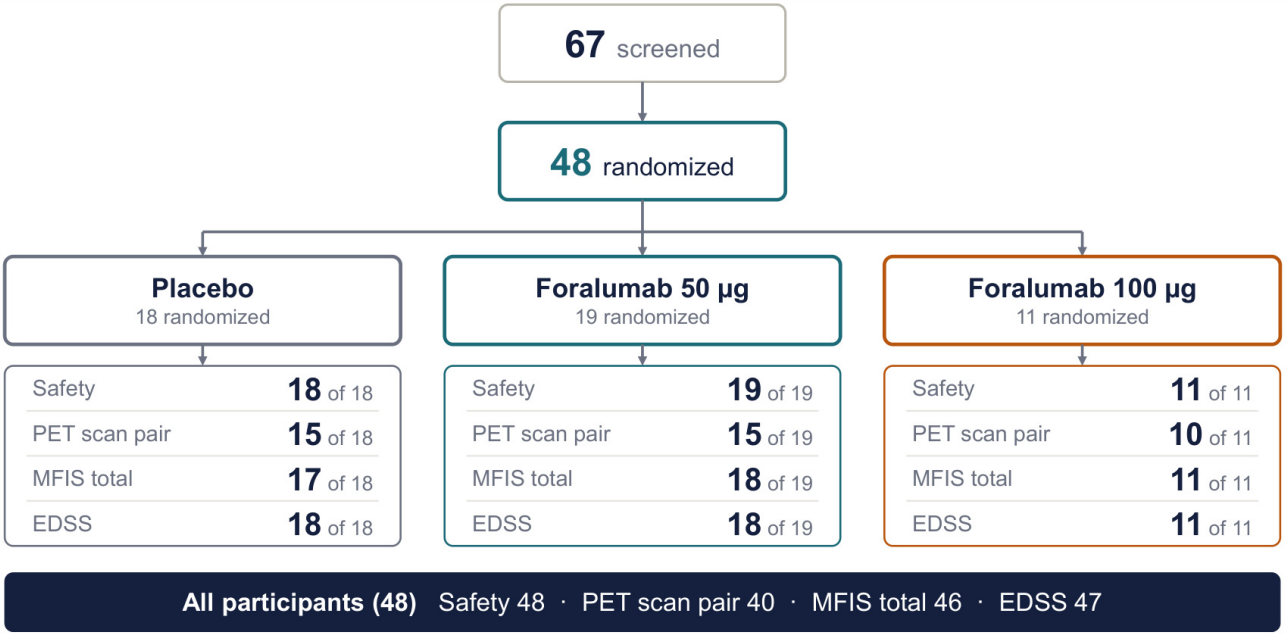
INFORMS-MS TOPLINE DATA

Phase 2 Placebo Controlled, Double Blind Trial of Intranasal Foralumab Confirms Results of EA Program

Non-active Secondary Progressive Multiple Sclerosis (na-SPMS)



INFORM-MS: Participant Flow and Evaluable Data



INFORM-MS: Topline Results Overview

Both primary endpoints (TSPO-PET Neuroinflammation and safety) were met. Secondary MFIS endpoint also met.

PET

Microglial Activation

50 µg vs Placebo

p = 0.0168

Statistically significant reduction in TSPO-PET signal demonstrating decreased microglial activation.

In an exploratory dose arm (100 µg) no significant change in PET signal. Fewer patients enrolled in this arm. Prior data with 250 µg also showed less immunomodulatory effects than the 50 µg dose.

FATIGUE (MFIS)

Clinically Meaningful

Change from baseline → Week 12

−6.17 / −7.18

50 µg (p=0.035) · 100 µg (p=0.040)

Within-arm paired improvements at both doses.

Fatigue is a key driver of quality of life in progressive MS.

SAFETY

Clean Profile

Both doses

No Drug Related SAEs

The first non-invasive anti-CD3 therapy shown to be safe and well tolerated

No study-drug related serious adverse events.

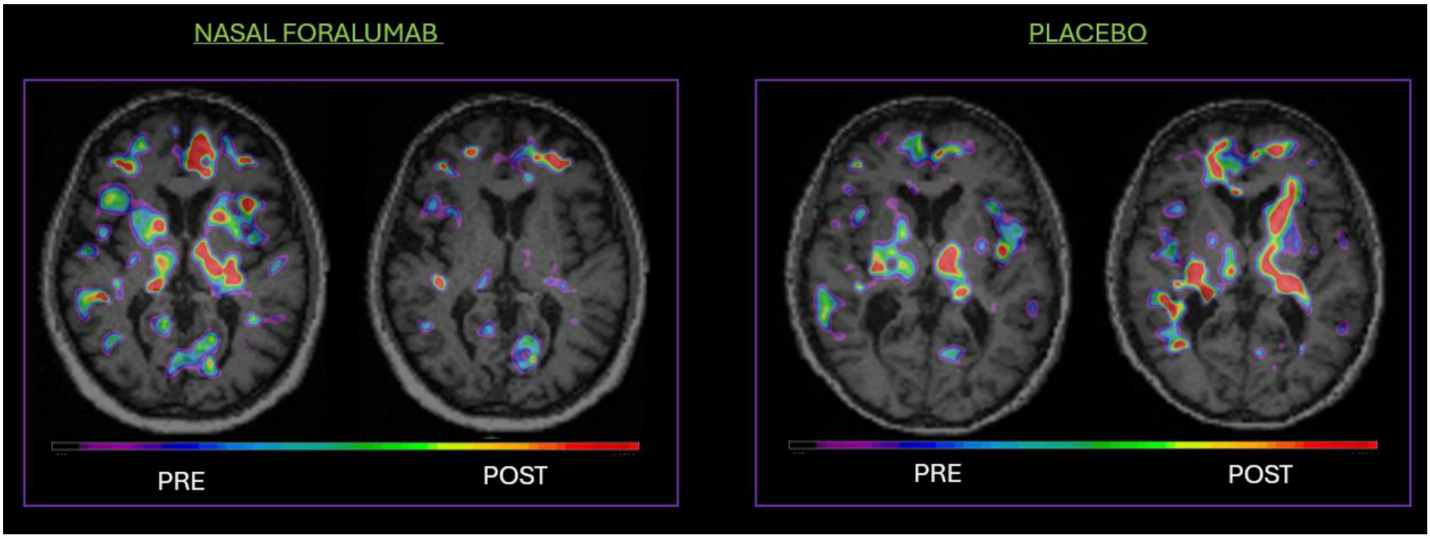
All 48 participants completed treatment

No discontinuations due to AEs.

All 48 participants completed the 12-week treatment period · Both doses safe and well-tolerated · Supports advancement toward registrational path

INFORM-MS: Neuroinflammation Was Statistically Significantly Reduced

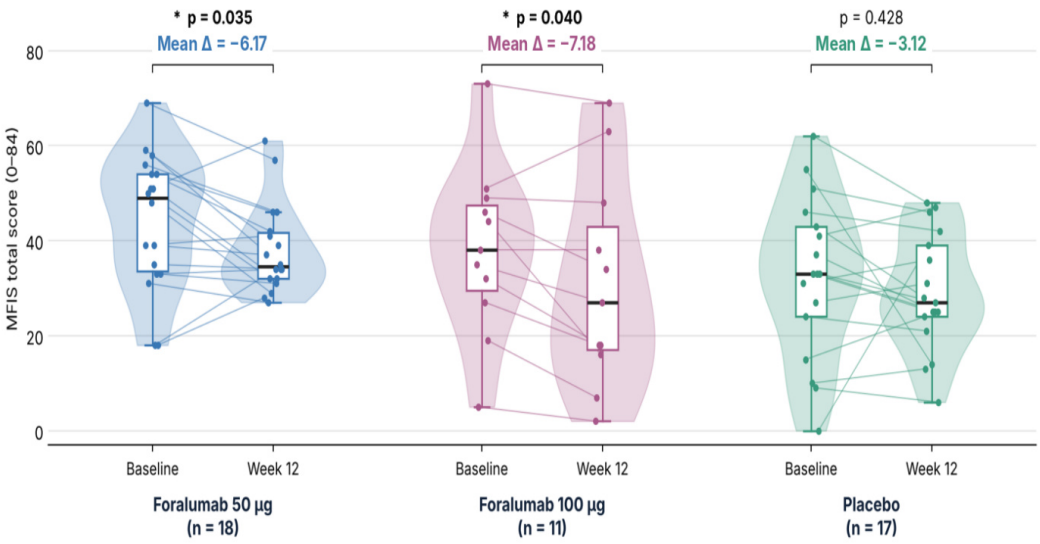
On ANCOVA analysis, [^{18}F]PBR06-TSPO PET demonstrated a significant reduction in globally normalized White Matter SUVR (p=0.0168) after 12 weeks of treatment between the 50 ug nasal foralumab treatment arm and placebo.



Examples of individualized patient mGALP z-score maps following treatment with 50mcg of nasal foralumab and with placebo

INFORM-MS: Nasal Foralumab Reduced Fatigue (Lowered Modified Fatigue Impact Scores; “MFIS”)

MFIS total score, baseline to Week 12





Multiple Sclerosis and Related Disorders 35 (2019) 158–163

Contents lists available at ScienceDirect

Multiple Sclerosis and Related Disorders

journal homepage: www.elsevier.com/locate/msard

Clinical trial

Minimally important difference of the fatigue severity scale and modified fatigue impact scale in people with multiple sclerosis

Scott Rooney[a,*], Dr Angus McFadyen[b], Dr Leslie Wood[a], Dr Fiona Moffat[c], Professor Lorna Paul[a]

[a] School of Health and Life Sciences, Glasgow Caledonian University, Cowcaddens Road, Glasgow G4 0BA, Scotland, UK
[b] AFM Stats, Statistical Consultant, Glasgow, Scotland, UK
[c] NHS Forth Valley, Scotland, UK

ARTICLE INFO

Key words:
Multiple Sclerosis
Fatigue
Minimally important difference
Fatigue Severity Scale
Modified Fatigue Impact Scale

ABSTRACT

Background: Fatigue is a common and debilitating symptom of Multiple Sclerosis (MS); however, it is unknown what constitutes a clinically significant change in fatigue. Establishing the minimally important difference (MID) of fatigue outcome measures can inform the interpretation of changes in fatigue by estimating the level of change that is considered clinically relevant.

Aim: Determine the MID for the Fatigue Severity Scale (FSS) and Modified Fatigue Impact Scale (MFIS) in people with MS.

Methods: This cross-sectional study collected information on self-reported fatigue (FSS and MFIS) and quality of life (EQ-5D and MS Impact Scale 29) through an online survey. Anchor-based methods were used to estimate MID, and ordinal logistic regression models were used to determine the difference in fatigue that would predict a significant effect on quality of life.

Results: 365 people with MS (81.9% female, 69.3% relapsing-remitting MS, mean age 46.2 ± 11.6 years, mean time since diagnosis 9.6 ± 8.7 years) responded to the survey. MID estimates for the FSS and MFIS ranged from 0.45–0.88 and 3.86–8.11 respectively, accounting for 6.4–12.6% of maximum FSS score and 4.6–9.7% of maximum MFIS score.

Conclusions: MID estimates derived from this study indicate that a difference of at least 0.45 points on the FSS or 4 points on the MFIS constitutes a clinically significant difference in fatigue. Therefore, these estimates represent a threshold value which can be used to interpret changes in the FSS and MFIS over time or in response to an intervention.

1. Background

Fatigue is a complex symptom of Multiple Sclerosis (MS) that is reported in 70% of the population (Lerdal et al., 2007; Hadjimichael et al., 2008; Rooney et al., 2019), and is often perceived as the most debilitating symptom which significantly impacts upon quality of life (QoL) (Bakshi, 2003). Fatigue may be described as exhaustion, a lack of energy, or overwhelming tiredness which can occur at rest (Mills and Young, 2008), and is commonly defined as “a subjective lack of physical and/or mental energy that is perceived by the individual or caregiver to interfere with usual and desired activities” (Multiple Sclerosis Council for Clinical Practice Guidelines, 1998). Due to the subjective nature of fatigue, patient reported outcome measures (PROMs) are commonly used to assess the severity and impact of fatigue, and two of the most frequently used in studies involving people with MS are the Fatigue Severity Scale (FSS) and the Modified Fatigue Impact Scale (MFIS) (Bilikman et al., 2013; Heine et al., 2015; van den Akker et al., 2016).

Interpreting changes in PROMs is important when evaluating the effectiveness of interventions, and it is recognised that conventional statistical analysis provides little information regarding the clinical significance of changes observed following an intervention (Goodman, 1999). However, the interpretation of meaningful changes in fatigue can be enhanced by establishing the minimally important difference (MID) for fatigue PROMs (Revicki et al., 2006). MID, which is defined as “the smallest difference in the outcome of interest which patients perceive as beneficial” (Jaeschke et al., 1989), is a threshold value used to interpret whether a change in an outcome is important from the patient’s perspective (Guyatt et al., 2002). MID can be determined using anchor-based or distribution-based methods – the

* Corresponding author.
E-mail address: scott.rooney@gcu.ac.uk (S. Rooney).

https://doi.org/10.1016/j.msard.2019.07.028
Received 26 February 2019; Received in revised form 29 June 2019; Accepted 27 July 2019
2211-0348/ © 2019 Elsevier B.V. All rights reserved.

tiziana LIFE SCIENCES

MFIS: * p < 0.05 is a within-arm paired t-test; no treatment-versus-placebo comparison is implied (n = 18, 11, 17 with a complete pair).
https://www.msard-journal.com/article/S2211-0348(19)30319-0/fulltext Rooney et al. 2019

INFORM-MS: Topline Results Overview

Both primary endpoints (TSPO-PET Neuroinflammation and safety) were met. Secondary MFIS endpoint also met.

PET

Microglial Activation

50 µg vs Placebo

p = 0.0168

Statistically significant reduction in TSPO-PET signal demonstrating decreased microglial activation.

In an exploratory dose arm (100 µg) no significant change in PET signal. Fewer patients enrolled in this arm. Prior data with 250 µg also showed less immunomodulatory effects than the 50 µg dose.

FATIGUE (MFIS)

Clinically Meaningful

Change from baseline → Week 12

−6.17 / −7.18

50 µg (p=0.035) · 100 µg (p=0.040)

Within-arm paired improvements at both doses.

Fatigue is a key driver of quality of life in progressive MS.

SAFETY

Clean Profile

Both doses

No Drug Related SAEs

The first non-invasive anti-CD3 therapy shown to be safe and well tolerated

No study-drug related serious adverse events.

All 48 participants completed treatment

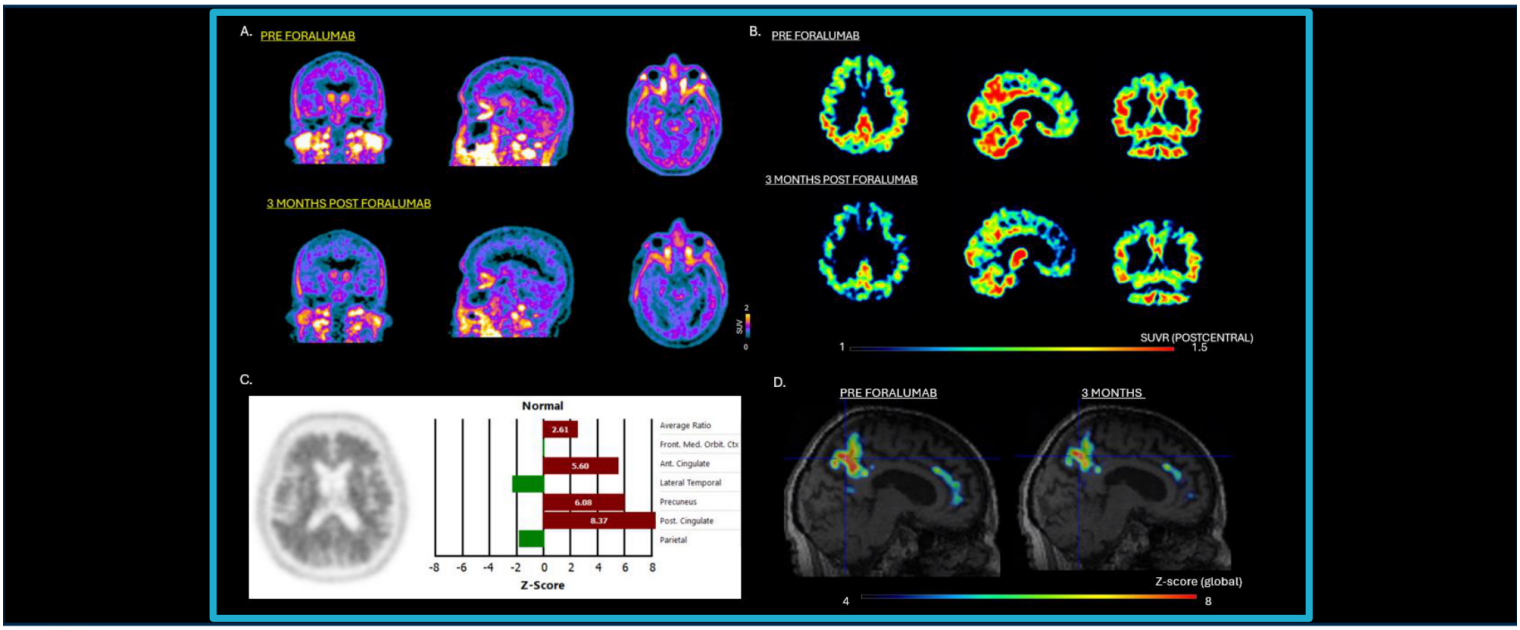
No discontinuations due to AEs.

All 48 participants completed the 12-week treatment period · Both doses safe and well-tolerated · Supports advancement toward registrational path

Intranasal Foralumab Pipeline

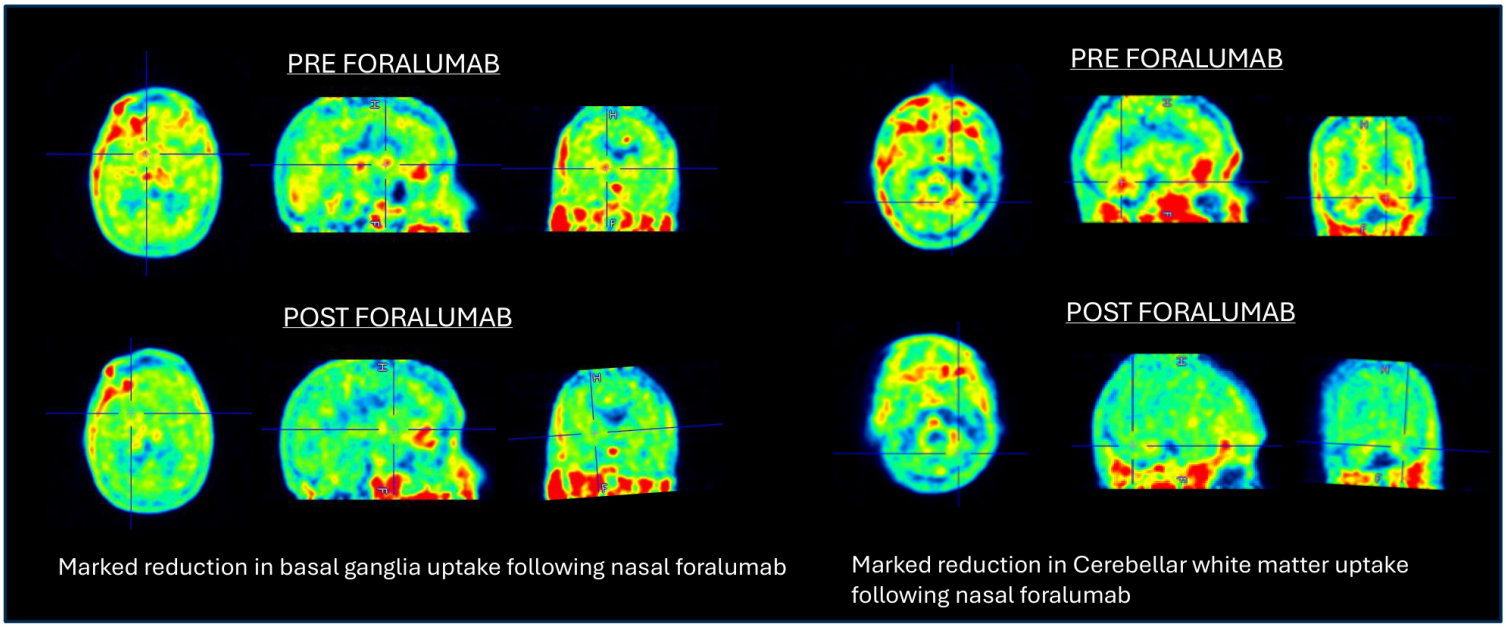
	Preclinical	IND	Phase 1	Expanded Access Program	Phase 2	Phase 3	
Non-Active Secondary Progressive Multiple Sclerosis Phase 2 Study							Positive Topline Data November 2026
Multiple System Atrophy (MSA) Phase 2 Study							Expecting Topline Data Q2 2027
Alzheimer's Disease (Mild) Phase 2 Study							Expecting Topline Data Q1 2027
ALS Phase 2 Study							First Patients Dosed Sept 2026
Non-Active Secondary Progressive Multiple Sclerosis (EA Program)							Ongoing Expanded Access Program
Moderate Alzheimer's Disease (EA Program)							Ongoing Expanded Access Program

Nasal foralumab dampens microglial activation in Alzheimer's Disease



Singhal T, Cicero S, Gale SA, Horan N, Dubey S, Marshall GA, Weiner HL. Dampening of Microglial Activation With Nasal Foralumab Administration in Moderate Alzheimer's Disease Dementia Clin Nucl Med. 2025 Aug 1;50(8):756-757

Nasal foralumab reduces microglial activation in Multiple System Atrophy



Marked reduction in basal ganglia uptake following nasal foralumab

Marked reduction in Cerebellar white matter uptake following nasal foralumab

Questions



Nasdaq: TLSA

US Headquarters (Boston)
Tiziana Life Sciences Ltd.
535 Boylston Street, Floor 8
Boston, MA 02116

UK Headquarters (London)
Tiziana Life Sciences plc
35a Albemarle Street
London
W1S 4JE

Investors:
+44 (0)207 495 2379
info@tizianalifesciences.com



Nasdaq: TLSA