



FOR IMMEDIATE RELEASE

Caladrix and Oxford Brain Diagnostics Ltd Partner to Incorporate Advanced MRI Biomarker (CDM[®] Cortical Disarray Measurement) as a New Translational Imaging Endpoint in the Forthcoming Phase 1b Trial of C-001, an ABCC1 Activator, in Alzheimer's Disease

- Collaboration integrates next-generation diffusion MRI biomarkers to visualize cortical microstructure and quantify neuroinflammation and neuronal disorganization *in vivo*
- CDM[®] was granted FDA breakthrough device designation and CDM Insights is FDA 510(k)-cleared. This pioneering imaging biomarker—enables quantitative insight into how ABCC1 activation modulates glial and neuroinflammatory pathways
- Integration of CDM[®] enhances Caladrix's multidimensional assessment of disease modification in early Alzheimer's, uniting molecular, fluid, and structural biomarkers

PALO ALTO, California / MELBOURNE, Australia / OXFORD, United Kingdom – November 2025 – Caladrix Inc., a precision-neurotherapeutics company developing first-in-class small-molecule activators of the ABCC1 efflux pathway in Alzheimer's disease, today announced a collaboration agreement with Oxford Brain Diagnostics Ltd. (OBD) to deploy its FDA 510(k)-cleared advanced MRI biomarker platform, Cortical Disarray Measurement (CDM[®]), as an exploratory imaging endpoint in Caladrix's Phase 1b clinical trial (CALABC-001) of its lead candidate C-001 for early Alzheimer's disease.

The collaboration will enable quantitative assessment of cortical microstructure from diffusion MRI data to examine how ABCC1 activation by C-001 influences cortical integrity, neuroinflammation, and neuronal organization, key drivers of disease progression in Alzheimer's disease.

Dr Markus Krohn, Co-Founder and Chief Scientific Officer of Caladrix, commented:

“Integrating CDM® imaging into our Phase 1b study gives us an unprecedented opportunity to visualize, in patients, how ABCC1 activation engages the brain’s clearance networks. By linking fluid biomarkers with quantitative measures of cortical microstructure, we can translate molecular biology into living evidence of disease modification. For Caladrix, this represents both a scientific breakthrough and a decisive step toward de-risking our therapeutic platform for future partnerships.”

Dr Ged Ridgway, CSO, Oxford Brain Diagnostics, said:

“We’re excited to see Cortical Disarray Measurement (CDM®) used in a pioneering therapeutic trial like this one. By combining OBD’s microstructural MRI biomarkers with Caladrix’s novel ABCC1-activating approach, we can begin to map how cellular-level neuroinflammation and disorganization respond to targeted intervention in vivo. It’s a powerful opportunity to connect molecular and imaging evidence in early Alzheimer’s disease, and a great example of translational collaboration.

Dr Steven Chance, Chief Executive Officer and Co-Founder of Oxford Brain Diagnostics, added:

“Cortical Disarray Measurement (CDM®) has been validated against post-mortem pathology and correlates with plasma GFAP, a marker of astroglial activation. By bringing CDM to Caladrix’s trial, we are combining two complementary approaches - molecular and microstructural - to capture how a novel clearance-enhancing therapy may influence neurodegeneration and neuroinflammation directly.”

Jonas Fischer, Co-Founder and Chief Executive Officer of Caladrix, said:

“This collaboration advances our commitment to a multidimensional trial architecture that integrates pharmacokinetics, fluid biomarkers, and imaging into a unified translational framework. Incorporating CDM® provides a quantitative bridge between molecular activation and structural brain change, creating data that are both scientifically rigorous and directly relevant to regulatory validation and partnering decisions.”

About the CALABC-001 Trial

The Phase 1b trial is enrolling 95 participants randomized 1:1:1 to placebo, C-001 6.5 mg, or C-001 13 mg once daily. C-001 is the first oral, small-molecule program designed to engage all three hallmarks of Alzheimer’s pathology: amyloid- β , tau, and neuroinflammation. Each participant will complete up to 36 weeks of study involvement, including a 24-week dosing period and a 4-week follow-up.

In addition to primary safety and tolerability endpoints, importantly, the trial integrates a comprehensive biomarker suite spanning plasma, CSF, and imaging. Exploratory analyses will quantify amyloid- β , p-tau 181/217, GFAP, NfL, and total tau alongside advanced MRI-based

Cortical Disarray Measurement (CDM®) imaging to visualize microstructural brain changes in vivo.

Overseen by an independent Data Safety Monitoring Board (DSMB), the trial includes a planned interim analysis after approximately 30 participants complete 12 weeks of treatment to evaluate early pharmacokinetic and pharmacodynamic signals of target engagement. This interim analysis represents a pivotal milestone for Caladrix, expected to inform next-stage development and partnership strategy. Several prospective licensing and co-development partners will be closely monitoring these results as an early indicator of platform value and clinical readiness.

About C-001

C-001 (thiethylperazine dimaleate, immediate-release) is a brain-penetrant allosteric activator of ABCC1 (MRP1), designed to enhance the brain's natural efflux of amyloid- β while mitigating microglial-driven neuroinflammation. Unlike antibody-based or single-target agents, C-001 is a once-daily, orally delivered small molecule manufactured at commercial scale with drug-like gross margins. It represents the first multimodal therapeutic mechanism demonstrated to act concomitantly on the three principal hallmarks of Alzheimer's disease, amyloid, tau, and neuroinflammation, within a single agent. The program is underpinned by pre-clinical and human proof-of-concept data showing rapid, reproducible modulation of Alzheimer's-related biomarkers following short-term exposure.

About Oxford Brain Diagnostics Ltd.

Oxford Brain Diagnostics Ltd is rethinking how brain health is assessed and managed. Founded in neuropathological and neuroimaging expertise, the company's patented Cortical Disarray Measurement (CDM®) technology uses MRI brain scan data to support early and differential diagnosis, track progression, and predict the decline of neurodegenerative diseases. Oxford Brain Diagnostics is committed to assessing brain health based on changes in the cellular structure, supporting drug development, and helping clinicians around the world in their fight to defeat Alzheimer's and other neurodegenerative diseases.

For more information, visit www.oxfordbraindiagnostics.com.

About Caladrix Inc.

Caladrix Inc. is a precision-neurotherapeutics company advancing a first-in-class portfolio of small-molecule activators of the ABCC1 efflux pathway to restore the brain's endogenous clearance systems. Headquartered in Palo Alto, California, with clinical operations in Melbourne, Australia, and discovery research in Germany, Caladrix is pioneering a non-immunologic, oral approach to disease modification in neurodegeneration.

Its lead candidate, C-001, represents the first once-daily, commercially scalable small molecule designed to engage the three core hallmarks of Alzheimer's disease, amyloid, tau, and neuroinflammation, through a single therapeutic mechanism. By combining drug-like manufacturability with multi-modal biomarker validation across plasma, CSF, and imaging,

Caladrix is defining a new generation of CNS medicines that are accessible, globally deployable, and aligned with the evolving priorities of patients, regulators, and strategic partners.

Trademarks and Trade Names

All trademarks or trade names referred to in this press release are the property of Caladrix Inc., or, to the extent trademarks or trade names belonging to other companies are referenced in this press release, the property of their respective owners. Solely for convenience, the trademarks and trade names in this press release are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that Caladrix Inc., or, to the extent applicable, their respective owners, will not assert, to the fullest extent under applicable law, the company's or their rights thereto. The use or display of other companies' trademarks or trade names does not imply a relationship with, or endorsement or sponsorship of, Caladrix Inc. by any other companies.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Caladrix's clinical development plans, regulatory strategy, anticipated milestones, potential therapeutic benefits, and partnering objectives. Forward-looking statements are based on current expectations and projections about future events and involve inherent risks and uncertainties that could cause actual results to differ materially from those expressed or implied. Factors that may cause such differences include risks related to clinical development, regulatory review, manufacturing, commercialization, financing, and strategic collaboration. For further discussion of these and other risks, prospective investors and partners should review Caladrix's publicly available materials and updates. Except as required by law, Caladrix undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of this release.

For more information, visit www.caladrix.bio or contact info@caladrix.bio

SOURCE: Caladrix Inc.