



Diadem Builds Out Executive Team As It Prepares for Commercialization of Its AlzoSure® Predict Prognostic Test for Alzheimer's Disease

—Diadem to Participate in the 15th Clinical Trials on Alzheimer's Disease (CTAD) Conference—

Milan, Italy, November 21, 2022 – Diadem SpA, (or Diadem US, Inc.) a company developing the first blood-based test for the early prediction of progression to Alzheimer's disease (AD), today announced key additions to its senior management team. Sam Agus, MD, has been appointed Chief Medical Officer (CMO), James Clark, PhD, has been named Head, External Affairs and Collaborations, and Peter Bream is Diadem's new Chief Financial Officer (CFO). They join Simona Piccirella, PhD, Vice President of Operations and Development and Chief Executive Officer Paul Kinnon at Diadem.

Separately, the company announced that it will participate in the upcoming [15th Clinical Trials on Alzheimer's Disease \(CTAD\) conference](#) being held November 29-December 2, 2022 in San Francisco. Diadem will present, *U-p53AZ in prognostication of early onset Alzheimer's disease up to 6 years in advance of the clinical diagnosis*, in a Late Breaking Oral Communication Session at 4:20 pm on Friday, December 2nd. The company will also participate in a CTAD Task Force on Blood Biomarkers roundtable "Point of View from the Assay Industry" discussion on November 29 from 9:55 to 10:25 am.

"We are pleased to welcome these highly experienced executives to Diadem as we prepare for the commercialization of our revolutionary AlzoSure® Predict blood test that can accurately identify whether or not an individual will progress to Alzheimer's as much as six years before symptoms of the disease are apparent," said Mr. Kinnon. "Sam, James and Peter are seasoned executives with decades of success in building and leading pharmaceutical, diagnostics and life science organizations. Simona has already played a major role in growing Diadem and developing the AlzoSure technology to this stage. Their contributions will be instrumental as we prepare for the commercialization of AlzoSure® Predict in the new year."

Mr. Kinnon continued, "We also welcome the opportunity to participate in several sessions at the upcoming CTAD conference, one of the year's most important Alzheimer's scientific meetings. This is an excellent opportunity to continue our campaign of educating AD researchers, clinicians and drug developers about the potential of AlzoSure® Predict to help transform the diagnostic and therapeutic landscape of Alzheimer's disease."

Mr. Kinnon concluded, "Dr. Agus's expertise will be very helpful as we conduct additional clinical trials to further validate the diagnostic utility of AlzoSure® Predict and to facilitate obtaining regulatory approvals, as well as to help us strengthen the critical relationships with the medical community that will be essential for its widespread adoption and use. We expect to establish additional partnerships and collaborations to accelerate the commercial and clinical availability of this important advance, and Dr. Clarke's long-standing relationships throughout the industry will be invaluable to this effort. Dr. Piccirella's combination of scientific acumen and organizational skills will continue to be central to the continued evolution of the company. Finally, every successful company in our sector requires a first-rate CFO who appreciates the complexity of the healthcare ecosystem, and we are fortunate to have Peter coming onboard as a core member of our team. I enthusiastically welcome them to Diadem."

CMO Sam Agus, MD is a board-certified neurobiologist with more than 20 years of global experience in multiple therapy areas. He has served as a senior leader in clinical development and medical affairs at pharmaceutical companies, such as Lundbeck, Shire, Abbott, Solvay and Teva, and as CMO at a number of biotechnology firms. His experience spans clinical, medical, and regulatory strategy, multidisciplinary team leadership, portfolio management, clinical trial design and execution, regulatory strategy, product launches, and market access. Additionally, Dr. Agus has taken an active part in public-private partnerships, collaborations and business alliances, and in completing a number of financing rounds.

Head of External Affairs and Collaborations James Clarke, PhD, has more than 20 years of leadership

experience as a senior executive in pharmaceutical, diagnostic and precision medicine companies of varied sizes, phases of development and geographies. He has led R&D units, managed certified laboratories in the US and UK, overseen special projects, and has successfully developed and commercialized more than 15 global diagnostic products. Dr. Clarke earned a PhD degree from Glasgow University.

CFO Peter Bream has over 35 years of experience in international business including serving as chief financial officer of public companies in the medical diagnostics, pharmaceuticals, engineering, and chemical sectors. Most recently he was CFO of two Cambridge-based genomics start-ups and was a non-executive director and board committee member for a listed healthcare business. Mr. Bream has a degree in Engineering and Management from Cambridge University and is a Chartered Accountant.

Vice President Operations and Development Simona Piccirella, PhD, is an experienced researcher and business manager with deep knowledge of the life sciences sector. She co-founded the company VisMederi srl, where she was chief operating officer until 2016, serving clients such as Sanofi, Novartis, Glaxo SmithKline and Takeda in immunogenicity evaluations of biologics and analytical assay validation. Dr. Piccirella earned a degree in Natural and Biological Sciences and a PhD in Molecular Medicine from the University of Siena.

AlzoSure[®] Predict is a non-invasive biomarker blood test that can identify with high accuracy whether individuals over the age of 50 with signs of cognitive impairment will or will not progress to Alzheimer's disease up to six years before diagnosis. AlzoSure[®] Predict uses a proprietary antibody (U-p53^{AZ}) to measure blood levels of a conformational variant of the p53 protein that has been implicated in the pathogenesis of AD. Previous [studies](#) suggest that this p53 variant has utility as a diagnostic and as a predictive biomarker to identify individuals likely to progress to AD up to six years before symptoms appear.

The utility of AlzoSure[®] Predict is supported by [clinical data](#) from a large longitudinal study that was the basis for AlzoSure[®] Predict's Breakthrough Device designation from the U.S. Food & Drug Administration and its CE-IVD marking in the EU. AlzoSure[®] Predict requires only 1mL of blood and 4 to 5 days for analysis to detect AD at the asymptomatic and prodromal (early symptomatic) stage, with an accuracy greater than 95% up to at least 6 years in advance of the clinical onset of symptoms. Previous research also demonstrated that AlzoSure[®] Predict can discriminate between the different kinds of dementia with high accuracy.

About Diadem

Diadem was founded as a spin-out of the University of Brescia (Italy). The company is developing the first blood-based prognostic test for the early detection of dementia, with a focus on Alzheimer's disease. The lack of accurate, accessible and affordable diagnostic tools is a major contributor to the absence of effective treatments for this devastating condition. As a result, patients are not diagnosed until late in the illness, when effective treatment is no longer possible. Diadem's rapid, accurate and cost-effective blood-based prognostic test makes it possible for the first time to identify patients early in the disease process, when effective interventions and better outcomes are far more feasible. The utility of the approach has been demonstrated in longitudinal clinical studies that were the basis for awarding CE-IVD marking in the E.U. and a Breakthrough Device designation in the U.S. Additional retrospective and prospective clinical trials are ongoing to further validate clinical claims and support widespread adoption and use. Diadem is preparing for commercialisation of AlzoSure[®] Predict in collaboration with global strategic partners. The company is also developing AlzoSure[®] Confirm, a blood-based diagnostic test for AD that has shown promising results in early studies. For more information, visit diademdx.com/.

Contacts:

Corporate:

Diadem
Paul Kinnon
CEO
ExecAdmin@Diademdx.com

Media:

Barbara Lindheim :
BLL Partners for Diadem
blindheim@bllbiopartners.com
+1 (917) 355-9234