

Paris (France), 9 September 2025

Alcediag successfully completes European multicentric study, further validating clinical performance of the first-in-class diagnostic test EDIT-B to differentiate unipolar depression from bipolar disorder.

Alcediag, in collaboration with a multidisciplinary European consortium, is proud to announce the successful completion of recruitment and data analysis of the Clinical Validation Study for EDIT-B Test, **an Aid for Differential Diagnosis of Unipolar Depression (UD) and Bipolar Disorder (BD), Based on RNA Editing Blood Biomarkers (EDIT-B)** and intended for adult patients treated for moderate to severe depression symptoms. The study was launched to generate the data necessary for regulatory compliance with new IVDR regulation 2017/746. This study also serves as an additional external validation that confirms previously published data with a large pan-European independent cohort. The consortium is particularly satisfied with the quality and robustness of the data obtained, which further strengthens the clinical relevance of RNA biomarker-based testing in psychiatric diagnostics. The full results will be submitted for publication in a **peer-reviewed scientific journal** later this year.

BD affects an estimated 2–3% of the global population, yet it is frequently misdiagnosed as UD. Studies show that the average delay in correct diagnosis can exceed 8 years. During this time, patients may receive inappropriate treatments, as unipolar and bipolar depression should be treated differently. This can worsen their condition or delay effective care. Improving early diagnosis could have a transformative impact, enabling timely, more targeted interventions and potentially changing the course of illness for millions of patients and their loved ones. As such, the completion of the EDIT-B study marks a critical advancement in the field of precision psychiatry, where objective blood biomarkers are used to guide diagnosis and treatment.

Prof. Eduard Vieta, Head of the Psychiatry and Psychology Department at Hospital Clínic of Barcelona and Principal Investigator of the study, stated:

"We are pleased to announce the completion of EDIT-B clinical study, conducted over the past few years in close collaboration with a highly committed and skilled consortium. Reaching this milestone marks an important step forward and opens new perspectives for the use of biological testing in clinical routine in psychiatry. Our team is now focused on preparing the forthcoming publication, which we believe will contribute meaningfully to the field of precision psychiatry."

Alcediag's CEO, Alexandra Prieux, added:

"This milestone reinforces our commitment to our mission: transforming mental health diagnostics and developing solutions that improve long-term outcomes for patients. We are grateful to our clinical investigators and partners, as well as proud and happy to see EDIT-B, the result of more than 10 years of R&D, move closer to routine clinical use."

About the EDIT-B Test and its Impact

EDIT-B is an **innovative blood test** utilizing RNA sequencing technology and Artificial Intelligence (AI) based algorithms for the differential diagnosis of Bipolar Depression and Unipolar Depression in adults displaying symptoms of depression. Designed as a comprehensive decision-support tool for mental

healthcare professionals, it aims to streamline the process of differentiating patients into two distinct categories: unipolar or bipolar, leveraging RNA editing modifications of specific targets measured in blood and individualized patient data.

With EDIT-B, the objective is to address the longstanding diagnostic challenge associated with bipolar disorder, which often entails an average of **8 years of diagnostic uncertainty**. The early diagnosis of Bipolar Disorder is critical for patients' long-term outcomes as treatment pharmacologically and psychologically differ substantially for depression and bipolar disorder.

About the EDIT-B Consortium

The success of this effort is largely attributed to the **highly committed and expert consortium**, which includes many leading clinicians in the field of psychiatry. The EDIT-B study adopted a cross-sectional design and was conducted in expert clinical centers across Europe.

The project was awarded co-funding from the **European Institute of Innovation and Technology for Health (EIT Health)**, one of Europe's leading healthcare innovation networks, with funding of €2.5 million. The EDIT-B Consortium, launched in early 2022, brought together ALCEDIAG and four expert clinical centers:

- Hospital Clínic de Barcelona, Spain, under the leadership of Prof. Eduard Vieta as the Principal Investigator.
- The Center of Psychiatry of the Copenhagen region, Denmark, led by Prof. Lars Kessing.
- GHU Paris Psychiatrie & Neurosciences, France, led by Prof. Chantal Henry.
- Parc Sanitari Sant Joan de Déu, Spain, with Dr. Josep Maria Haro also serving as one of the investigators.
- Additional key partners include ProductLife Group (PLG) and Synlab Italy (part of Synlab International).

About ALCEDIAG: Founded in 2013, **ALCEDIAG** is a pioneering diagnostics company dedicated to transforming mental health through precision psychiatry. The company develops and commercializes innovative in-vitro diagnostic tests powered by cutting-edge molecular biology and artificial intelligence. Its proprietary platform leverages RNA editing biomarkers to bring objective, science-based tools into clinical psychiatric practice.

Contact Information: Aurore André, Chief Marketing & Communications, ALCEDIAG E: contact@alcediag-alcen.com W: www.editb-project.com