

Paris and Issy Les Moulineaux (France), July 19th 2021

METAFORA BIOSYSTEMS, AP-HP AND CERBA HEALTHCARE PRESENTED THE FINDINGS OF THE VALIDATION STUDY FOR THE METAGLUT1 TEST AT THE 3RD EUROPEAN CONFERENCE ON GLUT1 DEFICIENCY SYNDROME

The METAglut1™ test is the result of a collaborative initiative between METAFORA biosystems, the teams at AP HP and over 30 clinical trial sites, and Cerba HealthCare. Its aim is the early diagnosis of this rare disease, which still remains underdiagnosed

The De Vivo disease, or GLUT1 deficiency syndrome, is a rare and debilitating neurological disease that is still relatively unknown among the medical community, but it can be treated. It is estimated¹ that more than 3,000 people suffer from the De Vivo disease in France, and over 90% of them have currently gone undiagnosed. In GLUT1-deficient patients, the transporter necessary for glucose uptake by brain cells is impaired. The decreased glucose level in the brain causes epileptic seizures, abnormal movements and developmental delay. However, unlike many genetic diseases, treatment is available for De Vivo disease in the form of a high-fat diet (known as a ketogenic diet), which significantly improves symptoms in patients. Molecules designed to bypass the deficiency related to the lack of glucose supplied to the brain are also currently being assessed. Diagnosing the disease as early as possible so that proper treatment can be established is therefore of crucial importance.

This new blood diagnostic test promises to help quickly (within 48h) and easily identify affected children and adults, compared to the current diagnostic tests which rely on an invasive procedure (lumbar puncture) or complex genetic analysis.

The partners announced the key findings of a multicentre validation study at the 3rd European GLUT1D Conference on Friday 11 June 2021. The study highlighted similar performance between the diagnostic test and the more invasive standard approach – lumbar puncture – for detecting this metabolic abnormality. In particular, the test resulted in almost 100% specificity and its sensitivity was identical to the lumbar puncture at around 80%.

“This rapid and precise blood diagnostic test, readily available to all physicians and, especially, paediatricians and neurologists, is a major milestone for patients with this rare disease, as their diagnosis and treatment will be much faster,” stated Dr Fanny Mochel, Principal Investigator for the study, geneticist and Head of the Reference Centre for Adult Neurometabolic Diseases at AP-HP Pitié-Salpêtrière Hospital.

“METAglut1 offers patients and their families major prospects in the fight against delayed diagnosis, which can mean years before they get to the bottom of their symptoms, despite treatments being available,” explained Magali Sorret, Founder and President of the ASDGLUT1 patient support group.

¹ <https://ghr.nlm.nih.gov/condition/glut1-deficiency-syndrome> and Symonds et al. Incidence and phenotypes of childhood-onset genetic epilepsies: a prospective population-based national cohort. Brain. 2019 Aug 1;142(8):2303-2318.

Thanks to this new and innovative blood test, it will be possible to screen for the disease in any patient showing learning difficulties and/or epilepsy and/or abnormal movements.

“We are delighted to have been supporting Metafora and the clinicians since the test was in its very first development phases, and especially to have participated in this major multicentre study. The consortium has successfully demonstrated how robust this innovative test is on a large scale, which means it will be distributed nationwide,” explained Jérôme Sallette, Chief Scientific Officer at Cerba HealthCare.

This validation study of the diagnostic performance of METAglut1 was conducted under the Forfait Innovation programme, which is a French Coverage with Evidence Development scheme for innovative in vitro diagnostic medical devices or procedures in the early stages of development. It is awarded subject to completing a study to confirm the value of the technology. This is the first diagnostic technology to benefit from the Forfait Innovation as part of its validation.

“We are grateful to all our partners for the quality of their work and for their involvement, which made this ambitious study possible. The Forfait Innovation offered a particularly suitable framework for us to see it through, and we would like to thank the French Ministry of Social Affairs and Health as well as the HAS for the trust they have placed in us,” concluded Vincent Petit, CEO of Metafora biosystems.

About ASDGLUT1

ASDGLUT1 is an association, recognized as being of general interest, created by parents of children of all ages affected by Glut1 Deficiency. ASDGLUT1 works to raise awareness of the disease among health professionals and organizations, in order to facilitate early detection, by allowing more systematic recognition of symptoms following an effective diagnosis and thus proceeding as soon as possible to the placement on a ketogenic diet, the only effective treatment.

ASDGLUT1 accompanies patients and their families, who are often at a loss in their daily lives, by offering a listening ear and moral support, through advice and sharing experiences. ASDGLUT1 works in collaboration with other international associations on Glut1 deficiency and related events.

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About AP-HP

The AP-HP and its 39 hospitals are the largest university hospital center in Europe and are organized into six university hospital groups (AP-HP. Center - Université de Paris; AP-HP. Sorbonne University; AP-HP. Nord - University of Paris; AP-HP. Université Paris Saclay; AP-HP. Henri Mondor University Hospitals and AP-HP. Hôpitaux Universitaires Paris Seine-Saint-Denis) and are structured around five Ile-de-France universities. Closely linked to major research organizations, AP-HP has three world-class university hospital institutes (ICM, ICAN, IMAGINE) and the largest French health data warehouse (EDS). As a major player in applied research and innovation in healthcare, the AP-HP holds a portfolio of 650 active patents, its clinical researchers sign nearly 9,000 scientific publications each year and more than 4,000 research projects are currently under development, all sponsors included. In 2020, the AP-HP obtained the Carnot Institute label, which rewards the quality of its partnership research: the Carnot@AP-HP offers industrial players applied and clinical research solutions in the field of health. In 2015, the AP-HP also created the AP-HP Foundation for Research to support biomedical and health research conducted in all of its hospitals.

<http://www.aphp.fr>

About METAFORA biosystems

METAFORA biosystems is developing an innovative technology, capable of assessing the nutrient requirements of cells in a simple and rapid manner, and thus of evaluating and detecting anomalies in their energy needs. Proprietary reagents and state-of-the-art algorithms are at the heart of the technology platform and allow the detection of "metabolic reprogramming" induced during many disease processes.

The company plans to launch in Europe in 2022 its first diagnostic test, METAgut1™, dedicated to the early diagnosis of De Vivo disease, a neurometabolic disorder. The company is actively developing its IVD platform for oncology applications. Beyond IVD, the company has two other pillars: AI software to support the deployment of flow cytometry assays, and a solution to increase the clinical efficacy of cell therapies and reduce production costs.

<http://www.metafora-biosystems.com>

About Cerba Healthcare

Cerba HealthCare, a leading player in medical diagnostics, aims to support the evolution of healthcare systems towards more prevention. It draws on more than 50 years of expertise in medical biology to better assess the risk of disease development, to screen and diagnose pathologies earlier and to optimize the effectiveness of treatments by personalizing them.

Every day, on all five continents, the Group's 9,600 employees are helping to transform medicine, driven by the same deep-seated conviction: advancing diagnosis means advancing health.

Cerba HealthCare, illuminating health.