

Metafora biosystems receives exceptional reimbursement for new blood test to help diagnose De Vivo disease

METAglut1 test enables early detection of this rare under-diagnosed disease

A 30-month long study will be carried out on 3,000 patients in 60 centers across France

Paris, France, April 11, 2018 – Metafora biosystems, a company developing diagnostic tests to detect abnormalities in cellular energetics, today announces it has been granted 'Forfait Innovation' funding for METAglut1, its test for the early diagnosis of De Vivo disease (GLUT1 deficiency syndrome). This is the first diagnostic test to secure funding through the *Forfait Innovation* program supported by the French Ministry of Solidarity and Health.

Forfait Innovation provides special temporary funding for medical technologies, *in vitro* diagnostic devices or innovative procedures that are in the early diffusion stage. The funding is dependent on the completion of a study prospectively demonstrating the technology's potential.

With the *Forfait Innovation* funding, Metafora will be able to conduct a 30-month study in over 60 pediatric and adult neurology centers in mainland France and its overseas territories. The study aims to demonstrate the efficacy of the Metafora test for the detection of this metabolic dysfunction as compared to the more invasive conventional approach involving lumbar puncture. The results of this study should be published in 2021.

"This quick and accurate blood test is a real asset for doctors. They will be able to perform a simple and specific diagnostic. They can then choose from available treatment options, and hopefully in the near future, from other treatments currently under evaluation," said Dr. Fanny Mochel, neurologist and the study's principal investigator, who serves as the head of the reference center for adult neurometabolic diseases at the Hôpital de la Pitié-Salpêtrière, Paris (AP-HP). "It will prove highly beneficial in preventing misdiagnosis of these patients, who usually have to wait several years before the real cause of their symptoms is identified, even though treatments are available."

De Vivo disease is a rare, debilitating illness, relatively unknown in the medical profession. The protein responsible for transferring glucose from the blood into the brain cells malfunctions and the lack of sugar in the brain results in epileptic seizures, ataxia and developmental delay. Metafora's blood test can detect the disease early. This allows the condition to be managed appropriately and thus reduces debilitating symptoms in patients.

According to recent estimates¹, there are approximately 12,000 cases of De Vivo disease in EU and the USA, 80 per cent of which remain undiagnosed. However, unlike many other rare diseases, De Vivo disease is treatable. Once correctly diagnosed, patients can follow a special diet (called the ketogenic diet) significantly improving their quality of life.

¹ <https://ghr.nlm.nih.gov/condition/glut1-deficiency-syndrome>

Studies are also underway with molecules that compensate for the lack of available glucose in the brain cells.

"Metafora is delighted to have been awarded the *Forfait Innovation*. We would like to thank the Ministry of Solidarity and Health as well as the HAS for the trust they have placed in us," said Vincent Petit, CEO of Metafora. "This first test represents a key milestone for our company and, once it has been validated, we plan to apply our technology to other diseases, particularly in oncology."

METAGlut1 is the first diagnostic test that Metafora has developed using its proprietary technology. The company published initial results in the *Annals of Neurology*² (*A simple blood test expedites the diagnosis of glucose transporter type 1 deficiency syndrome. Gras et al. Ann Neurol. 2017 Jul; 82(1): 133-138*) and obtained CE marking for the test in 2017. Metafora and Laboratoire Cerba signed a partnership last year and announced a successful technology transfer.

About Metafora biosystems

Metafora develops a platform for the discovery, development and distribution of blood tests that detect abnormalities in cellular energetics.

Using RBDs (Receptor Binding Domains), patented reagents that quantify cell nutrient transporters, coupled with powerful algorithms, the platform is able to detect abnormal nutrient consumption that may be the cause of illnesses such as neuro-metabolic diseases, cancer or inflammatory disorders.

Its first product, awarded CE marking in 2017, is a specific, rapid and reliable test to help diagnose De Vivo disease (also known as GLUT1 deficiency syndrome), a seldom diagnosed rare disease. Metafora obtained *Forfait Innovation* funding for this test in 2018 and will soon kick-start a 30-month clinical trial in over 60 centers across France.

Founded in 2011, Metafora is led by an experienced team and holds six patent families. The company, based in Evry and Paris, has already raised €4 million (\$5M) from business angels and has a dozen employees.

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² <https://onlinelibrary.wiley.com/doi/10.1002/ana.24970>