

VALBIOTIS opens a new Clinical Investigation Center at the Institut Pasteur in Lille as part of the Phase IIa study on TOTUM-63, the active ingredient of Valedia®

La Rochelle, 06 September 2017 (7:30 am CEST) – VALBIOTIS (FR0013254851 – ALVAL – PEA/PME eligible), a company that specializes in developing innovative nutrition solutions designed to prevent cardiometabolic diseases and provide nutritional support for patients, has announced today the opening of a new Clinical Investigation Center at the Institut Pasteur in Lille¹ as part of the Phase IIa study on TOTUM-63.

Following the conclusive results obtained for the Phase I/II study, VALBIOTIS has initiated a Phase IIa study to demonstrate the efficacy of a high dose of the active ingredient of Valedia® on prediabetics (ultimate proof of efficacy). Like the three other trials carried out as part of the Phase II study, this Phase IIa is expected to be completed by 2019 in view of the submission of a proprietary health claim request, first, to the EFSA. This will make it possible to market the product in Europe by 2020, and then in the United States by 2021 after a health claim request has been submitted to the FDA, once EFSA approval has been obtained.

The opening of this new Clinical Investigation Center at the Institut Pasteur in Lille which follows the opening of the first Biofortis Mérieux NutriSciences Clinical Investigation Center in Nantes in November 2016 will help accelerate the recruitment of volunteers for the Phase IIa clinical study. Professor Jean-Michel Lecerf is the investigator for the clinical study that will be conducted at this Clinical Investigation Center.

The Phase IIa is conducted in France on 80 adult volunteers, with abdominal obesity associated with prediabetes or untreated type 2 diabetes and hypertriglyceridemia, who will receive 6 months of supplementation. It will take the form of a multicenter, randomized (unbalanced, 3 verum for 1 placebo) double-blind, placebo-controlled study.²

"We are pleased to announce the opening of a new Clinical Investigation Center at the Institut Pasteur in Lille. This is an important step forward for VALBIOTIS which will enable us to accelerate the recruitment of volunteers, and thus meet the deadlines for this Phase IIa study. This step also marks our association with a new Center of Excellence that brings together multidisciplinary and transversal expertise, particularly in relation to metabolic diseases, diabetes and obesity", said Sébastien Peltier, CEO of VALBIOTIS.

¹ More information on: <https://www.pasteur-lille.fr/accueil/>

² [ClinicalTrials.gov](https://clinicaltrials.gov), reference NCT02868177

ABOUT VALBIOTIS

VALBIOTIS specializes in developing innovative nutrition solutions designed to prevent cardiometabolic disease and provide nutritional support for patients. Its products are made for manufacturers in the agro-food and pharmaceutical industries. VALBIOTIS particularly focuses on solutions to prevent type 2 diabetes, NASH (nonalcoholic steatohepatitis), obesity and cardiovascular disease.

Valbiotis was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers in France and abroad, including the La Rochelle University, the CNRS and the Clermont Auvergne University located in Clermont-Ferrand, where the company opened a second office. These partnerships have enabled Valbiotis to benefit from strong financial leverage, particularly thanks to experts and technical partners who support its projects. Valbiotis is a member of the “BPI Excellence” network and received the “Innovative Company” status accorded by BPI France. Valbiotis has also been awarded “Young Innovative Company” status and has received major financial support from the European Union for its research programs by obtaining support from the European Regional Development Fund (ERDF).

All information about VALBIOTIS:

<http://valbiotis.com/>



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