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DYSLIPIDAEMIA



MEDICAL
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PRESS RELEASE

VALBIOTIS completes Phase I/II clinical study recruitment for VAL-070, a product to reduce a cardiovascular risk factor

- The VAL-070 candidate aims to reduce lipid profile abnormalities, which are risk factors for cardiovascular diseases
- 40 volunteers with a mild to moderate raise of LDL cholesterol and triglyceride levels were included
- Clinical safety and efficacy results are expected for mid-2018, as set out in the clinical development plan

La Rochelle, 27 February 2018 (5:35 pm CET) - VALBIOTIS (FR0013254851 - ALVAL / PEA/SME eligible), a company that specializes in developing innovative nutrition solutions designed to prevent cardio-metabolic diseases and provide nutritional support for patients, has announced it has completed the recruitment for the Phase I/II clinical study involving its product candidate, VAL-070. VAL-070 aims to reduce lipid profile abnormalities (dyslipidaemia), which are risk factors of developing cardiovascular diseases, in subjects with mild to moderate dyslipidemia.

Dyslipidaemias, one of the major parameters of the cardiovascular risk¹, affect 44 % of adults in France². High blood LDL cholesterol is frequent (prevalence of 30% in adults in France) and, with obesity, diabetes and high blood pressure, is part of a major risk factor for arteriosclerosis, inducing cardiovascular diseases (ischemic cardiopathies, strokes, peripheral arteriopathies), which are the second cause of mortality in France³. At the global level, hypercholesterolemia affects 39% of adults⁴.

To improve the lipid profile in early stages, VALBIOTIS has developed VAL-070.

¹ Ferrières J, Dyslipidémies et risque cardiovasculaire : données épidémiologiques, Endocrinologie et nutrition, 2010

² De Peretti C, Perel C, Chin F, Tuppin P, Iliou MC, Vernay M, et al. Cholestérol LDL moyen et prévalence de l'hypercholestérolémie LDL chez les adultes de 18 à 74 ans, étude nationale nutrition santé (ENNS) 2006-2007, France métropolitaine. BEH 2013;(31):378-85

³ Aouba A, Eb M, Rey G, Pavillon G, Jouglu E. Données sur la mortalité en France : principales causes de décès en 2008 et évolutions depuis 2000. BEH 2011;(22):249-55.

⁴ Global Health Observatory (GHO) data, World Health Organization, 2008, www.who.int/gho/ncd/risk_factors/cholesterol_prevalence/en/.



VAL-070: confirmation of efficacy expected to reduce a cardiovascular risk factor

The first VAL-070 trial on humans aims to prove the product's efficacy and assess its benefits on the lipid profile of included subjects: blood total cholesterol levels, LDL cholesterol, HDL cholesterol, triglycerides and free fatty acids.

The study is conducted on 40 volunteers aged 18 to 70 years presenting with untreated mild to moderate hypercholesterolemia and hypertriglyceridemia. It is also expected to demonstrate VAL-070's good hepatic, renal and cardiac tolerance.

As with every study, VALBIOTIS is putting in place rigorous methodological standards for this Phase I/II trial, which will be randomized, placebo-controlled, double-blind. It will be completed during the first semester of 2018 and the results will be known mid-2018

Sébastien Peltier, Chairman of the VALBIOTIS Board of Directors, comments: *“The successful recruitment for this Phase I/II trial falls in line with our VAL-070 clinical development plan, which schedules the results announcement at the end of the first half of 2018. It marks a key step in the development of this product focusing on the major health subject of dyslipidaemias, a common risk factor for cardiovascular diseases. The year 2018 will be important, with the publication of 3 clinical results on reducing the risk factors of cardiometabolic diseases.”*

ABOUT VALBIOTIS

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

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 agreements enable it to benefit from a considerable leverage effect since it was set up thanks, in particular, to the experts and technical partners mobilized for these 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).

Find out more about VALBIOTIS:

<http://valbiotis.com/>





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