VALBIOTIS announces the First Patient's First Visit in the Phase II HEART clinical study on TOTUM-070 and steps up its research program against hypercholesterolemia in 2021

The first subject, with blood LDL-cholesterol ("bad cholesterol") levels greater than 130 mg/dL, has undergone the initial medical examination for the HEART protocol on the active substance TOTUM-070.

The HEART study will include 120 people with elevated blood LDL-cholesterol, a risk factor for cardiovascular disease and the primary endpoint of the study. Results are expected in early 2022.

In parallel, VALBIOTIS will carry out a clinical study on TOTUM-070 in 2021 to characterize all the metabolites of this active substance and identify their effects on human cell models.

Extensive preclinical work will simultaneously be conducted on the R&D platform and submitted to the American Heart Association (AHA) Annual Meeting in November 2021.

This development program will provide comprehensive data in early 2022 to position TOTUM-070 as a breakthrough innovation in the cardiovascular risk prevention market.

La Rochelle, February 22, 2021 (5:40 pm CET) **VALBIOTIS** (FR0013254851 - ALVAL, eligible for the PEA/SME), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **announces the First Patient's First Visit in the Phase II HEART clinical study evaluating TOTUM-070, an innovative active substance for the reduction of blood LDL-cholesterol levels, a risk factor for cardiovascular disease.**

The Company is stepping up development of TOTUM-070 in 2021, with the completion of a complementary clinical study and preclinical work on lipid metabolism. These preclinical results will be submitted to the American Heart Association (AHA) meeting at the end of the year.

"The start of recruitment for the Phase II HEART clinical study kicks off a decisive year for the development of TOTUM-070. This study should demonstrate the clinical efficacy of our active substance against excess blood LDL-cholesterol, a major risk factor for cardiovascular disease worldwide. Pending these results in early 2022, and given the potential of TOTUM-070, we have decided to conduct several complementary clinical and preclinical studies simultaneously this year. This is an ambitious program, which should provide a maximum amount of data by early next year and confirm TOTUM-070 as an additional innovation for people at risk of cardiovascular disease."

Murielle CAZAUBIEL,
Member of the Management Board,
Head of Development and Medical Affairs at VALBIOTIS

The randomized, double-blind, placebo-controlled, multicenter, Phase II HEART clinical study is designed to evaluate the efficacy of a 5g daily dose of TOTUM-070 on blood LDL-cholesterol levels, its primary endpoint. The study will include 120 people with LDL-cholesterol levels between 130 and 190 mg/dL. Results are expected in early 2022.

Development of TOTUM-070 stepped up in 2021

Simultaneously with the HEART study, VALBIOTIS has decided to conduct a complementary clinical study to expand knowledge of TOTUM-070 and its effects on lipid metabolism in humans. Conducted on a limited number of volunteers, it will combine a bioavailability study, metabolomic analysis (characterization and quantification of TOTUM-070 metabolites) and targeted *ex-vivo* mode of action tests on human cell models, mainly hepatic. Results are expected before the end of 2021.

Finally, a series of preclinical experiments will be launched and completed in 2021. Conducted on the VALBIOTIS R&D platform, this work is intended to detail the impact of TOTUM-070 on lipid metabolism in a predictive model of human pathophysiology. The results will be submitted to the annual meeting of the American Heart Association (AHA), the leading American learned society in the cardiovascular field, to be held from November 13 to 15, 2021.

Once development is complete, TOTUM-070, a new Health Nutrition product, will be positioned for individuals with LDL-hypercholesterolemia, at levels up to 190 mg/dL, with a moderate overall cardiovascular risk. At the end of 2020, the Company provided detailed market data on hypercholesterolemia and the role of TOTUM-070 in its management (see press release of October 27, 2020).

ABOUT THE HEART STUDY

The Phase II HEART clinical study is designed to evaluate the efficacy of a 5g daily dose of TOTUM-070 on blood LDL-cholesterol levels, a risk factor for cardiovascular disease, in the absence of lipid-lowering treatment.

This randomized, double-blind, placebo-controlled, multicenter study will include 120 people with untreated moderate hypercholesterolemia and blood LDL-cholesterol levels between 130 and 190 mg/dL. Participants will be divided into 2 equivalent arms of 60 people, supplemented for 6 months with TOTUM-070 or placebo.

The primary endpoint of the study will be the reduction of blood LDL-cholesterol levels, with several metabolic secondary endpoints of interest.

ABOUT TOTUM-070

TOTUM-070 is an innovative active substance derived from food plant extracts, without phytosterols or red rice yeast, developed to act on lipid metabolism in hypercholesterolemic individuals.

Once development is complete, this new Health Nutrition product will be positioned in particular for people with LDL-hypercholesterolemia, at levels up to 190 mg/dL, with a moderate overall cardiovascular risk. TOTUM-070 may be recommended in this large population for whom no first-line drug treatment is currently recommended, with the aim of reducing LDL-cholesterol levels and thus overall cardiovascular risk.

ABOUT VALBIOTIS

VALBIOTIS is a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases in response to unmet medical needs.

VALBIOTIS has adopted an innovative approach, aiming to revolutionize healthcare by developing a new class of nutritional health solutions designed to reduce the risk of major metabolic diseases, based on a multi-target approach and made possible by the use of plant-based ingredients.

Its products are intended to be licensed to players in the health world.
VALBIOTIS was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers. The Company has established three sites in France – Périgny, La Rochelle (17) and Riom (63).

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). VALBIOTIS is a PEA-SME eligible company.

Find out more about VALBIOTIS: www.valbiotis.com

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This press release contains forward-looking statements about VALBIOTIS' objectives, based on rational hypotheses and the information available to the company at the present time. However, in no way does this constitute a guarantee of future performance, and these projections can be reconsidered based on changes in economic conditions and financial markets, as well as a certain number of risks and doubts, including those described in the VALBIOTIS core document, filed with the French Financial Markets Regulator (AMF) on 31 July 2020 (application number R20-018), these documents being available on the Company's website (www.valbiotis.com).

This press release, as well as the information contained herein, does not constitute an offer to sell or subscribe to, or a solicitation to purchase or subscribe to, VALBIOTIS' shares or securities in any country.

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