valbiotis®

Press release

Valbiotis announces completion of recruitment for the Phase II/III HEART 2 clinical trial with Lipidrive® to combat hypercholesterolemia, a risk factor for cardiovascular disease

- **The last volunteer has been included in the HEART 2 study; recruitment of the 180 participants in this multi-center, randomized, placebo-controlled clinical trial has been completed;**
- **The primary endpoint of the study is reduction in blood LDL-cholesterol levels, a risk factor for cardiovascular disease and the main risk factor for atherosclerosis[1];**
- **This Phase II/III clinical study will enable the submission of a proprietary health claim to the European Food Safety Authority (EFSA).**

La Rochelle, June 13, 2024 (17:40 p.m. CEST) - **Valbiotis** (FR0013254851 – ALVAL, PEA/SME eligible), French scientific research laboratory, specialized in the development and marketing of dietary supplements for the prevention and fight against metabolic disorders causing cardiovascular diseases, **announces that it has completed the recruitment of 180 volunteers for the Phase II/III HEART 2 clinical trial with Lipidrive® (ex-TOTUM•070) against hypercholesterolemia, a risk factor for cardiovascular disease. The results of the HEART 2 study will be available in the first quarter of 2025.**

The HEART 2 clinical trial is a multi-center, randomized, placebo-controlled, double-blind study involving 180 people with untreated moderate hypercholesterolemia between 130 and 190 mg/dL. Participants are divided into 2 equivalent arms of 90 people, supplemented for 3 months with **Lipidrive®** (5 g/day) or placebo. The primary endpoint of the HEART 2 study is the reduction of blood LDL-cholesterol levels, a risk factor for cardiovascular disease and, in particular, atherosclerosis. This clinical study will enable a proprietary health claim to be filed with the European Food Safety Authority (EFSA).

Murielle CAZAUBIEL, Director of Development, Medical, Regulatory and Industrial Affairs at Valbiotis, and member of the Executive Committee, comments: *"The clinical development of **Lipidrive®** is now in the homestretch with the completion of enrollment in HEART 2, a multi-center, randomized, placebo-controlled, double-blind study designed to meet the highest standards. HEART 2 should confirm the positive results obtained in the Phase II HEART study in people with untreated mild-to-moderate hypercholesterolemia and pave the way for a proprietary health claim."*

The result of nearly 10 years of Research & Development, **Lipidrive®** is a 100% natural, non-drug active substance patented in 19 countries, and has been the subject of two clinical efficacy studies (HEART and OLALIP) designed to meet the highest standards.

[1]2018 Guideline on the Management of Blood Cholesterol, a report from the American College of Cardiology / American Heart Association, Journal Of The American College Of Cardiology, 2019

The international, multi-center, randomized, double-blind, placebo-controlled Phase II HEART study, conducted with a **Lipidrive®** dose of 5 g/day in 120 subjects, showed a significant reduction in blood LDL-cholesterol ("bad cholesterol") levels in as little as 3 months:

- a 16% reduction in subjects whose LDL-cholesterol was greater than 1.30 g/L,
- and a 22% reduction in subjects with LDL-cholesterol above 1.60 g/L.

The OLALIP study, conducted at a **Lipidrive®** dose of 2.5 g/day, demonstrated a 13% reduction in subjects with LDL-cholesterol above 1.30 g/L.

Effective in 93% of individuals, these two clinical studies also concluded that **Lipidrive®** had a very good safety and tolerance profile, with perfect compliance.

Lipidrive® also offers a multi-targeted mode of action on lipid metabolism. The principal mechanism of action is a reduction in cholesterol absorption by enterocytes. In addition, **Lipidrive®** delivers a complementary mechanism of action by targeting cholesterol metabolism in the liver[2].

In terms of scientific endorsement, **Lipidrive®** has already been the subject of 15 presentations at international congresses and three scientific publications in peer-reviewed journals.

Sébastien BESSY, Director of Marketing and Sales Operations at Valbiotis, and member of the Executive Committee, says: *"Valbiotis remains faithful to its clinical strategy aimed at backing up its portfolio of dietary supplements with solid scientific evidence. The HEART 2 study is designed to bolster the commercial potential of* ***Valbiotis®PRO Cholestérol****, a product derived exclusively from the patented* ***Lipidrive®*** *substance, launched on the French market and now available in pharmacies and on the Company's website."*

Untreated hypercholesterolemia: a vast market for non-drug products

In the five major European countries (France, Germany, Italy, Spain and the UK) and the USA, an estimated 177 million adults have elevated LDL-cholesterol levels[3,4]. Thanks to a high rate of diagnosis, approaching 50%, the diagnosed population is now 84 million people[4].

However, in line with recommendations, only people with a high overall cardiovascular risk benefit from treatment. A large proportion of those diagnosed are already turning to non-drug products, notably in the USA (54% of those diagnosed), the UK (58%), France (34%) and Germany (35%)[4]. The market for these LDL-cholesterol-lowering products is estimated at nearly €1.2 billion in these regions, including over €600 million in the United States[5].

About Valbiotis

French scientific research laboratory, specialized in the development and marketing of dietary supplements for the prevention and fight against metabolic disorders causing cardiovascular diseases.
Valbiotis has adopted an innovative approach, aiming to revolutionize healthcare by developing a new class of health nutrition products designed to reduce the risk of major metabolic diseases, relying on a multi-target strategy enabled by the use of plant-based terrestrial and marine resources.
Internationally, its products are intended to be the subject of licensing agreements with global and regional health and nutrition players. In France, Valbiotis is responsible for marketing its own products.
Created at the beginning of 2014 in La Rochelle, the Company has forged numerous partnerships with leading academic centers. The Company has established three sites in France – Périgny, La Rochelle (17) and Riom (63) – and a subsidiary in Quebec City (Canada).
Valbiotis is a member of the "BPI Excellence" network and has been recognized as an "Innovative Company" by the BPI label. Valbiotis has also been awarded "Young Innovative Company" status and has received major financial support from the European Union for its research programs via the European Regional Development Fund (ERDF). Valbiotis is a PEA-SME eligible company.
For more information about Valbiotis, please visit: www.valbiotis.com

[2]Wauquier et al., Nutrients 2023 ; Langhi et al., Nutrients 2023
[3]Blood LDL cholesterol level greater than 100 or 130 mg/dL, depending on available data
[4]Données AEC Partners, 2024, for Valbiotis.
[5]Données AEC Partners, 2019, for Valbiotis.

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