



## Valbiotis announces the completion of recruitment for the Phase II HEART clinical study conducted with TOTUM•070 in hypercholesterolemia, a risk factor for cardiovascular disease

- Recruitment of the last volunteer, randomized at the beginning of September 2021, confirms the announced schedule of the HEART clinical study, the results of which will be available in the second quarter of 2022.
- The multi-center, randomized, placebo-controlled HEART clinical study is designed to evaluate the efficacy of TOTUM•070 in 120 people with mild to moderate untreated hypercholesterolemia.
- The primary endpoint of the study is the reduction in blood LDL-cholesterol levels, a risk factor for cardiovascular disease and the main risk factor for atherosclerosis<sup>1</sup>.
- The HEART study is a key step in the development of TOTUM•070 and in the commercialization strategy on the non-drug hypercholesterolemia market, estimated at 1.2 billion euros in Europe and the USA<sup>2</sup>.

**La Rochelle, September 6, 2021 (5:40 p.m. CEST) - Valbiotis (FR0013254851 – ALVAL, PEA/SME eligible), a French research and development company committed to scientific innovation for preventing and combating metabolic diseases, announces that it has completed the recruitment of 120 volunteers for the Phase II HEART clinical study at the beginning of September 2021, in accordance with the schedule announced by the Company. In line with its development plan, Valbiotis confirms that the results of the HEART study will be available in the second quarter of 2022.**

The HEART clinical study is a multicenter, international, randomized, placebo-controlled, double-blind study involving 120 people with untreated moderate hypercholesterolemia between 130 and 190 mg/dL. Participants are divided into two equivalent arms of 60 people, supplemented for 6 months with TOTUM•070 or placebo. The primary endpoint of the HEART study is the reduction of blood LDL-cholesterol levels, a risk factor for cardiovascular disease and in particular atherosclerosis, and it has several secondary objectives of interest.

Murielle CAZAUBIEL, Head of Development, Medical, Regulatory and Industrial Affairs, member of the Valbiotis Board of Directors, comments: *"We are completing enrollment in the HEART clinical study and we are delighted with the progress of this study and look forward to seeing the results in a few months. The medical need is real: according to the WHO, nearly 40% of the world's adult population has high cholesterol, a well-known cardiovascular risk factor. High-risk patients are generally treated with drug-based approaches. But for more moderate forms, there is a lack of a non-drug, open-label, clinically proven option to reduce excess blood LDL-cholesterol before it becomes too high risk. We are developing TOTUM•070 to bring this preventive option to as many people as possible."*

<sup>1</sup>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.

<sup>2</sup>Données AEC Partners, 2019, pour Valbiotis.

TOTUM•070 is an innovative active substance derived from food plant extracts, without phytosterols or red yeast rice, developed to act on lipid metabolism in people with hypercholesterolemia. Once development is completed, TOTUM•070 will be indicated for people with LDL-hypercholesterolemia, for levels up to 190 mg/dL, with a moderate overall cardiovascular risk. TOTUM•070 could be recommended in this large population for whom no first-line drug treatment is currently recommended ([see press release of October 27, 2020](#)).

Sébastien BESSY, Head of Marketing and Commercial Operations, member of the Valbiotis Board of Directors, states: *"The HEART clinical study is a key element in the marketing strategy: it is designed to demonstrate the efficacy of our active substance TOTUM•070 for people at risk who are not currently receiving treatment. The market for untreated hypercholesterolemia is already very significant and is worth 1.2 billion euros in Europe and the United States<sup>2</sup>. In these vast markets, the success of HEART would give TOTUM•070 a decisive advantage with consumers."*

### **Untreated hypercholesterolemia: the large market of non-drug products**

In the 5 major European countries (France, Germany, Italy, Spain, United Kingdom) and the United States, an estimated 174 million adults have elevated LDL-cholesterol levels<sup>2,3</sup>. Thanks to a high diagnosis rate, approaching 50%, the diagnosed population is 83 million people<sup>2</sup>.

However, in accordance with the recommendations, only people at high overall cardiovascular risk are treated. A large proportion of those diagnosed are therefore already turning to non-drug products, notably in the USA (54% of people diagnosed), the UK (58%), France (34%) and Germany (35%)<sup>2</sup>. The market for these LDL-cholesterol lowering products is today estimated at nearly €1.2 billion in these regions, including more than €600 million in the United States<sup>2</sup>.

## — 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 health nutrition products designed to reduce the risk of major metabolic diseases, based on a multi-target approach enabled by the use of plant-based ingredients.

Its products are intended to be licensed to players in the health sector.

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](http://www.valbiotis.com).

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<sup>3</sup>Blood LDL-cholesterol level greater than 100 or 130 mg/dL, depending on available data.



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This press release contains forward-looking statements about Valbiotis' objectives. Valbiotis considers that these projections are based on rational hypotheses and the information available to Valbiotis at the present time. However, in no way does this constitute a guarantee of future performance, and these projections may be affected by changes in economic conditions and financial markets, as well as certain risks and uncertainties, including those described in the Valbiotis Universal Registration Document approved by the French Financial Markets Regulator (AMF) on July 27, 2021 (application number R 21-039). This document is available on the Company's website ([www.valbiotis.com](http://www.valbiotis.com)).

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