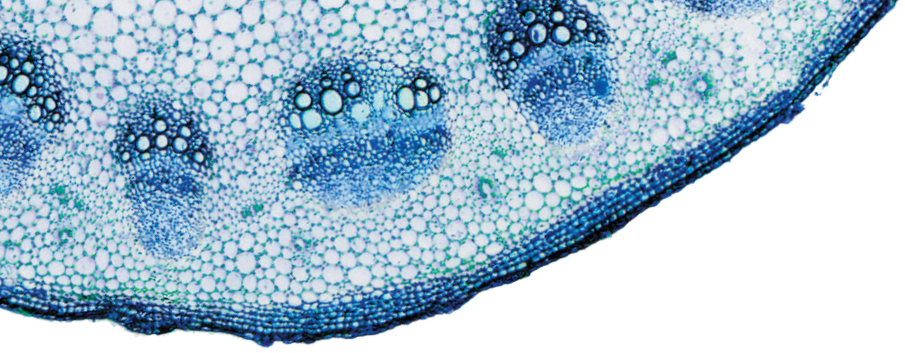

Valbiotis presents additional positive results from the HEART clinical study on TOTUM•070 for hypercholesterolemia

- TOTUM•070 demonstrates excellent results in volunteers with blood LDL cholesterol levels above 130 mg/dl at randomization, its commercially targeted population and the primary subpopulation of the HEART study:
  - Increased and lasting efficacy on blood LDL cholesterol levels, with a reduction of 13.7% after three months and 14.3% after six months, compared to placebo.
  - A very high response rate, reaching 92.5% of responders, from three months in this subpopulation and up to 100% responders when cholesterol levels at baseline exceeded 160 mg/dl.
- In addition, new data confirming the multi-targeted intestinal and hepatic mode of action of TOTUM•070 in preclinical and human studies will be presented at the upcoming American Heart Association Annual Meeting.
- TOTUM•070, a patented plant-based active substance, without phytosterols or red yeast rice, now has a strong record of clinical and scientific evidence supporting its commercial application.
- Backed by market studies[1], the Company confirms its objective of marketing the product by the first half of 2024 at the latest and is intensifying its discussions with major players in the health and nutrition sectors.

La Rochelle, October 3, 2022 (7:35 am CEST) - **Valbiotis** (FR0013254851 – ALVAL, PEA/SME eligible), a Research and Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, **presents additional positive results from the Phase II HEART clinical study with TOTUM•070 for hypercholesterolemia. In the commercially targeted population with cholesterol levels above 130 mg/dl at randomization, TOTUM•070 reduced blood LDL cholesterol levels by 13.7% at 3 months and by 14.3% at 6 months, compared to placebo, with a very high response rate. In parallel, Valbiotis has obtained new data confirming the intestinal and hepatic mode of action of this active substance, in preclinical and human studies, which will be presented at the next American Heart Association Annual Meeting. With this solid clinical and scientific package for TOTUM•070, backed up by market studies[1], the Company has validated its objective of commercialization by the first half of 2024 at the latest and is intensifying its exchanges with major players in the health and nutrition sectors.**

Prof. Jean-Marie BARD, professor of biochemistry and hospital pharmacy practitioner at the University Hospital of Nantes and the Institut de Cancérologie de l'Ouest (ICO), scientific advisor of the HEART study, comments: *"The analysis of the additional data from the HEART study reinforces the initial positive results previously announced. With these more precise data, focused on the final target population, TOTUM•070 is particularly effective for people with blood LDL cholesterol levels above 130 mg/dl. The magnitude of the reduction in LDL cholesterol, its rapidity and maintenance over time, with a high response rate, are excellent results, especially for a non-drug product. The HEART study now clearly demonstrates the efficacy of*

[1]Market studies conducted by the IFOP and A+A institutes for Valbiotis in 2022, with doctors and patients / consumers, in France, Germany and the USA.

TOTUM•070 for people with mild to moderate hypercholesterolemia, for whom pharmaceutical treatments are not recommended, in the prevention of cardiovascular risk."

Additional positive results from the HEART clinical study in the final target population

The Phase II HEART clinical study was a multi-center, international, randomized, placebo-controlled, double-blind study involving 120 people with untreated mild to moderate LDL hypercholesterolemia. The participants were divided into 2 equivalent arms of 60 people, supplemented for 6 months with a daily dose of 5 g of TOTUM•070 or a placebo, in two intakes. The first positive results were announced on June 13, 2022 (press release of June 13, 2022).

Of the 120 volunteers included in the study, 84 had blood LDL cholesterol levels greater than 130 mg/dl at randomization, which is the commercially targeted population for TOTUM•070.

In this population, TOTUM•070 showed increased efficacy on blood LDL cholesterol levels, with a 13.7% reduction obtained at 3 months and 14.3% at 6 months compared to placebo. Blood triglyceride levels were reduced by 14.3% at 3 months and 14.4% at 6 months, compared to placebo. Also in this population, the data show a very high response rate, with 92.5% of volunteers responding at 3 months. This rate even reached 100% when the cholesterol level at inclusion exceeded 160 mg/dl.

Furthermore, in the overall study population, stratified analysis showed that the magnitude of the reduction in blood LDL cholesterol was significantly correlated with the level of LDL cholesterol at baseline: TOTUM•070 was more effective the higher the initial cholesterol level.

New data on the multi-targeted intestinal and hepatic mode of action of TOTUM•070 selected by the American Heart Association Annual Meeting

Following the first mode of action data already published, extensive preclinical work explored the specific action of TOTUM•070 at the intestinal level. This work first demonstrated effects on the abundance and diversity of the intestinal microbiota, as well as on bacteria known to be involved in the regulation of metabolism, which could help explain the effects of TOTUM•070. Other studies have also confirmed and documented the effect of TOTUM•070 on intestinal cholesterol absorption, one of the main levers of action on hypercholesterolemia. They will be presented at the next annual meeting of the American Heart Association in November 2022.

At the hepatic level, the clinical mode of action study, which had previously reported positive results (press release of March 29, 2022), has delivered additional results at the molecular level[2]. RNA sequencing analyses demonstrate that TOTUM•070 metabolites modulate a large number of genes involved in the regulation of cholesterol, fatty acid and lipoprotein metabolism in human liver cells. These molecular data confirm the effect of TOTUM•070 on human liver cells and provide additional information on the hepatic mechanisms of action of TOTUM•070. These additional results will also be presented at the AHA meeting in November 2022.

Murielle CAZAUBIEL, Director of Medical, Regulatory and Industrial Affairs and member of the Valbiotis Board of Directors, comments: *"The additional clinical efficacy results from the HEART study are excellent for TOTUM•070. With all the preclinical and clinical studies conducted, we now have a very robust level of evidence to support the value and positioning of TOTUM•070 against excess LDL cholesterol in the frame of cardiovascular risk prevention."*

Sébastien BESSY, Director of Marketing and Commercial Operations and member of the Board of Directors, adds: *"The commercial potential of TOTUM•070 is clearly supported by the market studies[1] we have conducted with consumers and doctors in various international markets. This backs up our ambitious objectives of commercialization by the first half of 2024 at the latest, and of intensifying exchanges with major players in the health and nutrition sectors."*

[2]Protocol combining metabolomics and mode of action, designed and implemented by Clinic'n'Cell.

About Valbiotis

Valbiotis is a Research & Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular 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 and cardiovascular diseases, relying on a multi-target strategy enabled by the use of plant-based terrestrial and marine resources.
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

Contacts

Corporate communication
Valbiotis
Carole ROCHER / Marc DELAUNAY
+33 5 46 28 62 58
media@valbiotis.com

Financial communication
Actifin
Stéphane RUIZ
+33 1 56 88 11 14
sruiz@actifin.fr

Medias relations
PrPa
Damien MAILLARD
+33 6 80 28 47 70
damien.maillard@prpa.fr

Name: Valbiotis
ISIN code: FR0013254851
Mnemonic code: ALVAL
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