

## **Valbiotis to launch its 100% natural dietary supplement for the management of hypercholesterolemia on the French market in May**

- **Valbiotis®PRO Cholestérol, composed of the patented 100% natural origin active substance Lipidrive® (formerly TOTUM-070), for the treatment of mild to moderate LDL hypercholesterolemia, will be available in pharmacies and via the Company's website this May, on schedule;**
- **General practitioners will recommend Valbiotis®PRO Cholestérol to their patients, who will be able to obtain the product from their pharmacy. At the same time, to enable wider patient access, Valbiotis®PRO Cholestérol will also be available on the Company's dedicated e-commerce site;**
- **An internal team of 16 experienced Medical Promotion Officers deployed in high-potential geographical areas to promote Valbiotis®PRO Cholestérol among pre-identified healthcare professionals (general practitioners, nutritionists, and pharmacists);**
- **An initial industrial production run has already been completed, with rigorous formulation requirements and management of the entire value chain, from logistics to IT, to ensure that the Company's commercial goals are met;**
- **Discussions with a view to an international licensing agreement are ongoing.**

**La Rochelle, April 3, 2024 (08:30 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 the French launch, as of May, of Valbiotis®PRO Cholestérol, a dietary supplement composed exclusively from Lipidrive® (formerly-TOTUM-070), a patented active ingredient of 100% natural origin for the management of mild to moderate hypercholesterolemia.**

### **Valbiotis®PRO Cholestérol, a clinically tested non-drug solution for the management of mild to moderate hypercholesterolemia**

The result of nearly 10 years of Research & Development, **Lipidrive®**, the non-drug active substance contained in **Valbiotis®PRO Cholestérol**, patented in 19 countries and 100% natural origin, has been the subject of 2 clinical efficacy studies (HEART and OLALIP), meeting the most exacting standards.

The international, multicenter, 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 levels of LDL cholesterol ("bad cholesterol") in as little as 3 months of use:

- -16% in subjects with LDL cholesterol above 1.30 g/L,
- and -22% in subjects with LDL cholesterol above 1.60 g/L.

The OLALIP study, conducted with a **Lipidrive®** dose of 2.5 g/day, showed 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 the safety and tolerability profile was very good, and compliance was excellent.

**Lipidrive®** is based on a multi-target mode of action on lipid metabolism. The principal mechanism of action is a reduction in cholesterol absorption by enterocytes. **Lipidrive®** also has a complementary mechanism of action, acting on cholesterol at the level of hepatic metabolism<sup>1</sup>.

In terms of scientific recognition, **Lipidrive®** has already been the subject of 15 presentations at international congresses and 3 international scientific publications in peer-reviewed journals.

**Jean-Marie Bard, Professor Emeritus of Biochemistry, hospital pharmacy practitioner and scientific advisor to Valbiotis, explains:** "I am delighted that **Valbiotis®PRO Cholestérol**, the result of nearly a decade of in-depth research, will soon be available to patients and healthcare professionals. This patented plant-based solution, which has been the subject of two clinical efficacy studies, marks a significant step forward in the management of mild to moderate hypercholesterolemia. The natural and innovative characteristics of this product clearly position **Valbiotis®PRO Cholestérol** as a leader in the lifestyle and dietary management of hypercholesterolemia, a major risk factor for cardiovascular disease."

### First industrial production carried out

The first industrial production run of **Valbiotis®PRO Cholestérol** has been completed at a French pharmaceutical manufacturer qualified by Valbiotis' teams as part of its ISO 9001 certified quality management system. The following productions are already planned. They are based on highly rigorous formulation: **Valbiotis®PRO Cholestérol** is dye-free, gluten-free, lactose-free, allergen-free, and preservative-free.

In terms of packaging, **Valbiotis®PRO Cholestérol** will be sold in pillboxes in pharmacies and in doypacks on the Company's e-commerce site, both of which are fully recyclable.



### A logistics partner and an IT solution to guarantee successful market launch

In terms of logistics, the Company has entered into a contract with a leading partner, suitable for both launch and commercial ramp-up. In addition to securing supplies for pharmacies, their wholesalers/distributors and consumers, our partner promotes environmentally friendly solutions and carbon-neutral warehousing.

<sup>1</sup>Wauquier et al., Nutrients 2023 ; Langhi et al., Nutrients 2023

The IT transformation is nearing completion, with the integration of the supply chain and sales modules into the ERP, the implementation of a CRM tool, interfacing with the selected logistics partner and the finalization of the e-commerce platform.

### **An optimally sized sales force with 16 Medical Promotion Officers for launch**

The sales strategy is centered on two pillars:

1. An internal team of Medical Promotion Officers to present **Valbiotis<sup>®PRO</sup> Cholestérol** to healthcare professionals (general practitioners, nutritionists, and pharmacists), a Medical Expert and a management team;
2. Digital marketing directly targeting patient-consumers, led by a highly qualified team already in place.

The 16 Medical Promotion Officers recruited for the launch (32 in the medium term) provide Valbiotis with a sales force optimally sized to make its mark as one of France's leading players in the dietary supplement sector. These experienced professionals cover high-potential geographical areas in France. Supervised by an area manager reporting to the France Sales Director, they rely on a Medical Expert and a Customer Relations department, both of which are now operational.

**Valbiotis<sup>®PRO</sup> Cholestérol**, priced at €39.95 (recommended retail price) for a month's supply of supplements, may be recommended by the patient's general practitioner following a blood test. Available behind the counter in pharmacies, the dietary supplement will also be sold without a prescription with a pharmacist's recommendation. Pharmacies will be able to obtain supplies directly from Valbiotis or from their wholesalers/distributors. Finally, **Valbiotis<sup>®PRO</sup> Cholestérol** will be available to the widest possible number of people via the Company's dedicated e-commerce site.

### **The Valbiotis<sup>®PLUS</sup> range supports the Valbiotis<sup>®PRO</sup> range to tackle disorders commonly associated with cardio-metabolic diseases**

The Company's e-commerce platform will also offer exclusive access to **Valbiotis<sup>®PLUS</sup>**, the over-the-counter range of natural dietary supplements, addressing health problems commonly associated with hypercholesterolemia and meeting the needs of patient-consumers. The first six dietary supplements will be launched in May: Omega 3, Vitamin D3, Antioxidants, Weight management, Muscle comfort and Sleep.

### **International roll-out of Lipidrive<sup>®</sup>: discussions continue in preparation for an agreement**

Alongside the launch of **Valbiotis<sup>®PRO</sup> Cholestérol, exclusively containing Lipidrive<sup>®</sup>**, in France, the Company is pursuing its Business Development activities with a view to signing one or more licensing agreements for this product, either worldwide or regionally (outside France). Discussions are currently underway with several players in the nutrition and healthcare sectors. Bringing them to a successful conclusion will remain a priority for Valbiotis throughout 2024.

**Sébastien PELTIER, Chairman of the Executive Committee and Valbiotis co-founder:** *"All the Valbiotis teams are extremely enthusiastic about this major milestone, marking the market launch of the Company's very first product. We are entering this new chapter with peace of mind, focused on generating revenue from commercialization, in addition to the income from existing licensing agreements (with Nestlé Health Science for TOTUM•63) and those still to come. This is the culmination of a decade of R&D activity, which has ensured that our portfolio of dietary supplements boasts a high level of scientific proof. Today, Valbiotis has all the attributes to become a leader in the management of the early to moderate stages of cardiovascular disorders, and to establish itself as a future European champion in 100% plant-based dietary supplements with strong scientific credentials."*

## **An innovation in the management of hypercholesterolemia in France**

Cholesterol is a fatty substance that is essential to the body. But when it is present in excess (hypercholesterolemia), it can accumulate in the arteries, causing them to become clogged and increasing the risk of cardiovascular disease, such as heart attack or stroke.

In France, **1 in 2 people suffer from mild to moderate hypercholesterolemia**, and many are unaware of it. Some 20% of French adults have cholesterol levels in excess of 1.6g/L, exposing a large proportion of the population to cardiovascular risks<sup>2</sup>.

With **Valbiotis<sup>®PRO</sup> Cholestérol**, the Company aims to raise public awareness of the importance of early detection and proactive management of hypercholesterolemia.

**Valbiotis<sup>®PRO</sup> Cholestérol**, is an innovative, clinically tested solution for people confronted with this cardiovascular health challenge. It comprises a new generation of dietary supplements **with active ingredients of natural origin**, acting on several targets for comprehensive management.

Its patented **Lipidrive<sup>®</sup> formula incorporates 5 plant extracts - artichoke, olive, chrysanthellum, goji and black pepper** - offering a multi-target mechanism of action. A principal mechanism controls intestinal cholesterol absorption, while a complementary mechanism acts on hepatic metabolism for a comprehensive approach to the management of hypercholesterolemia.

Red yeast rice-free, **Valbiotis<sup>®PRO</sup> Cholestérol** is well tolerated and has no side effects.

## **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 will be 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](http://www.valbiotis.com)

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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 filed to the French Financial Markets Regulator (AMF) on April 26, 2023 under No. D.23-0347 as well as its Amendment filed with the AMF on December 11, 2023 under No. D. 23-0347.A01. This document is available on the Company's website ([www.valbiotis.com](http://www.valbiotis.com)).

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