



## Valbiotis announces the first visit of the first patient in the TOTUM•63 mode of action clinical study conducted by the INAF<sup>1</sup>, in partnership with Nestlé Health Science

- The TOTUM•63 mode of action clinical study has been officially launched, following the necessary authorizations from Health Canada and the CERUL<sup>2</sup> and the first medical visit of the first subject included in the study.
- This study conducted by the INAF at Laval University in Quebec City (Canada) under the supervision of Prof. André MARETTE and Prof. Marie-Claude VOHL, will explore the main hypotheses of the mode of action of TOTUM•63 in 20 overweight or obese volunteers at risk of developing metabolic diseases such as diabetes.
- The mode of action data obtained will complement the efficacy results of the ongoing pivotal Phase II/III REVERSE-IT study and will support the scientific communication on and commercialization of this active substance on the prediabetes market.
- The first visit of the first patient in this clinical study marks a milestone payment from Nestlé Health Science to Valbiotis, as part of the global strategic partnership.

**La Rochelle, April 28, 2022 (17:40 pm CEST) - Valbiotis** (FR0013254851 – ALVAL, PEA/SME eligible), a Research and Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, **announces the first visit of the first patient in the TOTUM•63 mode of action clinical study conducted by the Laval University Institute of Nutrition and Functional Foods (INAF) in Quebec City, in partnership with Nestlé Health Science.** The study has now been launched, after receiving approval from Health Canada and the CERUL<sup>2</sup>.

This study, co-designed by Valbiotis in consultation with experts from the INAF and Nestlé Health Science as part of the global strategic partnership, will include 20 volunteers and will explore the mechanism of action of TOTUM•63 in humans. It will provide additional data to support scientific communication on TOTUM•63 and accompany its commercialization. It will be scientifically supervised by André MARETTE and Marie-Claude VOHL, professors at the Laval University Faculty of Medicine and researchers at the INAF.

Murielle CAZAUBIEL, Director of Medical, Regulatory and Industrial Affairs, member of the Valbiotis Board of Directors, comments: *“This exploratory mode of action study will identify the mechanisms of action of TOTUM•63 in overweight or obese subjects with metabolic disturbances. These data will complement the efficacy data from the pivotal Phase II/III REVERSE-IT clinical trial, which is currently underway. We are excited to enter this final push into the prediabetes market and thank the INAF and our partner Nestlé Health Science for their involvement right alongside us.”*

The TOTUM•63 clinical mode of action study will explore the main hypotheses of the mode of action in humans established thanks to the results of preclinical work. It will include 20 volunteers who are overweight or obese with metabolic abnormalities. With a large number of scientific objectives, the

<sup>1</sup>Institute of Nutrition and Functional Foods (INAF) ;

<sup>2</sup>Health Sciences Sectoral Committee of the Laval University Ethics Committee for Research with human subjects.

protocol will evaluate the effect of TOTUM•63 administration for 8 weeks on several of the mechanistic parameters involved in the pathophysiology of prediabetes and type 2 diabetes, using in-depth physiological explorations: mainly intestinal nutrient absorption, metabolomics, inflammation, gut microbiota composition and gastrointestinal hormones (incretins, including GLP-1).

As part of the global strategic partnership on TOTUM•63, today's announcement of the first visit of the first patient is a milestone that results in a new lump-sum payment from Nestlé Health Science to Valbiotis, to be received in the first half of 2022.

Sébastien PELTIER, CEO and Chairman of the Board of Directors, adds: *"2022 will be a decisive year in the acceleration of our clinical calendar with important results expected in our main indications. Today, in the field of prediabetes, we are reaching a new milestone that materializes the strength of the project built with our partner Nestlé Health Science. Together, we are moving forward on the roadmap that will lead us to the future launch of a product with proven scientific value that will support its potential for commercialization around the world. This also marks an opportunity to benefit from a new milestone payment that further strengthens our financial position as we pursue our ambitious strategic market plan."*

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## About INAF

Created in the early 2000s to address the challenges of sustainable nutrition and the prevention of metabolic diseases, the INAF brings together some 100 researchers in the biofood, health and social sciences sectors from 14 universities and scientific institutions in Quebec. Its multidisciplinary approach and the quality of the projects it coordinates have earned it a reputation for scientific excellence on the North American continent.

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## About TOTUM•63

TOTUM•63 is a unique and patented combination of 5 plant extracts that targets the pathophysiological mechanisms of type 2 diabetes.

TOTUM•63 has already been shown to be safe and effective in healthy volunteers in a Phase I/II clinical study. Results from a randomized, placebo-controlled, international Phase II study showed that when compared to the placebo, TOTUM•63 reduced fasting blood glucose and 2-hour blood glucose levels, two risk factors for type 2 diabetes. In these subjects, who were also abdominally obese, TOTUM•63 also significantly reduced body weight and waist circumference.

TOTUM•63 benefits from intellectual property validated by patents in the world's leading markets: Europe (covering 39 countries), the United States, Russia, China, Japan, Mexico, Indonesia, Israel, South Africa, New Zealand and national phases are still underway in a dozen other countries including Brazil and Australia. Production capacity for TOTUM•63 has been validated in accordance with North American and European standards. TOTUM•63 already has marketing authorizations related to its status in Europe.

In February 2020, Valbiotis signed a long-term global strategic partnership with Nestlé Health Science for the development and worldwide commercialization of TOTUM•63. This unique partnership in the field of Health Nutrition foresees the marketing of TOTUM•63 by Nestlé Health Science on a worldwide scale, possibly before obtaining a medical clearance depending on the area. They will also fund the final stages of development of TOTUM•63.

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## 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 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](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 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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