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## Valbiotis announces the last visit of the last patient in the Phase II/III REVERSE-IT study on TOTUM•63, in partnership with Nestlé Health Science

- The last patient included in the study has completed the final protocol follow-up visit.
- The first results of the study will be released before the end of the first half of 2023, after the database is frozen and the statistical analysis work is completed.
- This international, multicenter Phase II/III study evaluates the efficacy of TOTUM•63, a plant-based active substance, in a population with impaired glucose metabolism, from prediabetes to untreated type 2 diabetes (early stage).
- Its primary objective is to reduce fasting blood glucose levels after 24 weeks of supplementation with a daily dose of 5 g of TOTUM•63, in 3 intakes, compared with placebo.
- The REVERSE-IT study was co-designed by Nestlé Health Science and Valbiotis as part of the overall strategic partnership between the two companies on TOTUM•63; as such, the results of the study are associated with milestone payments from Nestlé Health Science.

**La Rochelle, March 13, 2023 (5:40 p.m CET) - Valbiotis** (FR0013254851 – ALVAL, PEA / SME eligible), a commercially oriented Research and Development company, committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, **announces the last visit of the last patient enrolled in the Phase II/III REVERSE-IT study on the active substance TOTUM•63.** This international, multi-center, randomized, placebo-controlled study on 600 untreated prediabetic and type 2 diabetic patients (early stage) is designed to confirm the efficacy of TOTUM•63 on impaired glucose metabolism. The first results will be available and communicated before the end of the first half of 2023, in accordance with the schedule announced on September 15, 2022.

TOTUM•63 is a unique and patented combination of 5 plant extracts that targets the pathophysiological mechanisms of type 2 diabetes. It has been developed to address a large unmet need: to act on metabolic impairments in the early stages of type 2 diabetes, in particular prediabetes. Prediabetes currently affects nearly 900 million people worldwide, including 128 million in the United States and the five main European<sup>1</sup> countries, for whom no non-drug health product yet has solid proof of efficacy.

Nestlé Health Science has the exclusive and global commercial rights to use TOTUM•63 in the prediabetes and type 2 diabetes market.

Murielle CAZAUBIEL, Director of Medical, Regulatory and Industrial Affairs, member of the Valbiotis Executive Committee, comments: *"The development of TOTUM•63, our first innovative active substance, is nearing completion. The conclusion of the REVERSE-IT study is an unprecedented achievement for Valbiotis: with 600 patients enrolled in more than 50 centers worldwide, REVERSE-IT is one of the*

<sup>1</sup>AEC Partners data on Valbiotis' key markets, 2019



*largest and most ambitious studies conducted globally with non-drug approaches in early dysglycemia, from prediabetes to early type 2 diabetes. We would like to pay tribute to the long-term work carried out by all the teams involved, without whom this challenge could not have been met. We also thank the Nestlé Health Science teams for their guidance and support as part of our strategic partnership on TOTUM•63. The demanding work of analyzing the database will now begin, with the hope that it will confirm the potential of TOTUM•63 for people affected by the risk of diabetes and its early stages and pave the way for the commercialization of this breakthrough active substance."*

Hans-Juergen WOERLE, Chief Scientific and Chief Medical Officer at Nestlé Health Science, adds: *"We co-designed the REVERSE-IT study with Valbiotis to provide a large clinical dataset on TOTUM•63 for the benefit of people with early dysglycemia. An increasing number of people around the world are at risk of type 2 diabetes. We welcome the completion of this highly ambitious study and look forward to the initial results for the management of this early deterioration in glucose metabolism."*

The Phase II/III REVERSE-IT randomized, double-blind, placebo-controlled study includes 600 people with impaired glucose metabolism, ranging from prediabetes to untreated type 2 diabetes (early stage). Its primary objective will be to confirm the reduction of fasting blood glucose levels by TOTUM•63 taken three times daily for a total daily dose of 5 g over 24 weeks. The protocol will also evaluate the effect of the same daily dose of TOTUM•63 on fasting blood glucose levels but taken twice daily. Finally, REVERSE-IT will evaluate the effects of TOTUM•63 on other metabolic parameters of interest.

Following the collection and monitoring of data from the last follow-up medical visits planned in the protocol, the clinical database will be frozen for statistical analysis. At the end of this process in accordance with Good Clinical Practices, Valbiotis confirms that the first results of the REVERSE-IT study will be available and communicated before the end of the first half of 2023, as announced in the schedule published on September 15, 2022 ([September 15, 2022, press release](#)).

## **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 patients 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, Singapore, Saudi Arabia, Australia, Algeria, Ukraine, Malaysia, Chili, India, South Korea and national phases are still underway in Brazil, Argentina, Canada, Thailand, Qatar, United Arab Emirates. 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.



## About Valbiotis

Valbiotis is a commercially oriented 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.

Internationally, its products are intended to be the subject of licensing and/or distribution agreements with global or 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 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 May 19, 2022 and completed by an amendment on November 8, 2022. This document is available on the Company's website ([www.valbiotis.com](http://www.valbiotis.com)).

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