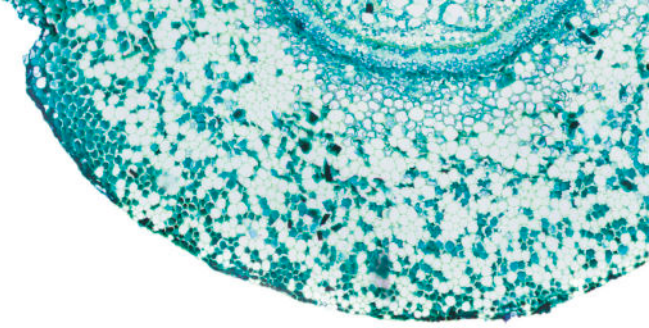

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Valbiotis announces the large success of the REVERSE-IT international multicentric Phase II/III clinical study on TOTUM•63: proven efficacy on the main risk factor of developing type 2 diabetes

- The study achieved its objective on the primary endpoint, the reduction of fasting blood glucose, a risk factor for type 2 diabetes, at a 5g daily dose in 3 intakes per day, with a high statistical significance.
- The endpoint of fasting blood glucose reduction was also achieved with a high level of statistical significance at a similar dose, but in two intakes per day, acknowledging the efficacy of this regimen.
- This clinical success triggers a lump sum payment of CHF 4 million from Nestlé Health Science, as part of the global strategic partnership on TOTUM•63.
- Unequivocal clinical efficacy of TOTUM•63 validates Valbiotis' scientific approach, based on the use of innovative and patented combinations of plant-based active ingredients for the prevention of metabolic and cardiovascular diseases.

La Rochelle, May 22, 2023 (17:40 CEST) – **Valbiotis** (FR0013254851 – ALVAL, PEA/PME eligible), a commercially oriented Research and Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, **announces the large success of the REVERSE-IT Phase II/III clinical study on TOTUM•63. Conducted in 636 prediabetic and untreated type 2 diabetic patients (early stage), this international, multicentric, randomized and placebo-controlled study confirms the efficacy of TOTUM•63 in reducing fasting blood glucose at 2 and 3 intakes per day. These positive results trigger a lump sum payment of CHF 4 million from Nestlé Health Science as part of the global strategic partnership.**

Sébastien PELTIER, co-founder and Chairman of the Valbiotis Executive Committee, comments: *"I am extremely proud of the results of the REVERSE-IT study on TOTUM•63, which represent a major breakthrough in the fight against diabetes and its complications for people with prediabetes and untreated type 2 diabetes (early stage). We have provided unequivocal clinical evidence that TOTUM•63 is a promising solution for millions of people worldwide, helping to prevent the progression to type 2 diabetes. This is a groundbreaking and exciting moment for our company, and I would like to extend my warmest thanks to our employees, our partners including Nestlé Health Science, and especially to the patients who participated in this study. Together, we have accomplished something truly remarkable, and we are determined to continue our mission to develop innovative solutions to improve the health of people around the world. Beyond this great achievement, which opens up a new path, it is also a personal satisfaction, after almost 10 years of hard work."*

Hans-Juergen WOERLE, Chief Scientific and Chief Medical Officer at Nestlé Health Science, comments: *"We are thrilled with the completion of this large clinical study, gathering more than 600 patients, designed to rigorously evaluate TOTUM•63. This non-drug, plant-based active substance has the potential to significantly impact the management of early impairments of glucose metabolism."*

Jean-Marie BARD, emeritus professor of biochemistry and hospital practitioner in pharmacy, scientific advisor of the REVERSE-IT study, President of the French Nutrition Society Scientific Committee, specifies: *"With more than 600 patients included in more than 50 centers internationally, REVERSE-IT is one of the largest and most ambitious studies in the world with non-drug approaches to early dysglycemia, from prediabetes to the early stages of type 2 diabetes. The results of this study represent a significant breakthrough for these people with glycemic impairment and confirm the data already obtained in 2019 with the Phase II study, published in the journal Diabetes, Obesity and Metabolism in 2022. I am delighted to have participated in the clinical validation of this new approach. Many healthcare professionals will be able to provide a solution for their patients and change their clinical practices, which until now have been limited to lifestyle recommendations alone."*

The REVERSE-IT study was co-designed with Nestlé Health Science's medical teams as part of the global strategic partnership between Valbiotis and Nestlé Health Science signed in February 2020. Under this agreement, positive results of the REVERSE-IT study on the primary endpoint trigger a lump sum payment of CHF 4 million from Nestlé Health Science to Valbiotis. This milestone payment from Nestlé Health Science will occur upon submission of the full study report during the summer.

The REVERSE-IT study and its results on its primary endpoint

The randomized and placebo-controlled REVERSE-IT Phase II/III study included 636 people with impaired glucose metabolism, ranging from prediabetes to untreated type 2 diabetes (early stage).

The volunteers were divided into three equally balanced arms, each with more than 200 participants. In the intervention arm, participants were supplemented with TOTUM•63 at a dose of 5 g/day in three daily intakes. To complete the study, a second open-label arm evaluated a similar dose of 5 g of TOTUM•63 in two daily intakes.

The REVERSE-IT study met its two objectives on its primary endpoint, fasting blood glucose, with a high statistical significance on the data obtained in ITT (Intention To Treat):

- the reduction in fasting blood glucose with TOTUM•63 after 6 months of supplementation with a 5g/day dose in three daily intakes, compared to placebo (p=0.015);
- the reduction in fasting blood glucose with TOTUM•63 after 6 months of supplementation with a 5g/day dose in two daily intakes, compared to placebo.

The statistical analysis conducted in the *per protocol* population also confirms the statistical significance of these two results.

At the end of all the analyses, the comprehensive results of the study will be communicated in a subsequent press release, on the secondary endpoints and exploratory analysis, and submitted for presentation at international congresses and publication in international peer-reviewed journals.

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 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, Chile, India, South Korea and national phases are currently ongoing in Brazil, Argentina, Canada, Thailand, Qatar and the 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 global 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 and cardiovascular 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.

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