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Valbiotis announces completion of recruitment for the Phase II/III REVERSE-IT clinical study with TOTUM•63 against prediabetes, in partnership with Nestlé Health Science

- The last volunteer was enrolled in the REVERSE-IT study; recruitment of the 600 participants in this international, multicenter, randomized, placebo-controlled clinical study is complete.
- This Phase II/III study is evaluating 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).
- The primary objective of the study will be the reduction of fasting blood glucose levels after 24 weeks of TOTUM•63 supplementation compared to placebo; the results will be announced at the end of the study.
- This Phase II/III clinical study was co-designed by Nestlé Health Science and Valbiotis, as part of the global strategic partnership between the two companies on TOTUM•63.

La Rochelle, July 28, 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, announces that it has completed the recruitment of 600 volunteers for the international multicenter Phase II/III REVERSE-IT clinical study on TOTUM•63.

This randomized, placebo-controlled 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). The primary objective will be the reduction of fasting blood glucose levels after 24 weeks of TOTUM•63 supplementation compared to placebo. The results will be communicated at the end of the study.

The Phase II/III REVERSE-IT study was co-designed by the Valbiotis and Nestlé Health Science medical and regulatory teams to demonstrate the efficacy of TOTUM•63 against prediabetes and untreated type 2 diabetes (early stage), as part of the global strategic partnership between the two companies. REVERSE-IT should confirm the positive results of the Phase II clinical study already obtained in a similar population with TOTUM•63.

Murielle CAZAUBIEL, Director of Medical, Regulatory and Industrial Affairs and member of the Valbiotis Board of Directors, commented: *"We have reached a very important milestone in the development of TOTUM•63 with the completion of enrollment in the Phase II/III REVERSE-IT study. With 600 volunteers enrolled in more than 50 centers worldwide, REVERSE-IT is among the most ambitious studies of early dysglycemia, from prediabetes to early-stage type 2 diabetes, using non-drug approaches. We would like to thank all the teams involved in this project, as well as our partner Nestlé Health Science. With a highly demanding design, REVERSE-IT was developed to provide comprehensive and robust efficacy data on these populations in preparation for the TOTUM•63 market launch."*

The randomized, double-blind, placebo-controlled Phase II/III REVERSE-IT study includes 600 people with impaired glucose metabolism, from prediabetes to untreated type 2 diabetes (early stage). It should confirm the efficacy of TOTUM•63 at a dose of 5 g/day (3 daily intakes) for 24 weeks on blood glucose abnormalities and other metabolic risk factors for type 2 diabetes, compared to a placebo. The protocol will evaluate the effect of TOTUM•63 on fasting blood glucose, the primary endpoint of the study, as well as on a number of secondary endpoints of interest, including two-hour blood glucose and anthropometric parameters (body weight, waist circumference and body fat mass).

———— 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 health claim depending on the area. They will also fund the final stages of development of TOTUM•63.

———— 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

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