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Valbiotis: the Phase II/III REVERSE-IT study selected for an oral presentation at the 2023 EASD congress, the main European learned society for diabetes

- The Phase II/III clinical study REVERSE-IT, carried out with the active substance TOTUM•63, in partnership with Nestlé Health Science, will be presented on October 3, during an oral communication at the congress of the European Association for the Study of Diabetes (EASD) 2023.
- This communication will detail the protocol of the REVERSE-IT study, against early glycemetic disorders, as well as the complete characteristics of the population included (636 volunteers), at the beginning of the study.
- After a presentation in the United States last June during the prestigious congress of the American Diabetes Association, the oral communication at the EASD this fall marks the undeniable scientific success of this study on an international scale.

La Rochelle, October 02, 2023 (17:40 CEST) – 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 selection of the Phase II/III clinical study REVERSE-IT for an oral presentation at the annual congress of the European Association for the Study of Diabetes (EASD), which takes place from October 2 to 6, 2023 in Hamburg (Germany).** The detailed protocol as well as the complete characteristics of the population included, at the start of the study, will be presented during an oral session scheduled for October 3 from 12:30 p.m. to 1:30 p.m.

In the field of early glycemetic disorders, the REVERSE-IT study carried out in partnership with Nestlé Health Science constitutes a world first for a non-drug active substance, both in terms of its scale (636 volunteers) and the number of centers involved internationally (52 centers in 7 countries). The full positive results, communicated on September 11, 2023 ([press release of September 11](#)), demonstrated the impressive efficacy of the active substance TOTUM•63.

“The success of the REVERSE-IT study constitutes a breakthrough for a non-drug approach to prediabetes and untreated early stages of type 2 diabetes. The results will of course be the subject of a very ambitious scientific communication plan. But already, the double selection of the protocol and population characteristics at baseline, this year, by the two main world diabetes congresses, the ADA then the EASD, with an oral communication, confirms the very great value of our work. This is undeniable scientific recognition for this international study. We are very proud to present it today to the community of European diabetologists.” welcomes Murielle CAZAUBIEL, Director of Medical, Regulatory and Industrial Affairs, member of the Valbiotis Executive Committee.



The oral communication will take place during session SO 55, Tuesday October 3 between 12:30 p.m. and 1:30 p.m. with number 724 and the following title:

“Baseline of the REVERSE-IT study, a 24-week and 600-people randomized placebo-controlled study on the metabolic effects of TOTUM•63, a five plant-extract combination”

About TOTUM•63

TOTUM•63 is a unique and patented combination of 5 plant extracts which targets the pathophysiological mechanisms of type 2 diabetes, and benefits from an unrivaled clinical demonstration of efficacy for a non-drug active substance. This innovation, both natural and clinically proven, offers new perspectives to the millions of people confronted with the risks of type 2 diabetes, as well as to all doctors and healthcare professionals currently lacking reliable, targeted preventive solutions.

TOTUM•63 benefits from intellectual property validated by patents in the world's major markets: Europe (covering 39 countries), the United States, Canada, 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 still underway in Brazil, Argentina, Thailand, Qatar and the United Arab Emirates.

TOTUM•63's industrial production capacity, in line with North American and European standards, has been validated. TOTUM•63 already has marketing authorizations linked 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 provides for the marketing of TOTUM•63 by Nestlé Health Science worldwide, possibly before obtaining a health claim depending on the area. It will also finance the final stages of TOTUM•63's development.

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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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. This document is available on the Company's website (www.valbiotis.com).

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