

VALBIOTIS selected at the 80th Scientific Sessions of the American Diabetes Association to present Phase II clinical results of TOTUM-63 in prediabetes

This publication, released during the world's leading diabetes congress, provides unequivocal scientific endorsement of results.

TOTUM-63, a plant-based active substance, demonstrates with European multi-center Phase II study of 51 prediabetic individuals its impact on fasting blood glucose levels, a well-established risk factor for type 2 diabetes.

Its availability under a global agreement with Nestlé Health Science could open the first opportunity for healthcare professionals to help their prediabetic patients with a clinically proven and plant-based product.

La Rochelle, 12 June 2020 (7:35 AM CEST) VALBIOTIS (FR0013254851 – ALVAL /éligible PEA/PME), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, announces that the main results of its international Phase II clinical study demonstrating the metabolic benefits of TOTUM-63 in prediabetic patients are being presented at the 80th Scientific Sessions of the American Diabetes Association (ADA).

This is the fourth time that VALBIOTIS has had its work on TOTUM-63 selected by this major congress, which is being held from 12 to 16 June this year - in virtual format, due to the COVID-19 health crisis. TOTUM-63's clinical data on carbohydrate metabolism, weight and waist circumference are presented as an e-poster (www.valbiotis.com/en/scientific-publications). The presentation to the ADA serves as recognition by the global scientific community of the quality of the results obtained for a groundbreaking treatment to reduce the risk of developing type 2 diabetes. No clinically proven answer exists today for people with prediabetes, a reversible state of impaired glucose metabolism which, without intervention, has a 70 to 90% risk of developing into type 2 diabetes¹.

The positive results of this study were announced in two stages (press releases of [3 July 2019](#) and [2 September 2019](#)). In order to confirm these results on a larger population and to allow healthcare professionals worldwide access to this scientific innovation, VALBIOTIS entered into a global strategic partnership with Nestlé Health Science in early 2020.

This agreement covers the development and marketing of TOTUM-63 ([press release of 5 February 2020](#)), an innovative and patented combination of five plant extracts.



Prof. Jean-Marie BARD
Hospital Practitioner and
Professor of Fundamental and
Clinical Biochemistry at the
University of Nantes. Scientific
advisor of the study.

"The presentation of these results to the ADA marks both a real turning point in health nutrition and the recognition of the clinical efficacy of TOTUM-63. This randomized, placebo-controlled Phase II study showed a significant reduction in fasting blood glucose, its primary endpoint, as well as a significant improvement in glucose tolerance, body weight and waist circumference, secondary endpoints of the study, all known as critical risk factors for developing type 2 diabetes. The data is remarkable for its consistency and the clear metabolic impact demonstrated in 51 subjects, all with abdominal obesity associated with moderate hyperglycemia, 2-hour hyperglycemia (OGTT) and hypertriglyceridemia."

At the end of the 6-month supplementation period, fasting blood glucose levels were significantly reduced in subjects receiving 5 grams per day of TOTUM-63 compared to subjects in the control group receiving 5 grams of placebo (-0.04 ± 0.02 vs. $+0.09 \pm 0.04$ g/L, $p < 0.05$). TOTUM-63 also significantly reduced two-hour blood glucose, or postmeal blood glucose (-0.02 ± 0.07 vs $+0.32 \pm 0.17$ g/L, $p < 0.05$), body weight (-0.07 ± 0.42 vs $+1.83 \pm 0.57$ kg; $p < 0.05$) and waist circumference (-1.67 ± 0.73 vs $+2.81 \pm 0.65$ cm; $p < 0.001$).

These results place TOTUM-63 as the first clinically approved, already marketable product for prediabetic individuals (nearly 1 billion worldwide²) to reduce the risk of developing type 2 diabetes.



Murielle CAZAUBIEL,
Member of the Board,
Director of Development and
Medical Affairs at VALBIOTIS.

"Participating in the ADA is part of an outstanding series of achievements for VALBIOTIS' flagship prediabetes product. In just over a year, TOTUM-63 has been successfully scaled up to industrial production and confirmed its clinical efficacy on several metabolic targets and a number of cardiovascular risk factors. It is now the subject of a global partnership with a major player in the field of health nutrition, responsible for the final phase of its development. The international Phase II/III clinical trial REVERSE-IT ([press release of 2 April 2020](#)) co-conducted with Nestlé Health Science will start this year with 600 participants. This trial is designed not only to confirm the positive Phase II results on fasting blood glucose levels, but also to extend evaluation of TOTUM-63 to untreated type 2 diabetics."

²AEC Partners data

About VALBIOTIS

VALBIOTIS is a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases in response to unmet medical needs.

VALBIOTIS has adopted an innovative approach, aiming to revolutionize healthcare by developing a new class of nutritional health solutions designed to reduce the risk of major metabolic diseases, based on a multi-target approach and made possible by the use of plant-based ingredients.

Its products are intended to be licensed to players in the health world.

VALBIOTIS was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers. The Company has established three sites in France - Périgny, La Rochelle (17) and Riom (63).

VALBIOTIS is a member of the "BPI Excellence" network and received the «Innovative Company» status accorded by BPI France. Valbiotis has also been awarded "Young Innovative Company" status and has received major financial support from the European Union for its research programs by obtaining support from the European Regional Development Fund (ERDF). VALBIOTIS is a PEA-SME eligible company.

Find out more about VALBIOTIS: www.valbiotis.com

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This press release contains forward-looking statements about VALBIOTIS' objectives, based on rational hypotheses and the information available to the company at the present time. However, in no way does this constitute a guarantee of future performance, and these projections can be reconsidered based on changes in economic conditions and financial markets, as well as a certain number of risks and doubts, including those described in the VALBIOTIS core document, filed with the French Financial Markets Regulator (AMF) on 31 July 2019 (application number R19-030) as well in its supplement approved by the AMF on Octobre 9, 2019. These documents being available on the Company's website (www.valbiotis.com). This press release, as well as the information contained herein, does not constitute an offer to sell or subscribe to, or a solicitation to purchase or subscribe to, VALBIOTIS' shares or securities in any country.



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