

## **VALBIOTIS selected to present 3 studies on TOTUM-63 by the European Association for the Study of Diabetes (EASD)**

EASD, the leading European association in the field of diabetes, has selected the positive results of the international Phase II clinical study on TOTUM-63 in prediabetes to be presented next September in its 56<sup>th</sup> annual meeting. These results were selected by the American Diabetes Association last June 2020.

Additionally, two preclinical studies have also been selected, providing a better understanding of the multitargeted mode of action of TOTUM-63 and its efficacy in prevention and reversion of weight gain and its impact in the carbohydrate metabolism.

The value of VALBIOTIS' scientific and clinical work keeps gaining momentum, with increased recognition from the international scientific community.

**La Rochelle, September 21, 2020** (7:35 am CEST) **VALBIOTIS** (FR0013254851 - ALVAL, eligible for the PEA/SME), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **announces the selection of 3 studies on TOTUM-63 by the European Association for the Study of Diabetes (EASD), which will be presented at the association's annual meeting in September 2020.**

For the third consecutive year, VALBIOTIS has seen its results on TOTUM-63, its active substance designed to reduce the risk of type 2 diabetes, selected by the main European diabetes meeting. This year, VALBIOTIS will present 3 studies at this major event, to be held from 22 to 25 September in virtual format due to the COVID-19 pandemic.

The clinical results of the international Phase II study of TOTUM-63 will first be presented by Prof. Jean-Marie Bard in the form of an e-poster (*Abstract #621*). Completed in the summer of 2019, this study showed a significant reduction in the main risk factors for type 2 diabetes (glycemic parameters, waist circumference, body weight) in prediabetic people, compared to a placebo. Already selected by the American Diabetes Association last June, these results have now been accepted by the two main scientific societies in the field of diabetes worldwide.



**Murielle CAZAUBIEL**

Member of the Management Board and Director of Development and Medical Affairs at VALBIOTIS

*"The excellent results of the TOTUM-63 Phase II clinical study exceeded our expectations and enabled us to enter into a strategic partnership with Nestlé Health Science last February. In 2020, we have launched a strategy for the scientific communication of these results, which has already led to selection for presentations at the two largest diabetes meetings in the world, the ADA and EASD, within three months. These publications constitute indisputable recognition of the quality of our work. They are also a great source of pride and an additional incentive to complete the clinical development of TOTUM-63 with our partner Nestlé Health Science."*

In addition to these clinical results, two preclinical studies demonstrating the positive effects of TOTUM-63 on obesity and carbohydrate metabolism disorders have also been selected by the EASD (*Abstract #448 and #623*). These studies highlight the efficacy of TOTUM-63 through two protocols: a protocol for the prevention of weight gain and associated metabolic disorders, carried out by the VALBIOTIS teams, and a protocol for the management of obesity and acquired disorders, carried out by the team of Dr Bruno Guigas (University of Leiden, Netherlands) with Vanderbilt University (Nashville, USA), one of the American expert centers for the study of diabetes. This preclinical work shows a reduction in body weight thanks to TOTUM-63 as well as an improvement in carbohydrate parameters in both protocols. It also provides a better understanding of the multi-targeted mode of action of TOTUM-63: reduced intestinal absorption of lipids and glucose, increased sensitivity of peripheral tissues to insulin and increased energy expenditure.



*"Since 2014, we have been conducting extensive preclinical work on TOTUM-63 in partnership with French and international universities, such as Leiden (the Netherlands) or Vanderbilt (USA) universities. These additional studies are essential, as they guide the clinical development of the active substances and document their mode of action. The two studies selected have demonstrated promising additional effects on the prevention and reversal of weight gain and its consequences on carbohydrate metabolism. We are now very proud to present them to the European diabetology community."*

**Pascal SIRVENT**

Member of the Management Board, Director of Discovery, Preclinical and Translational Research

The three VALBIOTIS presentations at the EASD 2020 meeting are available at [www.valbiotis.com/scientific-publications](http://www.valbiotis.com/scientific-publications).

## ABOUT TOTUM-63

TOTUM-63 is a unique and patented combination of 5 plant extracts that targets the physiopathological 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 of an international randomized, placebo-controlled Phase II study showed that TOTUM-63 reduced fasting and 2-hour blood glucose levels, two risk factors for type 2 diabetes, compared to placebo. In these subjects, who also had abdominal obesity, TOTUM-63 also significantly reduced body weight and waist circumference.

TOTUM-63 benefits from intellectual property that has been validated by the granting of patents in the main world markets: Europe (covering 39 countries), the United States and Russia, and national phases are underway in more than 20 countries including China, Japan, Brazil and Australia. TOTUM-63's industrial production capacity, in accordance 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 marketing of TOTUM-63. This unique partnership in the field of Health Nutrition provides for the worldwide marketing of TOTUM-63 by Nestlé Health Science, possibly before obtaining a health claim depending on the region. It will also finance 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 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](http://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 2020 (application number R20-018), these documents being available on the Company's website ([www.valbiotis.com](http://www.valbiotis.com)).



Name: VALBIOTIS - ISIN code: FR0013254851 - Mnemonic code: ALVAL

