

**VALBIOTIS presents positive results from a study on TOTUM-63, active substance of VALEDIA<sup>®</sup>, conducted by the CarMeN laboratory in Lyon, at the Annual Meeting of the European Association for the Study of Diabetes (EASD)**

- **This preclinical study conducted by the CarMeN laboratory, expert in metabolic diseases, confirms the major effects of the active substance TOTUM-63 on weight and glucose metabolism.**
- **Data demonstrates capacity of TOTUM-63 to significantly correct the secretion of three hormones, essential for blood glucose regulation (insulin, glucagon and GLP-1) in a preclinical model of metabolic disease.**
- **These results have been selected for presentation at the 55<sup>th</sup> EASD Annual Meeting which will be held September 16-20, 2019 in Barcelona.**



**55th Annual Meeting of the  
European Association for the  
Study of Diabetes**

**Barcelona, Spain  
16 - 20 September 2019**

**La Rochelle, 16 September 2019** (5:40 PM CEST) – **VALBIOTIS** (FR0013254851 - ALVAL / PEA/SME eligible), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **today announced the presentation of a preclinical study conducted by the CarMeN laboratory on the active substance TOTUM-63, at the 55<sup>th</sup> Annual Meeting of the European Association for the Study of Diabetes being held September 16-20, 2019 in Barcelona, Spain.**

This preclinical study evaluated the effect of TOTUM-63 on the secretion of certain hormones which play a fundamental role in glucose metabolism. In a murine model of metabolic disease, TOTUM-63 completely corrected insulin, glucagon and GLP-1 (Glucagon-Like Peptide-1) concentrations in the portal vein, in response to a glucose intake. These three hormones are central to the regulation of blood glucose.

This study confirms, via an independent laboratory, the effects already demonstrated<sup>1</sup> on blood glucose and weight by TOTUM-63, the active substance of VALEDIA®, a product designed to control blood glucose in prediabetics.

Béatrice MORIO-LIONDORE\*, Research Director at the CarMeN Research Laboratory, comments: *"We are delighted to be presenting this study at the 55<sup>th</sup> EASD Annual Meeting. The results obtained demonstrate the significant effects of TOTUM-63 on weight and glucose metabolism in this preclinical model. In addition, our study aimed to evaluate the effect of TOTUM-63 on the hormonal imbalances associated with metabolic diseases. We have proven that TOTUM-63 corrects the blood levels of three key hormones in glucose metabolism: insulin and glucagon, secreted by the pancreas, as well as GLP-1, an intestinal hormone essential for blood glucose control that is well-known in the field of diabetes."*



*"The results obtained by the CarMeN laboratory team have high value for VALBIOTIS: by examining the hormonal level, this study has made a fundamental contribution to increasing our understanding of the action of TOTUM-63 on metabolism. The hormonal effects reported today are consistent with the improvement in metabolic parameters that have already been widely observed, both in preclinical and clinical studies with TOTUM-63. These results provide clear evidence of the positive action of TOTUM-63 on the levels of hormones whose secretion is altered in prediabetes or diabetes."*

Pascal SIRVENT, Head of Discovery and Preclinical and Translational Research at VALBIOTIS

The poster of this study is available on the VALBIOTIS website:

<https://www.valbiotis.com/en/scientific-publications/>

## About CarMeN laboratory

The CarMeN laboratory - INSERM U1060 / INRA U1397 / INRA U1397 / Lyon1 University / INSA Lyon (directed by Hubert VIDAL) is a biomedical research laboratory in the fields of cardiovascular diseases, metabolism, diabetes and nutrition. It is a center of excellence, based in Lyon, that brings together the leading minds in research in the fields of metabolism, nutrition and cardiovascular diseases. With approximately 180 collaborators, including researchers, teachers and hospital practitioners, the CarMeN laboratory is supported by state-of-the-art technological (genomics, lipidomics, imaging) and clinical (CRNH, CIC) research platforms, providing a unique environment for conducting valuable translational research.

\***Béatrice MORIO-LIONDORE** is INRA Research Director for Team 3 ("Organelle communication and diabetes" headed by Jennifer RIEUSSET and Charles THIVOLET) of the CarMeN research laboratory and previously led a team working on obesity in the Human Nutrition Unit in Clermont-Ferrand. She has published more than 90 articles and journals.

<sup>1</sup>See press release of 3 July 2019: [https://www.valbiotis.com/app/uploads/2019/07/2019-06-21-PR\\_VALBIOTIS\\_PHASEIIA-VALEDIA.pdf](https://www.valbiotis.com/app/uploads/2019/07/2019-06-21-PR_VALBIOTIS_PHASEIIA-VALEDIA.pdf)

## About TOTUM-63, the active ingredient of VALEDIA®

Prediabetes is a growing public health problem worldwide, recognized by international organizations such as the WHO, the American Diabetes Association and the International Diabetes Federation, among others. Without effective treatment, 70% to 90% of prediabetic patients will develop type 2 diabetes.

VALEDIA® is the first clinically validated product specifically designed to help prediabetics reduce their risk of developing type 2 diabetes. VALEDIA® is the only product that contains the active ingredient TOTUM-63, a unique and patented combination of 5 plant extracts that act in synergy to target the physiopathological mechanisms of type 2 diabetes.

TOTUM-63 has already shown perfect tolerance and safety during a Phase I/II clinical study conducted in healthy volunteers. The results of the Phase IIA international randomized, placebo-controlled study showed that in patients with prediabetes, TOTUM-63 reduces fasting blood glucose and blood glucose at 2 hours, two risk factors of type 2 diabetes. In these subjects, who also presented with hypertriglyceridemia and abdominal obesity, TOTUM-63 significantly reduced body weight, waist circumference, blood triglycerides, blood LDL cholesterol, Fatty Liver Index and arterial hypertension.

## ABOUT VALBIOTIS

VALBIOTIS is a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases. Its products are made for major players in the health care sector. VALBIOTIS particularly focuses on solutions to prevent type 2 diabetes, NASH (nonalcoholic steatohepatitis), obesity and cardiovascular diseases.

VALBIOTIS was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers in France and abroad, including La Rochelle University, the CNRS and Clermont Auvergne University located in Clermont-Ferrand. These partnerships have enabled VALBIOTIS to benefit from strong financial leverage, particularly thanks to experts and technical partners who support its projects. The Company has established three sites in France - Périgny, La Rochelle (17) and Riom (63) - and an American office in Boston (MA).

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)



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



**C O N T A C T S**

**FRANCE.**  
**CORPORATE COMMUNICATION | VALBIOTIS**  
Carole ROCHER / Marc DELAUNAY  
+33 5 46 28 62 58 | [carole.rocher@valbiotis.com](mailto:carole.rocher@valbiotis.com) / [marc.delaunay@valbiotis.com](mailto:marc.delaunay@valbiotis.com)

**FINANCIAL COMMUNICATION | ACTIFIN**  
Stéphane RUIZ  
+33 1 56 88 11 14 | [sruiz@actifin.fr](mailto:sruiz@actifin.fr)

**MEDIA RELATIONS | MADIS PHILEO**  
Guillaume DE CHAMISSO  
+ 33 6 85 91 32 56 | [guillaume.dechamisso@madisphileo.com](mailto:guillaume.dechamisso@madisphileo.com)

**UNITED STATES.**  
**SOLEBURY TROUT**  
Rebecca JOHN / Patrick TILL  
+1.646.378.2935 | [rjohn@troutgroup.com](mailto:rjohn@troutgroup.com) / [ptill@troutgroup.com](mailto:ptill@troutgroup.com)

## Disclaimer

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). The document is available on the Company's website ([www.valbiotis.com](http://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.

