

## VALBIOTIS will present the results of the international Phase IIA clinical study of VALEDIA® before 31 July 2019

- The results of this study will evaluate the efficacy of VALEDIA® in prediabetic subjects for the first time
- Predicted to be the catalyst for concluding a commercial partnership with a major player in the healthcare sector
- Beyond prediabetes, additional results are expected to shed light on the potential development of other applications of VALEDIA®

La Rochelle, 14 May 2019 (5:40 pm CEST) – VALBIOTIS FR0013254851 - ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **announces the completion of the international Phase IIA clinical study evaluating VALEDIA® in prediabetic subjects, after the final follow-up visit was conducted with the last patient. VALBIOTIS will present the results of this study before 31 July 2019.**



 Announcing the results of the Phase IIA clinical trial represents a major development for VALBIOTIS. We would like to thank all those who participated in the study as well as our academic and scientific partners for their valuable contributions. We are confident in the results, which will evaluate the efficacy of VALEDIA® on the target population of prediabetics for the first time."

**Murielle CAZAUBIEL**  
Development and Medical Affairs Director of VALBIOTIS

The international Phase IIA, multicentric study was randomized, double-blind placebo-controlled, and included 66 prediabetic subjects<sup>1</sup>. The study evaluates the efficacy of TOTUM-63, the active ingredient of VALEDIA®, in

<sup>1</sup>Divided into two arms, for a period of 6 months. The subjects who were randomized to the supplemented arm received a 5g dose of VALEDIA® each day.

reducing one or more of the 3 risk factors for type 2 diabetes, from the 3 criteria chosen by the Food and Drug Administration<sup>2</sup> to obtain a healthclaim: insulin resistance, moderate fasting hyperglycemia and glucose intolerance.

In addition to these prediabetes results, the study will evaluate other physiological parameters, including, for example, triglyceride regulation or intestinal microbiota composition. This additional data will help confirm the potential of VALEDIA® for other applications.

## ABOUT TOTUM-63, THE ACTIVE SUBSTANCE OF VALEDIA®

Prediabetes is a growing public health issue worldwide that has been acknowledged by international organizations. Without appropriate management, 70% to 90% of prediabetic subjects will develop type 2 diabetes.

VALEDIA® intend to be the first natural and clinically proven solution specifically designed for prediabetics. VALEDIA® contains the active substance TOTUM-63, a unique and patented combination of 5 plant extracts, with high potential to target the physiopathological mechanisms of type 2 diabetes.

The launch of VALEDIA® is planned for 2021, with a health claim for reducing the risk of type 2 diabetes.

TOTUM-63 has already been proven safe and effective in healthy human volunteers during a Phase I/II clinical study.

## ABOUT VALBIOTIS

VALBIOTIS is a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases. Its products are made for major players in the healthcare 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 the La Rochelle University, the CNRS and the 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 is located at 3 sites in France - Périgny, La Rochelle (17) and Riom (63) - in addition to 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 PEA/SME eligible.

Find out more about VALBIOTIS:

[www.valbiotis.com](http://www.valbiotis.com)



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



C  
O  
M  
M  
U  
N  
I  
C  
A  
T  
I  
O  
N  
S

FRANCE.

**CORPORATE COMMUNICATION I 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 I ACTIFIN**

Stéphane RUIZ

+33 1 56 88 11 14 | [sruiz@actifin.fr](mailto:sruiz@actifin.fr)

**MEDIA RELATIONS I 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 concerning the objectives of VALBIOTIS. VALBIOTIS considers that these projections are based on information currently available by VALBIOTIS and on reasonable assumptions.

However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of VALBIOTIS filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number I.17-012 on April 5, 2017 as well as in its 2018 annual financial report filed with the French Financial Markets Authority on March 8, 2019. These documents are available on the Company's website ([www.valbiotis.com](http://www.valbiotis.com)).

VALBIOTIS declines all responsibility for updating or revising these forward-looking statements. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, VALBIOTIS shares in any country.

