VALBIOTIS

PRESS RELEASE

VALBIOTIS announces positive results from the Phase IIA clinical study of VALEDIA®, now the first product proven effective in people with prediabetes

- **VALEDIA® significantly reduced fasting and post-prandial blood glucose levels, two risk factors for type 2 diabetes, compared to placebo.**
- **VALEDIA® significantly reduced body weight and waist circumference, compared to placebo.**
- **VALEDIA® is now the first clinically validated product designed for people with prediabetes that reduces the risk factors for type 2 diabetes.**

La Rochelle, 3 July 2019 (6:30 pm CEST) – **VALBIOTIS** (FR0013254851 - ALVAL PEA/SME eligible), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **today announced positive results (topline data) for the Phase IIA* study of VALEDIA® (active substance: TOTUM-63), which evaluated this product's efficacy in a prediabetic population, compared to placebo.**

In this population, VALEDIA® significantly reduced fasting and post-prandial blood glucose levels, the two main risk factors for type 2 diabetes and the primary and secondary endpoints of the study, respectively. VALEDIA® also significantly reduced body weight and waist circumference.

Thanks to these results, VALEDIA® is the first clinically validated product designed for prediabetic people, to reduce several risk factors for type 2 diabetes. These results enable the concomitant launch of the last two Phase IIB clinical studies (REVERSE-IT and PREVENT-IT), to obtain the first health claims for the risk reduction of type 2 diabetes in Europe and North America. This regulatory process does not require a Phase III study. Commercialization is planned for 2021, as previously announced.

* ID-RCB Number: 2016-A00484-47

"The reduction of fasting blood glucose and blood glucose 2 hours after a glucose intake is a new advance for prediabetics. These results show the impact of VALEDIA® on metabolism, with even a decrease in body weight and waist circumference, usually hard to demonstrate in clinical studies. With such data VALEDIA® proves its efficacy to reduce type 2 diabetes risk factors."

Pr Jean-Marie BARD
Hospital Practitioner and Professor of Fundamental and Clinical Biochemistry at the University of Nantes,
Scientific expert for the study

"VALEDIA® was designed to carry out multiple actions on several metabolic targets, thanks to an original plant-based composition. This innovation has had clinical success in people with prediabetes: we now know that VALEDIA® acts on risk factors for type 2 diabetes. This study is a great success, and we'd like to express our thanks to all the volunteers who participated."

Murielle CAZAUBIEL
Member of the Board
Director of Development and Medical affairs of VALBIOTIS

Main results of the VALEDIA® Phase IIA clinical study in prediabetic people

This multicenter study, conducted in Europe, evaluated TOTUM-63, the active ingredient of VALEDIA®, in prediabetic people for 6 months. It was a randomized, double-blind, placebo-controlled study. Included subjects received a daily dose of 5 grams of VALEDIA® while the control group received 5 grams of the placebo. Dietary habits and physical activity levels remained unchanged in both groups during the study. The inclusion criteria were strict to ensure the robustness of the study: the subjects had to have moderate hyperglycemia, hyperglycemia 2 hours after glucose dose (OGTT, Oral Glucose Tolerance Test), abdominal obesity and hypertriglyceridemia. With such characteristics, the included subjects were particularly at risk of fast and pejorative evolution. Analyses were conducted on 51 subjects, 13 in the placebo group and 38 in the VALEDIA® group, according to the unbalanced study design.

Main characteristics of the study population:

- Age: 57.1 years old
- Gender: 35 women and 16 men
- Body Mass Index: 31.3 Kg/m^2
- Fasting glycemia: 1.26 g/L
- 2h-glycemia (OGTT): 1.85 g/L
- Blood triglycerides: 1.78 g/L

Main criterion met:
VALEDIA® significantly reduced fasting blood glucose levels, compared to the placebo, after 6 months (p<0.05).

Fasting Glycemia (g/L)

	6 months variation (g/L)	**Variation VALEDIA® *vs* placebo**[1]
Placebo (n=13 subjects)	+ 0.09 (± 0.04)	**- 9.3%**
Valedia® (n=38 subjects)	- 0.04 (± 0.02)	

Mean values (± SEM)

Moderate fasting hyperglycemia is the main risk factor for type 2 diabetes identified in people with prediabetes. With these results, VALBIOTIS defines the reduction of fasting blood glucose levels as the primary endpoint of the last two clinical studies that will be used to support requests for health claims in Europe, the United States and Canada.

Secondary criteria met:

VALEDIA® significantly reduces blood glucose levels after 2 hours (post-prandial blood glucose), the second risk factor for type 2 diabetes, compared to the placebo (p<0.05).

2 hours OGTT glycemia (g/L)

	6 months variation (g/L)	**Variation VALEDIA® *vs* placebo**[1]
Placebo (n=13 subjects)	+ 0.32 (± 0.17)	**- 22.5%**
Valedia® (n=38 subjects)	- 0.02 (± 0.07)	

Mean values (± SEM)

VALEDIA® significantly reduced two anthropometric parameters, compared to the placebo: body weight (p< 0.05) and waist circumference (p< 0.001).

Body weight (Kg)

	6 months variation (Kg)	**Variation VALEDIA® *vs* placebo**[2]
Placebo (n=13 subjects)	+ 1.83 (± 0.57)	**- 1.9 Kg**
Valedia® (n=38 subjects)	- 0.07 (± 0.42)	

Mean values (± SEM)

Waist circumference (cm)

	6 months variation (cm)	**Variation VALEDIA® *vs* placebo**[2]
Placebo (n=13 subjects)	+ 2.81 (± 0.65)	**- 4.48 cm**
Valedia® (n=38 subjects)	- 1.67 (± 0.73)	

Mean values (± SEM)

Furthermore, safety data confirm that this plant-based product achieves perfect tolerance.

[1] Difference of the means of individual variations expressed in %
[2] Difference of the means of individual variations

Sébastien PELTIER
CEO of VALBIOTIS

"The results of this clinical Phase IIA study exceed our expectations. They demonstrate that TOTUM-63, the active substance of VALEDIA®, reduces the two main risk factors for type 2 diabetes in people with prediabetes. This success validates the concomitant launch of the last two clinical studies for VALEDIA® to obtain the first health claims for the risk reduction of type 2 diabetes, in Europe and in North America. This major milestone strengthens our discussions with potential partners for marketing VALEDIA®. This is a critical milestone for VALBIOTIS: we have now scientifically validated in humans the efficacy of our new plant-based approach to prevent metabolic diseases. We would like to thank our teams, partners and shareholders."

TOTUM-63

About TOTUM-63, the active substance of VALEDIA®

Prediabetes is an increasingly prevalent public health problem worldwide and recognized by international organizations such as the WHO, the American Diabetes Association and the International Diabetes Federation. 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 to reduce the risk of developing type 2 diabetes. VALEDIA® is the only product that contains the active substance TOTUM-63, a unique and patented combination of 5 plant extracts that act synergistically 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 international Phase IIA randomized placebo-controlled study showed that TOTUM-63 reduces fasting blood glucose levels and blood glucose after 2 hours, two risk factors for type 2 diabetes in people with prediabetes.

All the results from the Phase IIA study, as well as all key company information are available in the updated corporate presentation, available here:

www.valbiotis.com/en/documents/

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 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

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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).
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.

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