

VALEDIA®: key data supporting the submission of a health claim, selected and presented at the 54th EASD Congress in Berlin

- ▶ Data obtained in clinically relevant models, relative to the mechanism of action, key for the health claim submission file to regulatory authorities.
- ▶ New results, including a maintained secretion of insulin by the pancreas, of which loss is one of the leading causes of type 2 diabetes.
- ▶ The *in vivo* characterisation of an innovative multi-targeted mechanism of action shown to impact 5 key organs to reduce the risk of type 2 diabetes.

La Rochelle, 3 october 2018 (5:35 pm CEST) – VALBIOTIS (FR0013254851 – ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, today announced the presentation of new data on VALEDIA®, selected at the annual EASD Congress (European Association for the Study of Diabetes), in Berlin, October 4, 2018. These new *in vivo* results, characterizing the mechanism of action of VALEDIA®, will be included in future health claim requests to American and European regulatory authorities (FDA and EFSA).



The mechanism of action of VALEDIA® has produced encouraging results in the prevention of type 2 diabetes, with significant impact on the two main causes of prediabetes: loss of pancreatic β -cell function and peripheral insulin resistance. Over time, insulin resistance can lead to depleted insulin secretion by the pancreas, known as insulin deficiency. As a result, prediabetes develops into type 2 diabetes, an irreversible condition. By simultaneously targeting the two determinant factors of the disease, as well as the liver and intestinal microbiota, VALEDIA® differentiates itself as a novel product, with a mechanism of action tailor-made for preventing the onset of type 2 diabetes. »

Professeur André Marette, PhD

Researcher at the Medicine Department of the University of Laval (Canada),
specialist in the physiopathology of diabetes

In clinically relevant *in vivo* models, TOTUM-63, the main active ingredient of VALEDIA®, preserves the insulin secretion function of the pancreas, of which impairment is one of the primary causes of type 2 diabetes. Additional data also indicate the action of VALEDIA® on peripheral insulin resistance in skeletal muscle and adipose tissue, as well as the benefit of the product on intestinal dysbioses and hepatic function. The innovative mechanism of action of VALEDIA® targets five organs in order to reduce the risk of type 2 diabetes :

> VALEDIA® preserves the pancreas, a key organ in the treatment of prediabetics

VALEDIA® was tested in a clinically relevant diabetic murine model (db/db) where pancreatic function is impaired. 12 weeks of VALEDIA® supplementation demonstrated a significant improvement in fasting insulinemia and insulinemia after an Oral Glucose Tolerance Test compared to control. These results demonstrate the protective effect of VALEDIA® on pancreatic β -cell function, responsible for insulin secretion, which must be maintained to reduce the risk of type 2 diabetes.

> VALEDIA® reduces peripheral insulin resistance in skeletal muscle and adipose tissue

In a prediabetic murine model (C57BL6, fed with a high fat diet), VALEDIA® induces a significant improvement in the intracellular signaling pathway of insulin (Akt pathway), which is deficient in prediabetic models. This cellular mechanism observed in muscle and adipose tissue largely accounts for the improvement in insulin sensitivity which has already been demonstrated in preclinical and clinical studies.

> VALEDIA® protects the liver to prevent hepatic insulin resistance

In the same model, VALEDIA® also demonstrated a significant 40% reduction in the accumulation of triglycerides in the liver in prediabetic models, compared to control. The accumulation of fat in the hepatocytes is one of the most critical factors in hepatic insulin resistance.

>VALEDIA® modulates the intestinal microbiota and acts on bacterial groups involved in prediabetes and type 2 diabetes

Lastly, metagenomic sequencing of the intestinal microbiota in this prediabetic model has pinpointed the modulating effect of VALEDIA® on intestinal dysbioses. VALEDIA® regulated significantly the relative abundance of 10 groups of intestinal bacteria, with two of these groups (*Parasutterella* and *Barnesiella*) known to be involved in metabolic diseases and particularly impacted by a high-fat diet.



The characterization of the mechanism of action of VALEDIA® is a major breakthrough, with these data being key to obtaining the required health claims for the reduction of type 2 diabetes. The data demonstrates VALEDIA®'s innovative mode of action: it simultaneously targets five key organs and mechanisms involved in prediabetes. The selection of these results for the annual EASD congress, a prestigious scientific event in European diabetology, marks the recognition of this unprecedented strategy in the field of metabolic diseases. »



Sébastien PELTIER,
CEO of VALBIOTIS

VALBIOTIS is a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases. Its products are made for manufacturers in the agri-food and pharmaceutical industries. 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 now located on 3 sites in France – Périgny, La Rochelle (17) and Riom (63) – and has 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).

Find out more about VALBIOTIS :

<http://valbiotis.com>



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