

## VALEDIA®: launch of “pivotal” REVERSE-IT clinical trial to obtain a health claim

- . An international trial on the first three target markets for VALEDIA®: Europe, the United States and Canada
- . Increased financial support from public partner institutions, up to M€1,05 since September 2017
- . Official presentation of the REVERSE-IT trial during the *Journées Francophones de Nutrition 2017*



La Rochelle, 8 November 2017 (5:35 pm CET) - VALBIOTIS (FR0013254851 - ALVAL / PEA/SME eligible), specialist in the development of innovative nutritional solutions for preventing cardiometabolic diseases and the provision of nutritional support for patients, announces that it has received authorization from the ANSM (French national agency for safety of medicines and health products) for the “pivotal” REVERSE-IT clinical trial evaluating the efficacy of VALEDIA® against risk factors for type 2 diabetes in prediabetic subjects. The first subjects will be included in the trial early 2018.

Sébastien Peltier, Chairman of the VALBIOTIS Board of Directors, comments: *"The launch of the REVERSE-IT clinical trial marks a strategic stage for VALBIOTIS. This trial, conducted in France, in the United States and Canada, will help provide the necessary data to European and North American health authorities to obtain the health claim for VALEDIA® on reducing a type 2 diabetes risk factor. We particularly wish to thank our partners and investors who were committed to our cause to create a zero-diabetes world and who made it possible to launch this key phase for VALBIOTIS."*

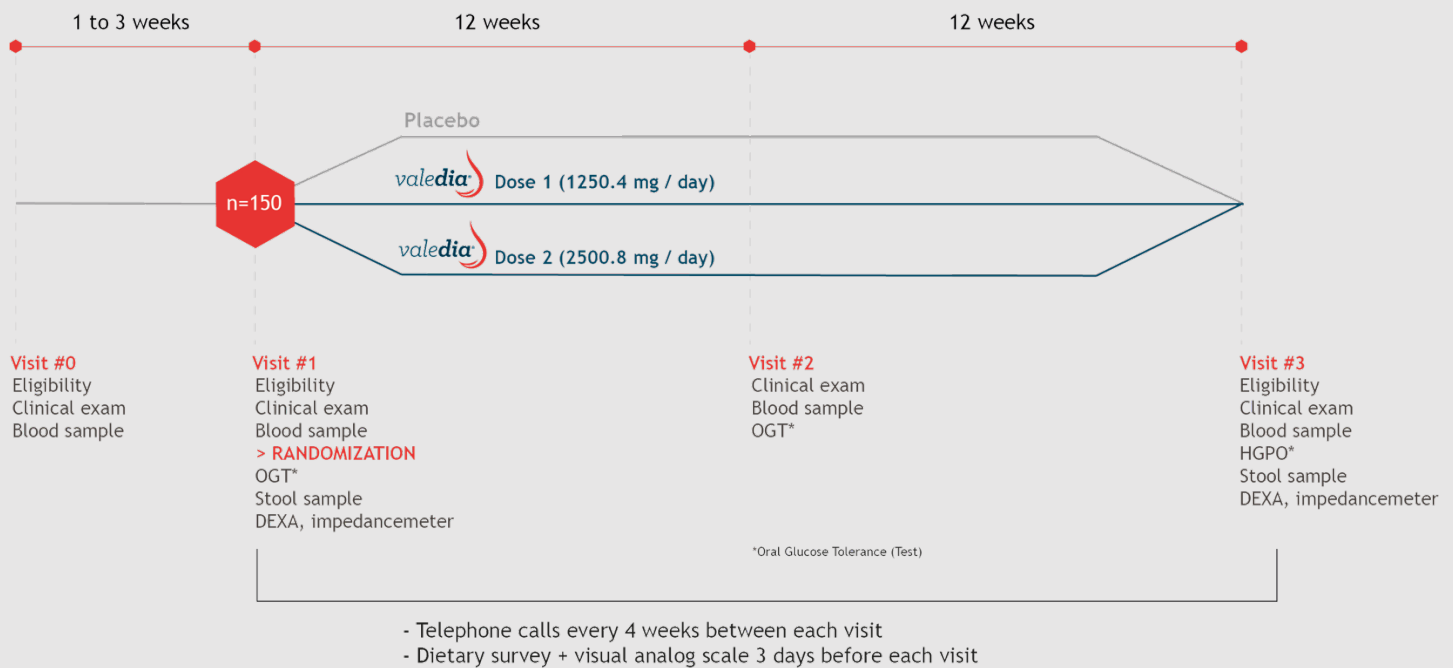
### > REVERSE-IT, an international trial to obtain the VALEDIA® health claim.

REVERSE-IT is the second of three human trials for VALEDIA® included in the product's clinical development plan, before accessing the market. From a regulatory standpoint, REVERSE-IT will provide essential data for obtaining a health claim to prove the efficacy of VALEDIA® in reducing a type 2 diabetes risk factor, in the target population. REVERSE-IT is an international phase IIb<sub>1</sub>, multicenter, randomized, controlled, double-blind trial conducted on 150 prediabetic volunteers (Fig. 1).

With its robust methodology, the REVERSE-IT trial aims to measure the effect of VALEDIA® on all the physiological parameters related to the onset of diabetes, *via* a complete panel of analyses: fasting blood sugar, HbA<sub>1c</sub> level, insulinemia, insulin sensitivity, pancreatic function, hepatic function, body fat mass, satiety, etc. All these clinical and biological parameters are evaluation criteria in the trial. Furthermore, REVERSE-IT is integrated into a transversal study program that studies the effect of VALEDIA® on the intestinal microbiota.

In addition to this data, REVERSE-IT will confirm the safety of VALEDIA® and will help determine the optimal dose.

**Fig. 1. REVERSE-IT design:** 150 participants randomized in a three-arm study over a 24-week period.



As is the case in Europe, the data collected in the United States and Canada will be used to obtain a health claim on these markets. They will also be a decisive asset for our partners marketing the product in North America.

The number of volunteers included (150) will require the production of industrial-sized clinical batches of VALEDIA®. This upscaling will be made possible by Pierre Fabre Médicaments Production at their ANSM-certified site in Cahors. The clinical batches for the REVERSE-IT trial will be produced according to Good Manufacturing Practice at the end of 2017 to begin the trial early 2018.

Finally, to carry out this “pivotal” trial, VALBIOTIS has partnered with an internationally-renowned expert: Professor Samy Hadjadj will be the Principal Investigator of REVERSE-IT. Professor Hadjadj is a hospital practitioner and a professor of endocrinology, diabetology and metabolic diseases at the Poitiers university hospital (CHU) in France. He was also the General Secretary of the Francophone Diabetes Society (SFD). Currently Vice-President of the European Diabetic Nephropathy Study Group (EDNSG), Prof. Hadjadj has contributed to over 100 articles published in international peer-reviewed journals.

## > Several public institutional partnerships formed with VALBIOTIS: €1,05 million granted since September 2017

In order to accelerate its development, VALBIOTIS has benefited from significant financial support from its public institutional partners. This support particularly enables the company to optimize financing of the REVERSE-IT trial. The trial will be conducted with support from:

- the Nouvelle-Aquitaine region, which has provided a grant of up to €350,000 as part of the innovation assistance program (October 2017).
- Bpifrance, which has provided €250,000 in a zero-interest loan (September 2017, after an initial zero-interest loan of €350,000 in May 2017).

VALBIOTIS also benefits from an EIF seed capital investment loan of €350,000 granted by Bpifrance to strengthen the company's financial structure (September 2017) and a cash advance of €100,000 provided by the Puy-de-Dôme revitalization fund, to support the staffing of Riom platform.

Since September 2017, a total of €1,05 million in non-dilutive funding has been invested to support the development of the company and its products. This is a sign of firm commitment from public partners.

## > *Journées Francophones de Nutrition* (Francophone nutrition days) 2017: the VALBIOTIS symposium to present the REVERSE-IT trial

The REVERSE-IT trial will be officially presented during the *Journées Francophones de Nutrition*<sup>1</sup> (JFN), which will be held from 13 to 15 December 2017 at the Conference Center in Nantes. The JFN is an international scientific event conducted in French and organized by the French society for nutrition and the francophone society for clinical nutrition and metabolism. Every year, this event gathers close to 2,000 health professionals involved in treating metabolic diseases.

The VALBIOTIS team, gold sponsor of the 2017 JFN, will be present throughout the event to exchange ideas with nutrition professionals.

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<sup>1</sup> <https://www.lesifn.fr/>

On Thursday 14 December, Professor Hadjadj, the Principal Investigator, will present the REVERSE-IT trial as part of the symposium entitled "VALEDIA<sup>®</sup>, REVERSE-IT study and prediabetes: the future of type 2 diabetes management". This symposium will be moderated by Professor Jean-Marie Bard, President of the JFN local organization committee and biochemist specialized in clinical research in nutrition.

## ABOUT VALBIOTIS

VALBIOTIS specializes in developing innovative nutrition solutions designed to prevent cardiometabolic diseases and provide nutritional support for patients. Its products are made for manufacturers in the agro-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, where the company opened a second office. These agreements have enabled the company to enjoy high leverage, particularly thanks to technical experts and partners rallying around its projects. VALBIOTIS is a member of the "BPI Excellence" network and received the "Innovative Company" status accorded by Bpifrance. 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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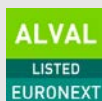
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