



Valbiotis announces the implementation of the TOTUM•63 mode of action clinical study by INAF¹ at Laval University in Quebec City, in partnership with Nestlé Health Science

- The TOTUM•63 mode of action clinical study was co-designed by Valbiotis teams, INAF experts and Nestlé Health Science experts, as part of the global strategic partnership with Nestlé Health Science.
- The study will explore the mode of action of TOTUM•63 in humans and provide additional data to support the scientific communication and the commercialization of this active substance on the prediabetes market.
- Its launch is scheduled for the 4th quarter of 2021 in Canada. André MARETTE, Professor at the Laval University Faculty of Medicine and researcher at INAF will be the scientific advisor.

La Rochelle, June 28, 2021 (5:40 pm CEST) - Valbiotis (FR0013254851 – ALVAL, eligible for the PEA / SME), a Research and Development company committed to scientific innovation for preventing and combating metabolic diseases, announces the implementation of the TOTUM•63 mode of action clinical study by the Institute of nutrition and functional foods (INAF) at Laval University in Quebec City, in partnership with Nestlé Health Science.

This study, co-designed by Valbiotis in conjunction with INAF and Nestlé Health Science experts as part of the global strategic partnership, will include 20 volunteers and will explore the mechanism of action of TOTUM•63 in humans. It will provide additional data to strengthen the scientific communication and support the commercialization of TOTUM•63. Scheduled to begin in the 4th quarter of 2021, it will be conducted under the scientific supervision of André MARETTE, Professor at the Laval University Faculty of Medicine and researcher at INAF.

Murielle CAZAUBIEL, Chief Medical, Regulatory and Industrial Affairs Officer at Valbiotis, member of the Board of Directors, comments: *"This very ambitious study will explore the mode of action of TOTUM•63, a multitarget active substance, in humans. It is the result of a high level of collective work with experts from INAF and Nestlé Health Science, whom we would like to thank for their commitment to this process. INAF is a key player in nutrition and metabolic sciences in North America, particularly in Canada, a country leading the way in the regulation of natural health products. This collaboration is an undeniable asset for the completion of TOTUM•63 development under the global strategic partnership with Nestlé Health Science. And this affiliation with the Canadian scientific ecosystem reflects our commitment to develop R&D activities in North America, the epicenter of global research and a leading commercial market in the field of metabolic diseases."*

¹Institute of nutrition and functional foods (INAF)

The TOTUM•63 mode of action clinical study will explore, in humans, the main mode of action hypotheses resulting from preclinical work. It will include 20 overweight or obese volunteers with associated metabolic abnormalities. With a large number of scientific objectives, the protocol will evaluate the effect of TOTUM•63 administration for 8 weeks on numerous mechanistic parameters involved in the pathophysiology of prediabetes and type 2 diabetes, through in-depth physiological investigations: mainly intestinal absorption of nutrients, metabolomics, inflammation, composition of the intestinal microbiota and gastrointestinal hormones (incretins, including GLP-1).

Prof. André MARETTE, Professor at the Laval University Faculty of Medicine (Quebec City) and researcher at INAF, scientific advisor of the study comments: *"This scientific collaboration between our two organizations makes perfect sense, as Valbiotis' approach is fully in line with INAF's research. As a member of Valbiotis' Scientific and Medical Board for the past 4 years, I am well aware of the relevance of their R&D in the field of metabolic disease and I am convinced of the multitarget approach of its active substances. This is what we will explore in humans, with this study on the mode of action of TOTUM•63. With the collaboration of Prof. Marie-Claude VOHL, expert in genomics applied to nutrition and metabolic health, we will be able to identify the mechanisms of action of TOTUM•63 on subjects with overweight or obesity associated with metabolic abnormalities, including metabolomic and (meta)genomic signatures related to expected metabolic health effects such as inflammation and gastrointestinal functions. We at INAF look forward to bringing our expertise and our investigative resources to the service of this exciting project."*

The study, designed to boost the scientific and commercial value of TOTUM•63, is part of the development plan established with Nestlé Health Science under the global strategic partnership for TOTUM•63. It will be the subject of milestone payments, dedicated in particular to its financing. Its launch is planned for the fourth quarter of 2021.

To support this scientific collaboration and the development of Valbiotis' R&D activities in North America, the Company is opening a subsidiary, with a full-time employee responsible for scientific coordination starting in September. The research project carried out under this collaboration will be eligible for the Canadian Scientific Research and Experimental Development (SR&ED) Program (system equivalent to the French research tax credit).

———— About INAF

Created in the early 2000s to address the challenges of sustainable nutrition and the prevention of metabolic diseases, INAF brings together some 100 researchers in bio-food, health and social sciences from 14 universities and scientific institutions in Québec. Its multidisciplinary approach and the quality of the projects it coordinates have earned it a reputation for scientific excellence on the North American continent.

———— About TOTUM•63

TOTUM•63 is a unique and patented combination of 5 plant extracts that targets the pathophysiological mechanisms of type 2 diabetes.

TOTUM•63 has already been shown to be safe and effective in healthy volunteers in a Phase I/II clinical study. Results from a randomized, placebo-controlled, international Phase II study showed that when compared to the placebo, TOTUM•63 reduced fasting blood glucose and 2-hour blood glucose levels, two risk factors for type 2 diabetes.

In these subjects, who were also abdominally obese, TOTUM•63 also significantly reduced body weight and waist circumference.

TOTUM•63 benefits from intellectual property validated by patents in the world's leading markets: Europe (covering 39 countries), the United States, Russia, China, Japan, Mexico, Indonesia, Israel, South Africa, New Zealand and national phases are still underway in a dozen other countries including Brazil and Australia. Production capacity for TOTUM•63 has been validated in accordance with North American and European standards. TOTUM•63 already has marketing authorizations related to its status in Europe.

In February 2020, Valbiotis signed a long-term global strategic partnership with Nestlé Health Science for the development and worldwide commercialization of TOTUM•63. This unique partnership in the field of Health Nutrition foresees the marketing of TOTUM•63 by Nestlé Health Science on a worldwide scale, possibly before obtaining a medical clearance depending on the area. They will also fund the final stages of development of TOTUM•63.

About Valbiotis

Valbiotis is a Research & Development company committed to scientific innovation for the treatment and prevention of metabolic diseases in response to unmet medical needs.

Valbiotis has adopted an innovative approach, aiming to revolutionize healthcare by developing a new class of health nutrition products designed to reduce the risk of major metabolic diseases, based on a multi-target approach enabled by the use of plant-based ingredients.

Its products are intended to be licensed to players in the health sector.

Created at the beginning of 2014 in La Rochelle, the Company has forged numerous partnerships with leading academic centers. The Company has established three sites in France: Périgny, La Rochelle (17) and Riom (63) - and has a subsidiary in Quebec City (Canada).

Valbiotis is a member of the «BPI Excellence» network and has been recognized as an «Innovative Company» by the BPI label. Valbiotis has also been awarded «Young Innovative Company» status and has received major financial support from the European Union for its research programs via the European Regional Development Fund (ERDF). Valbiotis is a PEA-SME eligible company.

For more information about Valbiotis, please visit: www.valbiotis.com

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