VALBIOTIS

VALBIOTIS announces the First Patient First Visit in the international Phase II/III REVERSE-IT clinical study on TOTUM-63 to reduce Type 2 Diabetes risk factors

First development milestone payment of CHF 3 million from Nestlé Health Science

The first subject, with fasting hyperglycemia, underwent the initial protocol medical visit prior to randomization at one of the study's clinical investigation centers.

The international REVERSE-IT study will include 600 subjects with altered glucose metabolism, spanning from elevated fasting glycemia to early, yet untreated, Type 2 Diabetes. Its primary endpoint is fasting glycemia and it will be led in more than 30 centers in France and abroad.

This First Visit of the First Patient triggers a first milestone payment of CHF 3 million from Nestlé Health Science, thereby strengthening VALBIOTIS' cash position.

La Rochelle, 15 July 2020 (5:40 CEST) **VALBIOTIS** (FR0013254851 – ALVAL /PEA/SME eligible), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **announces the First Patient First Visit in the international Phase II/III REVERSE-IT clinical study designed to assess TOTUM-63 for the reduction of Type 2 Diabetes metabolic risk factors.**

"The first visit of this first subject, a few days after obtaining both ANSM approval and the favorable decision from the CPP**, marks the concrete launch of the REVERSE-IT study, the results of which are expected in mid-2022. We are right on schedule and are delighted to be able to enter the operational phase of this major study so quickly. We also welcome the enthusiasm and commitment of all the partner investigation centers."*

Murielle CAZAUBIEL,
Member of the Management Board and Director of Development and Medical Affairs at VALBIOTIS

** ANSM: French National Agency for the Safety of Medicines and Health Products*
***CPP: French Research Ethics Committee*

PRESS RELEASE

"The first visit of the first subject in the Phase II/III study is a great step forward for TOTUM-63 and encouraging news for patients with prediabetes or untreated early stage Type 2 diabetes. With the 600 patients in this global clinical study, the objective is to demonstrate efficacy and safety of a new plant-based extract."

Dr Hans-Juergen WOERLE,
Chief Scientific and Medical Officer at Nestlé Health Science

The pivotal, randomized, double-blind, placebo-controlled REVERSE-IT study will include 600 patients with fasting hyperglycemia ranging from prediabetes to untreated early stage Type 2 Diabetes. The study should confirm the efficacy of TOTUM-63 - at a dose of 5g/day for 6 months - in addressing the metabolic risk factors for developing Type 2 Diabetes, compared to placebo. The protocol will assess the effect of TOTUM-63 on fasting blood glucose, the primary endpoint of the study, as well as on two-hour blood glucose and anthropometric parameters (body weight, waist circumference and body fat mass), all well-known risk factors for type 2 diabetes.

REVERSE-IT is being conducted in more than 30 centers in France and internationally.

As a result of this achievement, VALBIOTIS will receive the first milestone payment of CHF 3 million from Nestlé Health Science. The global strategic partnership with Nestlé Health Science, concluded in February 2020, includes an upfront payment of CHF5 million, already received by VALBIOTIS, development & sales milestone payments up to a maximum CHF66 million and tiered royalties on net sales. The agreement also includes the supply of TOTUM-63 by VALBIOTIS to Nestlé Health Science, representing an additional source of revenue.

ABOUT THE REVERSE-IT STUDY

The international Phase II/III REVERSE-IT study is the final step in the clinical development of TOTUM-63, an innovative plant-derived active substance designed to reduce the risk factors for type 2 diabetes.

This randomized, double-blind, placebo-controlled study will involve 600 patients with impaired glucose metabolism ranging from prediabetes to untreated type 2 diabetes (early stage). The protocol calls for oral intake of TOTUM-63 at a dose of 5 g/day for 6 months, *versus* placebo.

The REVERSE-IT study is expected to confirm the efficacy of TOTUM-63 on the major risk factors for type 2 diabetes: fasting blood glucose elevation, the primary endpoint of the study, two-hour blood glucose and anthropometric parameters (body weight, waist circumference and body fat).

REVERSE-IT is being conducted following the positive results of the TOTUM-63 Phase II clinical study, published in July and September 2019. It was co-designed with the medical and regulatory teams of Nestlé Health Science, as part of the global strategic partnership for the development and marketing of TOTUM-63, signed by the two companies in February 2020. It will be conducted in more than 30 clinical investigation centers in France and abroad.

ABOUT TOTUM-63

TOTUM-63 is a unique and patented combination of 5 plant extracts, with high potential to target the physiopathological mechanisms of Type 2 Diabetes.

TOTUM-63 has already been proven safe and effective in healthy human volunteers during a Phase I/II clinical study. The results of the international randomized, placebo-controlled Phase II study showed that TOTUM-63 reduced fasting and 2-hour blood sugar levels, two risk factors for Type 2 Diabetes, in prediabetics compared to placebo. In these subjects, who also had abdominal obesity, TOTUM-63 significantly reduced body weight and waist circumference.

TOTUM-63 benefits from intellectual property granted in the main markets worldwide: Europe (covering 39 countries), the United States, Russia and national phases are underway in more than 20 countries including China, Japan, Brazil, Australia. The ability to produce TOTUM-63 industrially, in compliance to North American and European standards, has been validated. TOTUM-63 already has marketing authorizations related to its status in Europe.

In 2020, VALBIOTIS has signed a global and long-term partnership with Nestlé Health Science for the development and worldwide commercialization of TOTUM-63. This unique partnership in the field of Nutrition Health plans that TOTUM-63 will be put on the market by Nestlé Health Science at a global level, possibly before obtaining a health claim, depending on the areas. It will also provide funding for the latest development stages of TOTUM-63.

ABOUT NESTLÉ HEALTH SCIENCE

Nestlé Health Science (NHSc), a wholly-owned subsidiary of Nestlé, is a globally recognized leader in the field of nutritional science. At NHSc we are committed to empowering healthier lives through nutrition for consumers, patients and their healthcare partners. We offer an extensive consumer health portfolio of industry-leading medical nutrition, consumer and VMS brands that are science-based solutions covering all facets of health from prevention, to maintenance, all the way through to treatment. Headquartered in Switzerland, NHSc employs over 5'000 people around the world, who are committed to making a difference in people's lives, for a healthier today and tomorrow.
For more information, please visit: www.nestlehealthscience.com

ABOUT VALBIOTIS

VALBIOTIS is a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases in response to unmet medical needs.

VALBIOTIS has adopted an innovative approach, aiming to revolutionize healthcare by developing a new class of nutritional health solutions designed to reduce the risk of major metabolic diseases, based on a multi-target approach and made possible by the use of plant-based ingredients.

Its products are intended to be licensed to players in the health world.
VALBIOTIS was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers. The Company has established three sites in France – Périgny, La Rochelle (17) and Riom (63).

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 a PEA-SME eligible company.

Find out more about VALBIOTIS: www.valbiotis.com

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