VALBIOTIS

VALBIOTIS: authorization to launch the international Phase II/III REVERSE-IT clinical study on TOTUM-63, to reduce Type 2 Diabetes risk factors

The favourable opinion from the French Ethical Committee (CPP) and the authorization from the French National Agency for the Safety of Medicines and Health Products (ANSM) allow the operational launch of REVERSE-IT, the last clinical development phase of TOTUM-63.

The REVERSE-IT study will be run under the scientific expertise of Pr. Samy HADJADJ, diabetologist and endocrinologist at Nantes University Hospital & Thorax Institute.

This Phase II/III study, has been designed jointly with Nestlé Health Science's teams as part of the global strategic partnership between both companies and is the latest phase of the development of TOTUM-63.

This international 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.

The first medical visit of the first patient applying to the study will be the subject of an upcoming communication.

La Rochelle, 8 July 2020 (7:35 CEST) **VALBIOTIS** (FR0013254851 – ALVAL / PEA/SME eligible), a Research & Development company committed to scientific innovation, for preventing and combating metabolic diseases, **announces the favourable opinion issued from the French Ethical Committee (CPP) and the authorization received from the French National Agency for the Safety of Medicines and Health Products (ANSM) to launch the international Phase II/III REVERSE-IT clinical study on TOTUM-63, to reduce Type 2 Diabetes risk factors.**

This clinical study primarly aims at confirming the Phase II positive results previously obtained on the reduction of fasting glycemia, a risk factor for developing Type 2 Diabetes, to obtain health claims from American and European authorities. This study is the latest phase of the development of TOTUM-63.

TOTUM-63 is an innovative active substance derived from plants, which has already shown metabolic benefits in people with prediabetes. The CPP favourable opinion and the ANSM authorization allow to initiate the enrollments of 600 subjects with prediabetes and untreated Type 2 Diabetes (early stage) in the study.

"From a prevention perspective, it is essential to act on early stages of metabolic imbalance, before the onset of Type 2 Diabetes or early at disease onset. This is the purpose of the REVERSE-IT study, designed and sized to establish the efficacy of this approach. To do so, we will assess the impact of TOTUM-63 on the main metabolic risk factors for developing Type 2 Diabetes, with particular attention to glycemic parameters, abdominal obesity and body weight".

Pr Samy HADJADJ,
Diabetologist and Professor of Endocrinology and Diabetology at Nantes University Hospital, scientific expert of the study

"We are satisfied to receive the CPP favourable opinion and the ANSM authorization to start the REVERSE-IT clinical study, which will complete the development of our active substance TOTUM-63. It is a major clinical study, through its objective and methodology, to validate our approach in the fight against Type 2 Diabetes. With our teams and all our partners at our side, we are now eager to carry it out, to offer all people with prediabetes the opportunity to benefit from it".

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

The REVERSE-IT study follows the positive results of the Phase II study on TOTUM-63, for the reduction of Type 2 Diabetes risk factors. These results were published in 2019 (Press releases of July 3 and September 2, 2019) and presented during the American Diabetes Association scientific sessions in June 2020. The REVERSE-IT study will take up the same primary endpoint (reduction of fasting blood glucose level), the same tested dose (5g/day) and the same regimen (three times a day during 6 months). It was co-designed with the medical and regulatory teams of Nestlé Health Science, as part of the global strategic partnership signed in February 2020 for the development and marketing of TOTUM-63.

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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