VALBIOTIS accelerates its pipeline clinical development in new indications: cardiovascular and hepatic steatosis risk reduction

Launch of a Phase II clinical trial in the third quarter of 2020 evaluating the effect of TOTUM-070 in reducing LDL-cholesterol, a risk factor for cardiovascular disease, in mild to moderate hypercholesterolemic patients;

Launch of a Phase II clinical trial in the fourth quarter of 2020 evaluating the effect of TOTUM-854 in reducing arterial hypertension, a risk factor for cardiovascular disease, in patients with mild to moderate hypertension;

Launch of a Phase II clinical trial in the second half of 2021 evaluating the effect of TOTUM-448 in reducing hepatic steatosis, a condition increasing the risk of developing NASH, in patients with non-alcoholic fatty liver (NAFL);

€500k grant to be received from the European Regional Development Fund (ERDF), Poitou-Charentes region, for the development of TOTUM-070; €630k repayable advance and innovation loan granted by Bpifrance for the TOTUM-854 and TOTUM-448 programs.

La Rochelle, 16 April 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 acceleration of its pipeline clinical development, of plant-derived active substances, in new indications: cardiovascular and hepatic steatosis risk.**

Building on its recent successes, VALBIOTIS is pursuing its innovation strategy focused on the prevention of chronic metabolic diseases by accelerating the clinical development of three additional innovative active substances: TOTUM-070, TOTUM-854[1] and TOTUM-448[1]. These substances, also developed by VALBIOTIS' proprietary R&D platform, target the early stages of chronic metabolic and cardiovascular diseases and address unmet medical needs.

PRESS RELEASE

[1]TOTUM-854 and TOTUM-448 are active substances stemming from the VAL-63 research program.

TOTUM-070 for reducing LDL-cholesterol

TOTUM-070, a patented combination of plant extracts, free from phytosterols and red rice yeast, is dedicated to the reduction of blood LDL-cholesterol ("bad cholesterol"), a risk factor for cardiovascular disease. In 2020, it is estimated that 174 milion people over the age of 25 have high cholesterol in the United States and Europe (top 5: Germany, Spain, France, Italy and the United Kingdom)[2], with a diagnosis rate estimated at around 50%. The current market for non-prescription products is estimated at €1.2 billion in these countries[2].

The randomized, double-blind, placebo-controlled Phase II clinical trial evaluating the efficacy of 3.75 g/day of TOTUM-070 for 6 months in 120 people with untreated mild to moderate high cholesterol (1.3 ≤ LDL < 2.2 g/L) is expected to begin in the third quarter of 2020 (with first inclusion planned for the fourth quarter of 2020). Initial results are expected in the fourth quarter of 2021. The primary endpoint of the study will the reduction of blood LDL-cholesterol. The program benefits from a €500k grant to be received from the European Regional Development Fund (ERDF) for the Poitou-Charentes region.

VALBIOTIS aims to obtain, notably in Europe and North America, the first proprietary health claim related to the reduction of LDL-cholesterol, a risk factor for cardiovascular diseases.

TOTUM-854 for reducing blood pressure

TOTUM-854 targets the reduction of blood pressure. Worldwide, 1.1 billion people suffer from arterial hypertension, the principal cardiovascular risk factor and leading cause of premature death3. TOTUM-854 is uniquely positioned in a non-drug management strategy for people with mild to moderate hypertension. In 2020, it is estimated that 124 milion people over the age of 20 have a slight to moderate blood pressure elevation (120 ≤ systolic blood pressure < 140 mm Hg; 80 ≤ diastolic blood pressure < 90 mm Hg) in the United States and in the top five European countries[2], with a diagnosis rate estimated at 61%. Of these 124 million people, 32 million have already been diagnosed and use non-drug products to control their blood pressure, which today equates to an estimated market of €1.15 billion[2].

[2]Data from AEC Partners for the United States and VALBIOTIS' 5 principal European countries (Germany, Spain, France, Italy and the United Kingdom), 2020.
[3]ESC/ESH Guidelines for the management of arterial hypertension, European Heart Journal, 2018.

The randomized, double-blind, placebo-controlled Phase II clinical trial evaluating the efficacy of 2.5 g/day of TOTUM-854 for 6 months in 100 people with mild to moderate hypertension is expected to begin in the fourth quarter of 2020 (with first inclusion scheduled for the first quarter of 2021). First results are expected in the first quarter of 2022. The main objective will be the measurement of systolic blood pressure at a clinical investigation center, following the official recommendations. 24-hour ambulatory blood pressure measurement (ABPM) will be one of the study's secondary endpoints.

VALBIOTIS has also entered into partnership with the Laboratoire Pharm-Ecologie Cardiovasculaire (Cardiovascular Pharm-Ecology Laboratory) at Avignon University (EA 4278) to further explore TOTUM-854's mechanism of action.

VALBIOTIS aims to obtain, notably in Europe and North America, the first proprietary health claim related to the reduction of systolic blood pressure, a risk factor for cardiovascular diseases.

TOTUM-448 for reducing hepatic steatosis

Finally, with TOTUM-448, VALBIOTIS is targeting hepatic steatosis, a condition that puts patients at high risk of developing non-alcoholic steatohepatitis (NASH). Without intervention, up to 40% of subjects with hepatic steatosis will at least develop NASH within 8 to 13 years[4]. The Phase II clinical study is expected to begin in the second half of 2021 and will be the subject of a subsequent announcement.

The TOTUM-854 and TOTUM-448 programs have been granted a repayable advance and innovation loan of €630k by Bpifrance.

VALBIOTIS, as part of the consolidation and updating of this pipeline, announces the discontinuation of its LpD64 program in obesity.

[4]EASL–EASD–EASO 2016 Clinical Practice Guidelines on the management of non-alcoholic fatty liver disease. J Hepatol 2016.

Endorsement of the business and scientific model

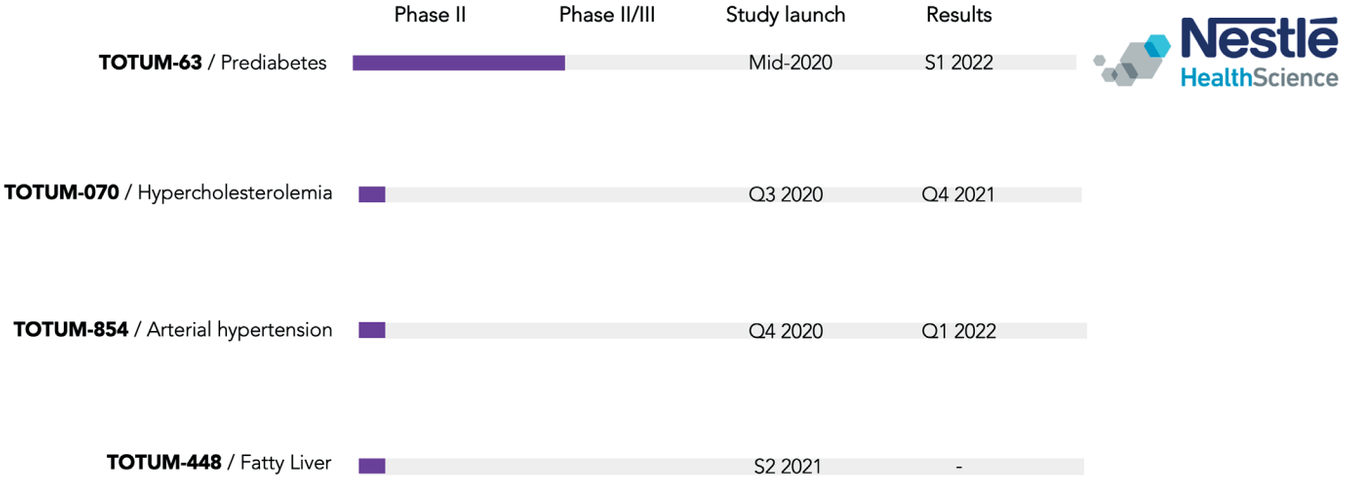
"Our recent successes are now opening up exciting prospects for the company. Our ambition is to clinically develop TOTUM-070, TOTUM-854 and TOTUM-448, on the basis of our proven business model, and to enter into new worldwide licensing agreements to ultimately benefit from revenues from a number of Nutrition Health products. Our proprietary R&D platform and the support of our partners provide a clear funding framework for these developments, until new agreements are concluded with major healthcare players, who may decide to market then even before obtaining a health claim."

Sébastien PELTIER
CEO, Chairman of the Board of Directors at VALBIOTIS

"Our ambition is clear: to develop new products for the prevention of metabolic diseases such as high cholesterol, arterial hypertension and hepatic steatosis (NAFL). We are now able to accelerate clinical development of our complete portfolio of active substances aimed at reducing the risk of metabolic and cardiovascular diseases, based on the same model as that validated in prediabetes."

Murielle CAZAUBIEL
Director of Development and Medical Affairs at VALBIOTIS

An advanced pipeline of active substances



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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