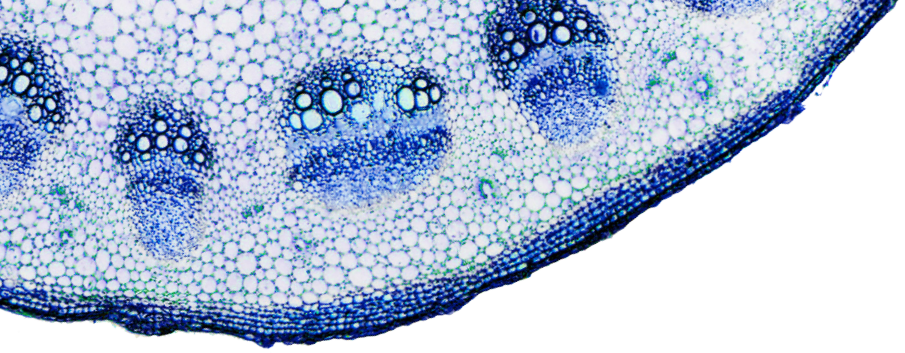

Valbiotis - Increased momentum in the clinical newsflow for major indications: results expected in 2022 for prediabetes, hypercholesterolemia and high blood pressure

- A decisive year, with the finalization of a number of clinical studies on innovative active substances in the portfolio to prevent metabolic and cardiovascular diseases:
  - TOTUM•63/prediabetes: the end of recruitment in Q2 2022, with results expected in Q4 2022 for the pivotal Phase II/III REVERSE-IT study and completion of a mode of action clinical study by INAF[1];
  - TOTUM•070/hypercholesterolemia: results of the Phase II HEART clinical efficacy study and the bioavailability and mode of action clinical study (Q2 2022);
  - TOTUM•854/high blood pressure: results of the bioavailability and mode of action clinical study (Q4 2022).
- Financial resources that secure the clinical calendar and the business plan to date.

La Rochelle, January 6, 2022 (7:35 am CET) - **Valbiotis** (FR0013254851 – ALVAL, eligible for the PEA / SME), a Research and Development company committed to scientific innovation for preventing and combating metabolic diseases, **updates its calendar, which will gain momentum in 2022 with a number of clinical study results expected during the year concerning the prevention of metabolic and cardiovascular diseases. Clinical results regarding three active substances in the portfolio will become available and will be key for the launch of these substances on the prediabetes, hypercholesterolemia and high blood pressure markets. The Company is fully able to finance this market plan today.**

Sébastien PELTIER, CEO of Valbiotis, commented: *"After a year of substantive work in 2021, dedicated in particular to moving the clinical plans for our three initial active substances forward, 2022 should provide significant clinical results for three key indications: prediabetes, hypercholesterolemia and high blood pressure. These clinical results are critical: they must demonstrate that our innovative active substances are effective for patients and meet the goal of preventing metabolic and cardiovascular diseases in their earliest stages. These results must also allow us to rapidly reach a new milestone in our development: converting our scientific expertise into a marketable reality. I hope that, by reaching these objectives, we will meet the expectations of all our stakeholders - patients, healthcare professionals, partners and investors - and confirm Valbiotis' positioning as a leader in disease prevention, in line with public healthcare policies."*

The clinical study results calendar announced for 2022 complies with the development plans adopted for Valbiotis' active substances. These plans were designed to support a highly differentiating marketing positioning on the prevention market, based on clinical evidence and proprietary health claims, with the goal being a rapid market launch.

[1]Institute of Nutrition and Functional Foods (INAF)

Murielle CAZAUBIEL, Member of the Board of Directors and Director of Medical, Regulatory and Industrial Affairs at Valbiotis, stated: *"Decisive clinical advances should be achieved in 2022 on three active substances in our portfolio, the first major high point being in the field of hypercholesterolemia with TOTUM•070. This will be followed by initial clinical bioavailability and mode of action data for TOTUM•854, which targets management of arterial hypertension - here again, the need is great - before the highly anticipated TOTUM•63 results at the end of the year. I strongly believe that our efforts will be rewarded with solid clinical results, which are both the DNA of our R&D and at the heart of our strategy to access the prevention market for metabolic and cardiovascular diseases."*

Details on the clinical results expected in 2022 are as follows:

Decisive clinical results for TOTUM•63 to combat prediabetes in the 4th quarter of 2022

The results of the pivotal Phase II/III REVERSE-IT study on TOTUM•63 should be available by the end of 2022[2]. This major international multicenter study, conducted on 600 hyperglycemic volunteers, should confirm the Phase II results obtained in 2019 in a similar population.
In addition, an exploratory study on the mode of action will be conducted by the Institute of Nutrition and Functional Foods (INAF) of Laval University in Quebec. This study will include 20 volunteers and will explore numerous mechanistic parameters of the pathophysiology of prediabetes and type 2 diabetes (press release of June 28, 2021).
The TOTUM•63 studies are conducted as part of a global strategic partnership with Nestlé Health Science and will be the subject of milestone payments, dedicated in particular to their financing.

Efficacy and mode of action results for TOTUM•070 in combating hypercholesterolemia in the 2nd quarter of 2022

The results of the Phase II HEART study will be announced in the second quarter of 2022. This multicenter study should demonstrate the efficacy of TOTUM•070 in reducing LDL-cholesterol levels compared to a placebo in 120 volunteers presenting untreated mild to moderate hypercholesterolemia. These results will be decisive for the market launch of TOTUM•070, an innovative active substance that is 100% plant-based, with no phytosterol or red yeast rice content, and for its positioning as a leading non-drug option to combat LDL-cholesterol.
At the same time, an open-label study on the bioavailability and mode of action of TOTUM•070, conducted on 10 volunteers, will also provide results in the second quarter of 2022. It combines a clinical evaluation, a bioavailability study, the identification of metabolites, and *in vitro* mechanistic explorations on human cell lines.

Bioavailability and mode of action results for TOTUM•854 in the management of arterial hypertension in the 4th quarter of 2022

The results of the open-label study on the bioavailability and mode of action of TOTUM•854, conducted on 10 volunteers, will be available in the fourth quarter of 2022. Like the TOTUM•070 study, this study combines a clinical evaluation, a bioavailability study, the identification of metabolites and *in vitro* mechanistic explorations on human cell lines involved in regulating blood pressure.
TOTUM•854 is an active substance based on five plant extracts, designed to reduce blood pressure. Its clinical development includes two Phase II/III studies, whose protocols were submitted in December 2021 (press release of December 1, 2021). They should demonstrate the efficacy of TOTUM•854 in reducing systolic blood pressure, compared to a placebo, in a population of volunteers presenting untreated mild to moderately high blood pressure.

In addition to these three active substances in their clinical phase, whose results will be available in 2022, Valbiotis is working on the development of TOTUM•448, an active substance to combat metabolic liver diseases (NAFL and NASH).

TOTUM•448: an updated plan to combat metabolic liver diseases (NAFL and NASH)

TOTUM•448, the fourth active substance in Valbiotis' portfolio, is being developed to address unmet needs in the treatment of metabolic liver diseases: non-alcoholic fatty liver disease and non-alcoholic

[2]Initially planned for mid-2022

The development plan has been updated to better meet the challenges of these emerging pathologies for which effective preventive and therapeutic strategies have yet to be identified. This plan will be based on an innovatively designed study, conducted in “real life” in healthcare centers, directly involving patient management. Combined with clinical studies on mode of action, this work, conducted very close to the field, will allow for TOTUM•448 to be optimally positioned for the management of NAFL and NASH. Details on this development plan will be announced at a future time.

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 health nutrition products designed to reduce the risk of major metabolic diseases, relying on a multi-target strategy enabled by the use of plant-based terrestrial and marine resources.
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 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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