

## Valbiotis announces its roadmap and strategic priorities on the eve of key milestones for its portfolio of innovative active substances

- Following the announcement of the major success of the Phase II/III REVERSE-IT study on its primary endpoint (TOTUM•63, prediabetes / type 2 diabetes), the full results of the Phase II/III REVERSE-IT study will be released in September;
- Clinical development operations are progressing on the portfolio's other active substances, TOTUM•854 (raised blood pressure), TOTUM•070 (hypercholesterolemia) and TOTUM•448 (hepatic steatosis);
- With regard to the launch of TOTUM•070, direct commercial launch in France is confirmed for the first half of 2024 and discussions are ongoing with a view to signing one or more international commercial partnerships;
- In preparation for the first market launches, Valbiotis is continuing to structure its industrial and commercial development.

**La Rochelle, July 12, 2023 (17:40 CEST) – Valbiotis (FR0013254851 – ALVAL, PEA/PME eligible), a commercially oriented Research and Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, today sets out its roadmap for the coming months, which promise to be rich in clinical, industrial and commercial developments.**

The next key milestone for the Company will be the communication of detailed results from the Phase II/III REVERSE-IT study on TOTUM•63, which will complement the announcement of the study's first success on its primary endpoint last May ([press release, May 22, 2023](#)). As a reminder, this international, multicenter, randomized, placebo-controlled study was carried out in a population of 636 volunteers with prediabetes and early-stage, untreated type 2 diabetes. The study met its primary endpoint with high statistical significance: TOTUM•63 reduced fasting blood glucose (a risk factor for type 2 diabetes) *versus* placebo after 24 weeks at a daily dose of 5 g taken 3 times a day; the fasting blood glucose reduction endpoint was also met with high significance at a similar dose but taken 2 times a day, the optimal dosing schedule. Valbiotis looks forward to the communication of full results of the REVERSE-IT study with great confidence, at the same time as the commercial phase of the global strategic partnership with Nestlé Health Science gets underway.

The next scientific steps will include the submission of clinical data from the REVERSE-IT study to international congresses and publication in international peer-reviewed journals. In addition, the results of the mode-of-action clinical study on TOTUM•63, conducted on 19 volunteers by INAF in Quebec City, are expected in the second half of 2023.

Strengthened by the scientific validation obtained for TOTUM•63, Valbiotis will pursue the clinical development of the other three active substances in its portfolio:

- The great success of the Phase II HEART study on TOTUM•070 (hypercholesterolemia) demonstrated the efficacy of this active substance after three months on blood levels of LDL cholesterol and triglycerides (respectively -13.7% and -14.3% per protocol) and after 6 months (-14.3% and -14.4% respectively), with an improvement in the overall lipid profile, in a population with mild to moderate hypercholesterolemia. The Company is preparing a final Phase II/III clinical stage, which will provide the clinical data required to file a health claim. This clinical phase will be conducted in parallel with, and independently of, the commercial launch of TOTUM•070 in France.
- Concerning TOTUM•854 (raised blood pressure), recruitment for the Phase II/III INSIGHT study is ongoing and should be completed in the fourth quarter of 2023. Recruitment for the second Phase II/III INSIGHT 2 study (100 people recruited to date out of a total of 400) will be completed at a later date.
- Finally, the definitive clinical strategy for TOTUM•448 (hepatic steatosis) and the academic partnerships involved will be unveiled in the coming months.

### Structuring for industrial and commercial growth

In parallel with these R&D efforts, the Company is continuing to structure itself, with a dual objective. Firstly, to prepare for the direct marketing of TOTUM•070, TOTUM•854 and TOTUM•448 in France. Secondly, to support the global agreement with Nestlé Health Science for TOTUM•63, as well as future international partnerships for the other three products. On the industrial processes front, Valbiotis is continuing to set up the supply chain, from sourcing plant raw materials through to marketing. Regarding marketing in France (in pharmacies and online), the IT infrastructure and e-commerce platform are being developed, and sales and marketing activities are being organized. The sales timetable in France has thus been confirmed, with TOTUM•070 due for launch in the first half of 2024.

Lastly, as regards TOTUM•070, Business Development activities are continuing in line with the plan and strategy announced, with the help of AEC Partners, Valbiotis' long-standing Business Development partner and the driving force behind the agreement with Nestlé Health Science. Discussions already initiated are ongoing with several global and regional players in the nutrition and health sectors. The ambition remains to sign one or more licensing and/or distribution agreements worldwide (excluding France).

**Sébastien PELTIER, Co-Founder and Chairman of the Valbiotis Executive Committee**, comments: *"The announcement of our success on the primary endpoint marks the first major milestone of our R&D strategy, which has always aimed to obtain a high level of clinical evidence for our plant-based active substances. The forthcoming communication of the full results will mark a decisive step: these results will establish the final clinical value of TOTUM•63 against prediabetes and the early stages of type 2 diabetes. At the same time, we are now structuring the Company with a view to its industrial and commercial ramp-up, with the next milestones shaping up to be particularly exciting: market launch of TOTUM•63, signature of a strategic agreement for TOTUM•070 and commercial launch of TOTUM•070 in France. Valbiotis remains on course to bring its four portfolio products to market, to meet the immediate needs of the millions of patients concerned by metabolic and cardiovascular risks, and to satisfy the high expectations of healthcare professionals in terms of prevention."*

## About Valbiotis

Valbiotis is a commercially oriented Research & Development company, committed to scientific innovation for preventing and combating metabolic and cardiovascular 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 and cardiovascular diseases, relying on a multi-target strategy enabled by the use of plant-based terrestrial and marine resources.

Internationally, its products are intended to be the subject of licensing and/or distribution agreements with global or regional health and nutrition players. In France, Valbiotis will be responsible for marketing its own products.

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 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](http://www.valbiotis.com).

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