



Valbiotis announces approval to launch the two Phase II/III INSIGHT and INSIGHT 2 clinical studies, the last step in the development of TOTUM•854 for the reduction of blood pressure

- These authorizations enable the simultaneous launch of recruitment for these international studies, which should be completed in the first half of 2023.
- The INSIGHT and INSIGHT 2 randomized, placebo-controlled studies are designed to include a total of 800 volunteers with mild to moderate elevated blood pressure, with 400 volunteers in each study.
- They will test the effect of a daily dose of 3.7 g and 2.6 g respectively of TOTUM•854, for 3 months, with the primary endpoint being the reduction of systolic blood pressure.
- The innovative active substance TOTUM•854 is entering the final stage of development for the management of the early stages of hypertension, one of the world's most prevalent cardiovascular risk factors.

La Rochelle, February 17, 2022 (7:35 am CET) - Valbiotis (FR0013254851 – ALVAL, PEA/SME eligible), a Research and Development company committed to scientific innovation for preventing and combating metabolic diseases, **announces that it has received approval to launch the two international multicenter Phase II/III INSIGHT and INSIGHT 2 clinical studies on TOTUM•854, for the reduction of blood pressure.** These two trials will include 800 volunteers with mild to moderate elevated blood pressure, a risk factor for cardiovascular diseases, with 400 volunteers in each study. The authorizations received enable the launch of clinical recruitment, scheduled to be completed in the first half of 2023.

Murielle CAZAUBIEL, member of the Board of Directors, Director of Medical, Regulatory and Industrial Affairs at Valbiotis, commented: *"The approvals received for the INSIGHT and INSIGHT 2 clinical studies are an important milestone for the development of TOTUM•854, which is now entering its final stage. They allow us to begin an ambitious recruitment phase - 800 volunteers in total - for these international Phase II/III studies. In addition, from a medical point of view, the validation of the protocols by the health authorities confirms the innovative positioning of TOTUM•854 in the field of hypertension. The INSIGHT and INSIGHT 2 trials, through their methodology, should now provide the clinical evidence that will support the promise of this active substance for the management of the early stages of arterial hypertension"*.

TOTUM•854 is the second plant-based active substance in the Valbiotis product portfolio to enter Phase II/III clinical studies and will address the lack of non-drug treatment for hypertension, complementing therapeutic solutions and supported by strong scientific evidence.

The results of the two INSIGHT and INSIGHT 2 clinical studies are essential for a health claim application for the reduction of blood pressure, a risk factor for cardiovascular diseases, in Europe and the United States. They will comply with the protocols validated by the competent authorities:

- The INSIGHT Phase II/III international, multicenter, randomized, placebo-controlled clinical study will be conducted on a population of 400 volunteers with mild to moderate elevated blood pressure (systolic blood pressure between 130 mmHg and 159 mmHg and diastolic blood pressure < 100 mmHg). It will include two groups: a TOTUM•854 group with a dose of 3.7 g/day and a placebo group. The primary endpoint will be a reduction in systolic blood pressure, after 3 months of supplementation, between the TOTUM•854 group and the placebo group. In addition, 24-hour ambulatory blood pressure measurement will be performed and will be one of the secondary endpoints of the study.
- The INSIGHT 2 clinical study, also international, multicenter, randomized and placebo-controlled, will be carried out on 400 other subjects with the same inclusion criteria. There will be two groups: a TOTUM•854 group receiving a reduced dose (2.6 g/day) and a placebo group. The primary endpoint will be a reduction in systolic blood pressure, after 3 months of supplementation, between the TOTUM•854 group and the placebo group.

In addition to these clinical efficacy studies, the development plan for TOTUM•854 includes a bioavailability and mode of action study in 10 volunteers to characterize TOTUM•854 metabolites and identify their effects on human cell lines. The results are expected by the end of 2022.

———— 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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