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Valbiotis announces that it has received Food and Drug Administration (FDA) approval for New Dietary Ingredient (NDI) status for a plant extract present in all its TOTUM products

La Rochelle, December 11, 2023 (08:00 pm CET) – **Valbiotis (**FR0013254851 – ALVAL, PEA / PME eligible), a commercially-oriented company specializing in dietary supplements, committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, **announces that it has received approval from the Food and Drug Administration (FDA) for New Dietary Ingredient (NDI) status for a plant extract present in all its TOTUM products.**

The US Food and Drug Administration (FDA) imposes specific requirements on manufacturers and distributors wishing to market dietary supplements containing "new dietary ingredients". These players must notify the FDA of all information relating to the quality and safety of the new ingredient, enabling them to conclude that a dietary supplement containing this new ingredient is safe under the conditions of use recommended or suggested on the label.

Sébastien PELTIER, CEO and co-founder, emphasizes: *"Obtaining the New Dietary Ingredient (NDI) status for this plant extract is a gratifying milestone, albeit expected, marking the conclusion of a standard authorization process. As the U.S. market stands as the world's leading market for dietary supplements, we are thrilled to be able to commercialize all our TOTUM products there, considering that all their individual ingredients are already authorized. We extend our sincere thanks to the Nestlé Health Science teams, with whom a fruitful collaboration has been established to secure this FDA notification, thereby strengthening our international presence."*

Murielle Cazaubiel, member of the Executive Committee and Director of Medical, Regulatory and Industrial Affairs at Valbiotis, comments: *"Obtaining New Dietary Ingredient (NDI) status for this plant extract present in all our TOTUM products, including TOTUM•63, reflects Valbiotis' determination and ability to develop safe, high-quality active substances. This approach guarantees widespread access to our products, reinforcing our commitment to take action before a person identified as being at risk becomes a confirmed patient. This comes at a time when the growing incidence of metabolic and cardiovascular diseases worldwide poses a public health challenge."*

The FDA's no-objection letter was granted to Valbiotis before the end of the standard 75-day review period, testifying to the diligence and quality of the steps taken by the Company.

About Valbiotis

Valbiotis is a commercially-oriented company specializing in dietary supplements, 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.

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