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Nestlé Partner Valbiotis Hails Trial Results For Prediabetes Supplement

by Tom Gallen

Valbiotis and Nestlé Health Science plan to launch in 2024 a dietary supplement targeted at sufferers of prediabetes and type-2 diabetes following positive results from a recent study which showed the product's efficacy on key markers of glucose metabolism.

France's Valbiotis has claimed a first for a non-drug active substance after its plant-based dietary supplement, TOTEM-63, showed in a recent clinical trial efficacy on key markers of glucose metabolism.

The company is now preparing for the global launch of TOTEM-63 in partnership with Nestlé Health Science, marketing the product to patients with prediabetes and early stage untreated type 2 diabetes.

According to Valbiotis, the Phase II/III study – yet to be peer reviewed – achieved its primary endpoint in demonstrating a reduction in fasting blood glucose levels after six months of TOTUM-63 supplementation at three intakes per day versus placebo.

In addition to a reduction in fasting blood glucose levels, the main markers of glucose metabolism – two-hour blood glucose, glycated hemoglobin and insulin resistance – were also significantly reduced by TOTUM-63 taken twice daily versus placebo, Valbiotis reported.

In prediabetic patients, TOTUM-63 reduced disease progression and the number of new cases of type 2 diabetes by 40% after six months, compared with placebo, with two intakes per day.

Over 600 Participants

The multicentric, randomized, double blind placebo-controlled study enrolled 636 patients: 501 prediabetics and 135 early-stage, untreated type 2 diabetics. Patients were divided into three arms, each with over 200 participants:

- A blind arm supplemented with TOTUM-63 (5 g/day) in 3 intakes per day,
- An open arm supplemented with TOTUM-63 (5 g/day) in 2 intakes per day,
- A placebo arm

"With the data announced today, the REVERSE-IT study is a breakthrough for the prevention of type 2 diabetes," commented Valbiotis' executive committee chair Sébastien Peltier. "The objective we set ourselves with our partner Nestlé Health Science has been achieved: to demonstrate with unequivocal clinical evidence that we can act successfully at a very early stage, for the benefit of patients."

Nestlé Health Science's chief scientific and chief medical officer Hans-Juergen Woerle said the company was "thrilled" with the outcome of the study. "This non-drug, plant-based active substance has the potential to significantly impact the management of early impairments of glucose metabolism," he stated.

Nestlé Deal

Valbiotis entered into a long-term strategic partnership with Nestlé Health Science in 2020 for the development and worldwide commercialization of TOTUM-63. Through this deal, Nestlé gained the exclusive, global commercial rights to use TOTUM-63 in food products for the prediabetes and type 2 diabetes markets. (Also see "[Nestlé Targets Diabetes Prevention With French Partner](#)" - HBW Insight, 10 Feb, 2020.)

The two companies are now preparing for the commercialization of TOTUM-63 with the first order anticipated in the first half of 2024. Valbiotis has patents in place globally, including the US, China and India, as well as Europe, where it says

Targets Diabetes

A unique patented combination of five plant extracts – olive leaves, bilberry, artichoke, chrysanthellum and black pepper – TOTUM-63 is said by Valbiotis to target a number of pathophysiological mechanisms of type 2 diabetes:

Muscle - restoration of insulin signaling pathways and insulin-stimulated glucose uptake.

White adipose tissue - restoration of insulin signaling pathways, reduction of inflammation.

Brown adipose tissue - activation of thermogenic genes, reduction of inflammation.

Liver - decrease in hepatic steatosis, reduction of pro-inflammatory macrophages, restoration of insulin signaling pathways.

TOTUM-63 has secured “marketing authorizations linked to its status.”

According to Valbiotis’ website, clinical development plans are in place with a view to obtaining specific health claim authorizations for TOTUM-63 from regulatory authorities including the US Food and Drug Administration and the

European Food Safety Authority. Potential claims previously suggested by Valbiotis include, for the US, “TOTUM-63 may reduce the risk of type 2 diabetes, a disease associated with several risk factors,” and for Europe, “TOTUM-63 reduces fasting glycemia, which increase is a risk factor for type 2 diabetes.”

To support the launch of TOTUM-63, Valbiotis and Nestlé plan to target consumers with an “appropriate online marketing strategy,” while also looking to build relationships with “high potential general practitioners” and “key pharmacies in the GPs perimeter.”

The results of a mode-of-action clinical study on TOTUM-63 conducted by Canada’s Institute of Nutrition and Functional Foods are expected in the second half of 2023.

Intestines - improvement in the composition of the microbiota and in particular the abnormalities observed in prediabetes, reduction in glucose absorption, and decrease in lipid absorption.