

VALBIOTIS confirms the publication of the results from international Phase IIA clinical study evaluating VALEDIA® for the risk reduction of type 2 diabetes, by mid-2019

- Last subject included in the the Phase IIA clinical study at the beginning of November 2018
- Results to be published mid-2019, as precedently announced
- Objective: obtaining the world's first proprietary health claim asserting efficacy in reducing the risk of type 2 diabetes

La Rochelle, le 6 November 2018 (5:40 CET) - VALBIOTIS (FR0013254851 - ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **confirms the publication of the results evaluating VALEDIA® for the risk reduction of type 2 diabetes, by mid-2019.**



Sébastien PELTIER
CEO of VALBIOTIS

«In recruiting the last subject for the Phase IIA clinical study evaluating the effects of VALEDIA® on the risk reduction of type 2 diabetes, VALBIOTIS has crossed an extremely significant milestone. We are happy that our development plan is proceeding as we predicted and we are now confidently awaiting the results of this study for mid-2019. We would like to thank all the subjects participating in this study, as well as the investigators. VALEDIA® is a completely innovative health product which represents a new approach to preventive health care, where modifiable risk factors can be targeted from the very first symptoms.»

VALEDIA®, A PRODUCT FOR THE PREVENTION OF TYPE 2 DIABETES

The Phase IIA clinical study is a randomized, multi-center, double-blind, placebo-controlled study conducted on the main active ingredient of VALEDIA®, TOTUM-63.

Authorization was granted by the French authorities in November 2016. Prediabetic subjects were recruited based on two criteria: high fasting glycemia levels and glucose intolerance, with abdominal obesity and moderate, untreated hypertriglyceridemia.

At the start of 2018, VALBIOTIS decided to open three European recruitment centers in addition to its existing French centers, in order to obtain clinical data from across Europe.

This recruitment is now complete and the results of the study are expected by the middle of 2019.

In particular, this study will enable the effects of the main active ingredient of VALEDIA® to be evaluated against three risk factors, recognized by the FDA (Food and Drug Administration, United States): fasting glycemia, post-prandial glycemia (glucose intolerance) and insulin resistance.

With these results, the risk factor can then be validated and used in our approach to European and North-American authorities. VALBIOTIS specifies that the validation of just one of these three risk factors would be sufficient to obtain a health claim related to reducing the risk of type 2 diabetes, therefore positioning VALEDIA® as the first product in the world to be specifically aimed at prediabetics.

ABOUT VALEDIA®

The main active ingredient of VALEDIA®, TOTUM-63 is based on a specific and patented combination of 5 plant extracts selected for their multi-target effect on the metabolism.

VALEDIA® has already been the focus of a Phase I/II clinical study, the results of which were presented at the 77th edition of the American Diabetes Association (ADA) scientific sessions, in June 2017.

À PROPOS DE VALBIOTIS

VALBIOTIS est une entreprise française de Recherche & Développement engagée dans l'innovation scientifique, pour la prévention et la lutte contre les maladies métaboliques. Ses produits sont destinés aux industriels de l'agro-alimentaire, et de l'industrie pharmaceutique. VALBIOTIS intervient notamment pour la prévention du diabète de type 2, de la NASH (stéatohépatite non-alcoolique), de l'obésité et des pathologies cardiovasculaires. Créée début 2014 à La Rochelle, l'entreprise a noué de nombreux partenariats avec des centres académiques d'excellence en France et à l'étranger, dont l'Université de la Rochelle, le CNRS, et l'Université Clermont Auvergne située à Clermont-Ferrand. Ces accords lui permettent de bénéficier depuis sa création d'un fort effet de levier grâce notamment à des experts et partenaires techniques mobilisés sur ses projets. L'Entreprise est installée sur 3 sites en France - Périgny, La Rochelle (17) et Riom (63) - auxquels s'ajoute un bureau américain à Boston (MA).

Membre du réseau « BPI Excellence » et bénéficiant du label BPI « Entreprise Innovante », VALBIOTIS dispose aussi du statut « Jeune Entreprise Innovante » et a obtenu un appui financier important de l'Union Européenne pour ses programmes de recherche via l'obtention de Fonds Européen de Développement Économique Régional (FEDER).

Find out more about VALBIOTIS:

www.valbiotis.com



Name: VALBIOTIS - ISIN Code: FR0013254851 - Mnemonic code: ALVAL



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