

VALBIOTIS initiates the clinical development of VALEDIA™ in the United-States with the REVERSE-IT clinical study

▶ Authorization has been granted by the American authorities* to launch the REVERSE-IT clinical study (Phase IIB1) in the United States – a multicenter, international, randomized, double-blind, placebo-controlled study, aimed to determine the most efficient dose of VALEDIA™ on 150 prediabetic volunteers

▶ Discussions initiated with the Food and Drug Administration (FDA) for a health claim regarding the reduction of the risk of Type 2 Diabetes for VALEDIA™

La Rochelle, May 15th 2018 (5:35 pm CEST) – VALBIOTIS (FR0013254851 – ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, today announced it has received authorization from the American authorities to launch the international REVERSE-IT (Phase IIB1) clinical study of VALEDIA™ in the United States. Simultaneously, discussions are initiated with the Food and Drug Administration (FDA) for a health claim regarding the reduction of the risk of Type 2 Diabetes.

“ The acceleration of our development in the United States marks the beginning of a key phase for VALBIOTIS. The authorization from the American authorities for the VALEDIA™ clinical study supports our access to these markets, and in particular to the prediabetes market, which affects more than 86 million people in the United States. We are delighted with these recent breakthroughs. ”



Sébastien
PELTIER

CEO
of VALBIOTIS

REVERSE-IT is an international, multicenter, randomized, double-blind, Phase IIB1 placebo-controlled study, aimed to determine the most efficient dose of VALEDIA™ on a population of prediabetic subjects. 150 prediabetic individuals will be included in the study. The American part of the study will be conducted in two centers, one in Miami, Florida and one in Chicago, Illinois. The approval from the American Authorities was granted after authorization was obtained in France in November 2017 from the French National Agency for Medicines and Health Products (ANSM).

ABOUT VALEDIA®

Flagship product of VALBIOTIS, VALEDIA™ improves insulin sensitivity and aims to reduce the risk of Type 2 Diabetes. It is designed for prediabetics and will apply for a health claim issued by the authorities in the United States, Canada and Europe. In a Phase I/II clinical study, VALEDIA™ has already demonstrated safety and early evidence of efficacy. It is now being tested in an international, multicenter clinical study on prediabetic subjects.

Since the beginning of 2018, VALBIOTIS holds a patent protecting the active ingredient of VALEDIA™ in the United States, granted by the United States Patent and Trademark Office. Covering the composition, production method and use of the product, this patent provides the highest level of protection in the United States and grants exclusive commercial rights to VALBIOTIS for the entire US territory.

ABOUT VALBIOTIS

VALBIOTIS is a French Research & Development company committed to scientific innovation, for preventing and combating metabolic diseases. Its products are made for manufacturers in the agri-food and pharmaceutical industries. VALBIOTIS particularly focuses on solutions to prevent type 2 diabetes, NASH (nonalcoholic steatohepatitis), obesity and cardiovascular diseases. VALBIOTIS was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers in France and abroad, including the La Rochelle University, the CNRS and the Clermont Auvergne University located in Clermont-Ferrand, where the company opened a second office. These partnerships have enabled VALBIOTIS to benefit from strong financial leverage, particularly thanks to experts and technical partners who support its projects. VALBIOTIS is a member of the "BPI Excellence" network and received the "Innovative Company" status accorded by BPI France. VALBIOTIS has also been awarded "Young Innovative Company" status and has received major financial support from the European Union for its research programs by obtaining support from the European Regional Development Fund (ERDF).

Find out more about VALBIOTIS:

<http://VALBIOTIS.com/en>



COMMUNICATION

VALBIOTIS

Carole ROCHER / Marc DELAUNAY

+33 5 46 28 62 58

carole.rocher@VALBIOTIS.com

marc.delaunay@VALBIOTIS.com

FINANCIAL COMMUNICATION

ACTIFIN

Stéphane RUIZ

+33 1 56 88 11 14

sruiz@actifin.fr

MEDIA RELATIONS

ALIZE RP

Caroline CARMANOL / Wendy RIGAL

+33 1 44 54 36 66

VALBIOTIS@alizerp.com



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

