VALBIOTIS

PRESS RELEASE

VALBIOTIS announces positive results from its Phase I/II clinical study conducted on LpD64 for obese subjects

- Results showed a significant effect on energy metabolism in obese subjects: a substantial improvement of over 33% on insulin sensitivity combined with an improvement in lipid profile.
- Validation of tolerability and safety.
- Study paves the way for the launch of a Phase II study, to be conducted on overweight and obese subjects.
- The comprehensive set of results will be presented at the International Diabetes Federation congress in Kuala Lumpur (Malaysia) on November 22, 2018.

La Rochelle, 11 September 2018 (5:35 pm CEST) – VALBIOTIS *(FR0013254851 – ALVAL / eligible PEA/PME), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases,* today announced the success of its Phase I/II clinical study conducted on LpD64 in obese subjects. This study, launched in 2017, had two objectives: to validate the tolerability and safety of LpD64 based on blood, urinary and hemodynamic biological parameters, and to provide proof of concept in obese subjects. Results showed good safety and tolerability as well as a significant effect on energy metabolism with an improvement of over 33% on insulin sensitivity combined with an improvement in lipid profile. These results validate the tolerability and safety of LpD64 in the target population. The significant effect achieved on insulin sensitivity combined with an improvement in lipid profile pave the way for the launch of Phase II clinical development, the final stage before applying for a health claim in North America and Europe.

20 obese male subjects participated in the Phase I/II, single center, controlled, open-label study. It was conducted at the Clinical Investigation Center, Inserm 1405, of the University Hospital Center in Clermont-Ferrand (France), and led by Prof. Gisèle PICKERING, Physician and Professor of Clinical Pharmacology. This study consisted of an initial 12-week period where supplements were administered at a dose of 2.6 g per day, followed by a 2-week washout period, and then another 12-week period where supplements were administered at a dose of 5.2 g per day.

This study validates the tolerability and safety of LpD64 and provides evidence of its efficacy on insulin sensitivity, demonstrating an improvement in the insulin sensitivity index of 33%, $p<0.001$ on the target population. Furthermore, an improvement in lipid profile was observed. These results are in line with the preclinical data obtained previously.

« This Phase I/II study demonstrates the benefit of LpD64 for obese or overweight patients. From a clinical perspective, the significant effect obtained on insulin sensitivity is very promising because insulin resistance, very common among obese subjects, is a major factor in the development of obesity. It is logical therefore to note the improvement in blood lipid profile. The Phase II studies aim to confirm these initial results in a larger population of obese subjects. »

Prof. Gisèle PICKERING, study investigator,
CHU Clermont-Ferrand

LpD64 is an extract derived from a blend of plants that has demonstrated significant efficacy on insulin sensitivity and a reduction in fat mass in preclinical studies on obesity models (press release published on October 16, 2017). In March 2018, new preclinical data revealed a clear and significant effect on the intestinal microbiota (press release published on March 6, 2018). Imbalances in the microbiota are considered to be a causative factor in the development of obesity.

« We have proven that LpD64 meets its objective: in addition to tolerability and safety, the effect on insulin sensitivity and the improvement of the lipid profile are now confirmed in humans. This study has provided us with the clinical proof of concept needed to launch Phase II. The results achieved by LpD64 are also consistent with the effects already observed on the intestinal microbiota. This confirms the relevance of our innovative approach, which aims to revolutionize healthcare by developing a new class of products designed to reduce the risk of severe metabolic diseases, based on a multi-target approach and made possible by the use of plant-based ingredients. »

Sébastien PELTIER

CEO of VALBIOTIS

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 CARMAGNOL / Wendy RIGAL
+33 1 44 54 36 66
VALBIOTIS@alizerp.com

ALVAL LISTED EURONEXT

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

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