

VALBIOTIS announces a significant effect of VALEDIA® on intestinal microbiota

- VALEDIA® acts on microbiota imbalances associated with metabolic diseases (preclinical)
- In addition to the Phase I/II efficacy results in humans, this additional data strengthens the value of VALEDIA® for preventing type 2 diabetes
- VALBIOTIS continues its metagenomics program to assess how its products affect the microbiota

La Rochelle, 22 January 2018 (7:30 am CET) - VALBIOTIS (FR0013254851 - ALVAL / PEA/SME eligible), a company that specializes in developing innovative nutrition solutions designed to prevent cardiometabolic diseases and provide nutritional support for patients, announces that VALEDIA® has shown significant effects on the intestinal microbiota, in murine models of metabolic diseases. These results were selected for presentation at the Keystone "Bioenergetics and Metabolic Disease" symposium from 21 to 25 January 2018 in Keystone, Colorado (United States).

Recent studies have proven that certain imbalances in the intestinal microbiota are associated with the development of metabolic disorders, particularly insulin resistance and type 2 diabetes¹. The data presented show that VALEDIA® acts on these imbalances. In physiological murine models, VALEDIA® significantly increases intestinal microbiota diversity, with a specific impact on populations of microorganisms involved in developing type 2 diabetes. This effect on the gut microbiota completes VALEDIA®'s multi-targeted mechanism of action and adds value to this product, which has already obtained positive clinical Phase I/II data for preventing type 2 diabetes.

Sébastien Peltier, CEO of VALBIOTIS, comments: *"This result is highly valuable as it proves for the first time that VALEDIA® is able to balance the intestinal microbiota in addition to its expected action on the other organs involved in the onset of type 2 diabetes. Given the strong link between microbiota and cardiometabolic diseases, it will be a real scientific and marketing asset for the product. More generally speaking, our microbiota research program, led in collaboration with recognized experts, will generate data with strategic value for our preventive products and will help VALBIOTIS to rank among the performing players in the field of microbiota."*

¹ Suez *et al.* Role of the microbiome in the normal and aberrant glycemic response, Clinical Nutrition Experimental, 2016



The microbiota: a leading field with massive R&D investments

Over the last 10 years, the microbiota has become a prolific area of health research, and the number of yearly publications on the subject has multiplied by 15 since 2008. The microbiota has long been referred to as the intestinal flora, and it designates the population of billions of multi-species microorganisms living in the human digestive tract. Modification – or dysbiosis – of this very diverse ecosystem is now correlated with multiple metabolic (obesity, diabetes and metabolic syndrome), digestive (IBD) and cancerous conditions (digestive tumours). Dysbiosis is even suspected to trigger certain neurological conditions^{1,2}.

Thanks to new metagenomics methods, the microbiota has become a high-valued target for developing innovative health applications. The many potential opportunities are leading to massive fund-raising, and the total amount surpassed a billion dollars in 2016 in Europe and the United States. In particular, the sector is drawing the attention of major global pharmaceutical players. Janssen, Roche, Boeringher, Celgene, BMS, Pfizer, Novartis and Nestlé Health Science have all aligned themselves with companies in the sector by signing license agreements, creating joint ventures or making private investments^{2, 3}. The challenge remains to show the clinical efficacy of these products acting on the microbiota.

Correct dysbiosis: a sought-after method of preventing cardiometabolic diseases

In the field of metabolic disorders, targeting intestinal dysbiosis is a documented pathway for the development of preventive products or even new treatments. Recent studies have shown a strong correlation between the onset of these diseases (obesity and type 2 diabetes), a lowering in microbiota diversity and specific changes in its composition. Dysbiosis then triggers an increase in lipid and carbohydrate absorption in the intestine, and promotes a pro-inflammatory state, one of the causes of insulin resistance¹.

VALEDIA®: significantly impacts intestinal microbiota imbalances, which supports the preliminary efficacy data obtained in clinics

VALEDIA® is designed to reduce risk factors of type 2 diabetes, and has already obtained positive Phase I/II clinical results concerning glucose metabolism in humans. To study its potential effect on the intestinal microbiota, VALBIOTIS launched an extensive metagenomic sequencing program, first conducted in murine models, to be continued in human subjects. The program benefited from collaboration with expert partners in the field: Biofortis-Merieux Nutrisciences and the Université Catholique de Louvain, with Prof. Patrice Cani.

² La Tribune, 12 June 2017, www.latribune.fr/entreprises-finance/industrie/chimie-pharmacie/les-investisseurs-de-plus-en-plus-seduits-par-les-therapies-basees-sur-le-microbiote-733963.html

³ The Wall street Journal, 18 sept 2016, www.wsj.com/articles/microbiome-companies-attract-big-investments-1474250460

The data presented shows the significant impact of VALEDIA® on the diversity and composition of the gut microbiota in murine models of metabolic diseases, especially on groups of microorganisms associated with type 2 diabetes (*Firmicutes*, *Bacteroidetes*, etc.).

In detail, the study revealed that a high-fat diet reduced the diversity and modified the composition of the microbiota compared to the control (normal diet), as expected. However, the models supplemented with VALEDIA® and fed the same high-fat diet were found to have a significantly higher taxonomic diversity (Shannon index), intermediate overall composition compared to the control, and a higher *Firmicutes/Bacteroidetes* ratio, closer to normal state. More precisely, VALEDIA® had a specific impact on the bacterial families whose abundance correlates with metabolic dysfunction: a significant increase of *Porphyromonadaceae* (*Bacteroidetes*) and *Sutterellaceae* (*Proteobacteria*) was identified, accompanied by a decrease in *Lachnospiraceae* (*Firmicutes*).

In light of current knowledge, these very positive results on the intestinal microbiota are coherent with the efficacy already shown by VALEDIA® on metabolic parameters, in animals and humans. Such results strengthen the rationale for preventing type 2 diabetes.

ABOUT VALBIOTIS

VALBIOTIS specializes in developing innovative nutrition solutions designed to prevent cardiometabolic diseases and provide nutritional support for patients. 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 agreements enable it to benefit from a considerable leverage effect since it was set up thanks, in particular, to the experts and technical partners mobilized for these 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/>



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