

VALBIOTIS obtains strategic patent for VALEDIA® in the United States

- Direct coverage for TOTUM-63, active ingredient of VALEDIA®, VAL-63-NAFLD and VAL-630, with the highest degree of protection (composition, application, method)
- Strengthened industrial property with the acquisition of exclusive operating rights for the entire American region
- A consolidated portfolio after a series of positive results, presented during international scientific congresses

La Rochelle, 15th March 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, today announces that it has obtained approval from the US Patent and Trademark Office (USPTO) for its TOTUM-63 patent "Compositions and methods to act on carbohydrate and lipid metabolism" ¹. This patent protects directly VALEDIA® in the United States as well as two other products in the VALBIOTIS portfolio.

"Obtaining this patent is a strategic step for VALBIOTIS' development in the United States. Prediabetes affects 30% of the US population², overweight and obesity affects more than 2 american out of 3³ and hepatic steatosis affects 3 american out of 10⁴. Obtaining this patent in such a short time—just over 2 years after registering it in October 2015—acknowledges the innovative nature and high potential of our solutions. This stage, which boosts our competitive edge in the United States, will also be a major asset for signing partnerships and licenses with high-profile industrial players in this key territory for VALBIOTIS", comments Sébastien PELTIER, Chairman of the VALBIOTIS Board of Directors.

A strengthened industrial property in the United States

This patent – which was developed in collaboration with the University of La Rochelle, the CNRS and the Clermont-Auvergne University – protects the active ingredient TOTUM-63 as a food product, health supplement or pharmaceutical ingredient, to prevent and/or treat carbohydrate and/or lipid metabolism disorders in humans or animals, through its synergistic mode of action.

¹ US 14/887,416

² Centers for Disease Control and Prevention, July 25, 2017
www.cdc.gov/diabetes/basics/prediabetes.html

³ Institute for Health Metrics and Evaluation, www.healthdata.org/news-release/vast-majority-american-adults-are-overweight-or-obese-and-weight-growing-problem-among

⁴ <http://time.com/4759498/nonalcoholic-fatty-liver-disease/>

It directly covers 3 of the 5 products in the current VALBIOTIS portfolio:

- **VALEDIA®** and **VAL-63-NAFLD**, aiming at a claim for reducing risk factors for developing type 2 diabetes and NASH, respectively;
- **VAL-630**, a medical nutrition product for patients with NASH, associated or not with Type 2 Diabetes.

Furthermore, obtaining this patent offers a high level of protection to the VALBIOTIS assets: beyond the wide main claims regarding the composition, the patent protects both the specific composition of the plant mixture, the exact final content in active molecules (definition of molecules and ratio in the mixture) and their possible combination with other existing food or pharmaceutical products. It protects also the use of TOTUM-63 for specific applications in healthcare, precisely defined by VALBIOTIS based on the efficacy data already obtained.

Obtaining this patent for TOTUM-63 in the United States after it was approved in France in 2016, confirms the potential of the innovation developed by VALBIOTIS and endorses its applications in international healthcare. According to the VALBIOTIS global territorial strategy, 61 other applications concerning patents from the same family are currently under review worldwide, including European and Canadian territories.

Status of the pipeline at the end of 1st quarter 2018

The worldwide surge of cardiometabolic diseases is a daily concern for VALBIOTIS. The company portfolio includes 5 products under development, of which 4 are positioned for reducing risk factors of these diseases:

- **VALEDIA® – indicated in prediabetes, to reduce risk factors for developing type 2 diabetes.**
Following the convincing Phase I/II results validating safety for use and an initial proof of efficacy for the active ingredient in VALEDIA®, VALBIOTIS has initiated a Phase IIA to prove the efficacy of the active ingredient in a high dose in prediabetics. This Phase IIA trial should be concluded at the end of 2018. In addition, a significant effect of VALEDIA® on the gut microbiota has been demonstrated in murine models. These results were presented during the Keystone Symposium “Bioenergetics and Metabolic Disease” in January 2018.
- **VAL-63-NAFLD – indicated in non-alcoholic fatty liver (NAFL), to reduce risk factor for developing non-alcoholic steatohepatitis.**
The positive preclinical results for the VAL-63-NAFLD active ingredient on non-alcoholic hepatic steatosis, as well as the associated metabolic parameters, were presented at the annual congress of the International Diabetes Federation in Abu-Dhabi (UAE) on 5 December 2017.
- **LpD64 – indicated in overweight and obesity, to reduce risk factors for developing cardiometabolic diseases.**
The efficacy of LpD64 on fat mass gain in three preclinical models was confirmed in October 2017 and enabled validation of the proof of concept for LpD64. These results were presented to the scientific community during the Cell Symposium “Metabolic Disease Therapies” in San Diego, October 15th 2017. Lastly, preclinical results have demonstrated a significant effect of LpD64 on the gut microbiota. These data were presented at the Keystone Symposium “Manipulation of the Gut Microbiota for Metabolic Health” in March 2018. In humans, the recruitment of volunteers (obese subjects) for the Phase I/II clinical study is completed and results will be revealed at the second semester 2018.

- **VAL-070** – indicated in mild to moderate dyslipidemia (LDL cholesterol), to reduce risk factor for developing cardiovascular diseases.
The recruitment of volunteers (subjects with mild to moderate hypercholesterolemia and dyslipidaemia) for the Phase I/II clinical study is completed, and results are expected at half-year 2018.
- **VAL-630** – the fifth portfolio line from VALBIOTIS and a medical nutrition product designed for patients with NASH associated or not with 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/>

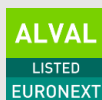


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