

VALBIOTIS succeeds in the industrial production of VALEDIA[®], a major scientific innovation for prediabetic people, in collaboration with the Pierre Fabre group

- **Confirmation of VALBIOTIS's capacity to produce VALEDIA[®] in compliance with North American and European industrial standards.**
- **A key stage in the health claim application for the two leading markets worldwide, North America and Europe.**
- **An accomplishment due to the combined expertise of VALBIOTIS and the Pierre Fabre Group, which specializes in the industrial manufacture of plant-based products.**

La Rochelle, 28 May 2019 (5:40 CEST) – VALBIOTIS FR0013254851 - ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **announces the successful industrial production of VALEDIA[®] (active substance TOTUM-63), the most advanced product in the VALBIOTIS portfolio. This achievement is the result of a collaboration with the Pierre Fabre group, a world-renowned expert in the industrial production of plant-based active substances.**



Since securing industrial property rights in Europe and the United States, VALBIOTIS has made another major breakthrough by demonstrating its capacity to produce VALEDIA[®] industrially, and in accordance with the regulations governing these two markets.



“ The industrial production of VALEDIA[®] has come at the best possible time for VALBIOTIS, after obtaining strong preclinical and clinical results and securing the industrial property rights, in the lead-up to the publication of our Phase IIA clinical results. This is an important milestone, thus completing our health claim application and supporting our negotiations with a partner company to market the product in 2021. This development confirms the sustainability of our project to market plant-based products which target the causal mechanisms of metabolic diseases. To achieve this, we are following the regulatory process for dietary supplements with a health claim, while maintaining almost pharmaceutical-grade development standards.”

Sébastien PELTIER
CEO of VALBIOTIS

VALEDIA® will be the first of a new class of products, aiming to prevent and combat metabolic diseases.

INDUSTRIAL BATCHES FOR FUTURE STUDIES

VALBIOTIS is currently developing VALEDIA® for two labels: prediabetes and hepatic steatosis. The results of the Phase IIA clinical trial for prediabetes are expected by 31 July, 2019. They will be followed in the second half of the year by the launch of the European Phase IIB clinical study (REVERSE-IT) and the Phase IIB study (PREVENT-IT) in North America. The data from these studies will be used to submit the application to European and North American regulatory authorities, for a health claim to reduce the risk of type 2 diabetes, with a view to marketing the product in 2021.



“ The success of this industrial production means we can progress to the next stages of clinical development with complete confidence. The new production capacities established with the Pierre Fabre group will be used in our two upcoming confirmation studies. This collaboration has enabled VALBIOTIS to benefit from leading expertise in the production of plant-based active substances, from extraction to standardization, ensuring that these results can be reproduced with both large and small quantities.”

Murielle CAZAUBIEL
Director of Development and Medical Affairs

“ In 2015, we put our expertise in extracting plant-based active substances at the service of VALBIOTIS and accompanied them in their development. We produce 3 plant extracts that make up VALEDIA® at our Gaillac (Tarn) extraction site. Today, we are happy to accompany them in this industrial transposition by manufacturing the capsules on our Cahors (Gers) production site specialized in phytotherapy and aromatherapy”.

François MACAREZ
Business Developer at Pierre Fabre Médicament

ABOUT TOTUM-63, THE ACTIVE SUBSTANCE OF VALEDIA®

Prediabetes is a growing public health issue worldwide that has been acknowledged by international organizations. Without appropriate management, 70% to 90% of prediabetic subjects will develop type 2 diabetes.

VALEDIA® intend to be the first natural and clinically proven solution specifically designed for prediabetics. VALEDIA® contains the active substance TOTUM-63, a unique and patented combination of 5 plant extracts, with high potential to target the physiopathological mechanisms of type 2 diabetes.

The launch of VALEDIA® is planned for 2021, with a health claim for reducing the risk of type 2 diabetes.

TOTUM-63 has already been proven safe and effective in healthy human volunteers during a Phase I/II clinical study. The results of the first international Phase IIA study are expected before 31 July 2019.

ABOUT VALBIOTIS

VALBIOTIS is a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases. Its products are made for major players in the healthcare sector. 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. These partnerships have enabled VALBIOTIS to benefit from strong financial leverage, particularly thanks to experts and technical partners who support its projects. The company is located at 3 sites in France - Périgny, La Rochelle (17) and Riom (63) - in addition to an american office in Boston (MA).

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).

VALBIOTIS is PEA/SME eligible.

Find out more about VALBIOTIS:

www.valbiotis.com



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



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Disclaimer

This press release contains forward-looking statements concerning the objectives of VALBIOTIS. VALBIOTIS considers that these projections are based on information currently available by VALBIOTIS and on reasonable assumptions.

However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of VALBIOTIS filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number I.17-012 on April 5, 2017 as well as in its 2018 annual financial report filed with the French Financial Markets Authority on March 8, 2019. These documents are available on the Company's website (www.valbiotis.com).

VALBIOTIS declines all responsibility for updating or revising these forward-looking statements. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, VALBIOTIS shares in any country.

