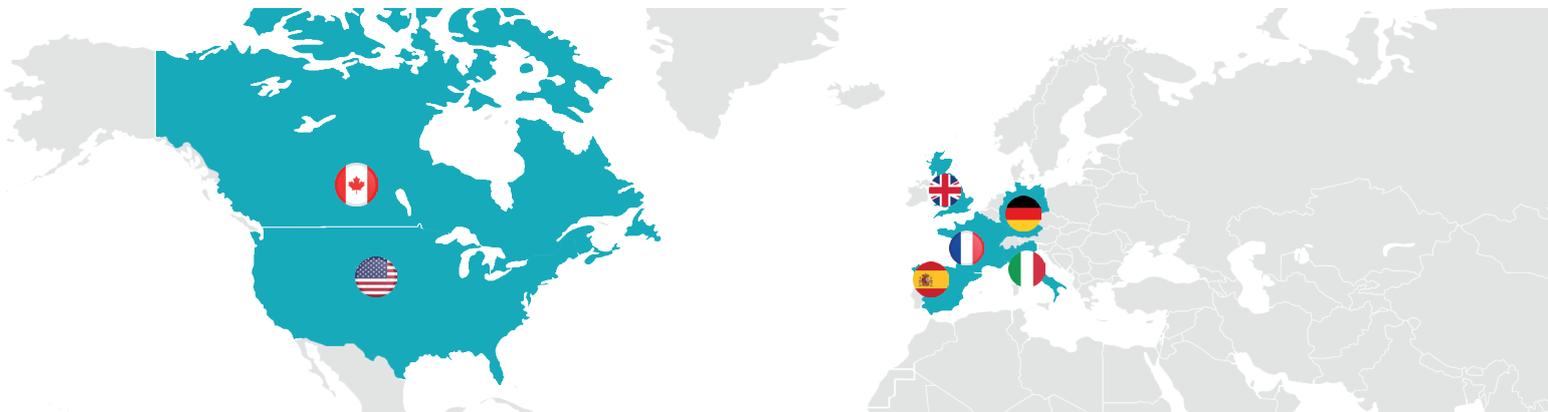


VALBIOTIS reports exclusive data on the prediabetes market: a considerable potential for VALEDIA®

- In 2018: 134 million prediabetics in the United States, Canada and in the 5 leading European countries¹
- In these 7 countries, a market value of €600 million in 2018 and expected to reach €1.8 billion in 2027¹
- An average current diagnosis rate of 10%, expected to be 13% in 2027 in these areas¹
- In the United States, health care expenditure related to prediabetes has already been evaluated at \$44 billion in 2012²

La Rochelle, 11 March 2019 (7:35 CET) – VALBIOTIS (FR0013254851 - ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, today reported exclusive data on the prediabetes market, arising from a study conducted by AEC Partners in the United States, Canada and in 5 leading European countries (Germany, United Kingdom, France, Spain and Italy).



Josep INFESTA
Head of Global Business Development³

“ This exclusive market study conducted by AEC Partners clearly presents a sizable market and demonstrates the value of the VALBIOTIS project. This is an exceptional opportunity: to market the first product with a strong health claim applicable to a population of more than 130 million prediabetics in North American and 5 European countries. By 2027, this market could grow threefold to €1.8 billion, driven by the increasing prevalence of prediabetes, the continuous progression of screening (13% expected in 2027, against 10% in 2018), the development of prevention programs and the growth of the market of prediabetes healthcare products.

VALEDIA® could lead this market, with a prediabetes indication and unequivocal clinical proof of efficacy in this population. These data confirm the validity of VALBIOTIS’s strategic priorities in North America and Europe. And the potential in the rest of the world - 90% of the world’s population - remains huge.” Explains Josep INFESTA, HGBD of VALBIOTIS.

Type 2 diabetes has become a global epidemic: the number of diabetics has increased by 50% between 2009 and 2017⁴, reaching 425 million people affected (8.8% of the adult population)⁵. By 2045, this number will rise to 630 million worldwide (9.9% of the adult population).⁵

This disease could be avoided. Type 2 diabetes is preceded by a high-risk clinical stage, precursor to the disease, known as prediabetes. **Sometimes known as “intermediate hyperglycemia” or “dysglycemia”, prediabetes has been defined by international organizations^{6,7,8} as an intermediate reversible stage, recognized in the 7 countries studied.** Screening is based on simple blood tests, that can be performed in routine medical practice (ie. measurement of fasting blood glucose, oral glucose tolerance test, glycated hemoglobin levels). At this stage, an effective intervention can prompt a return to a normal physiological state or, at least, delay the onset of the disease.

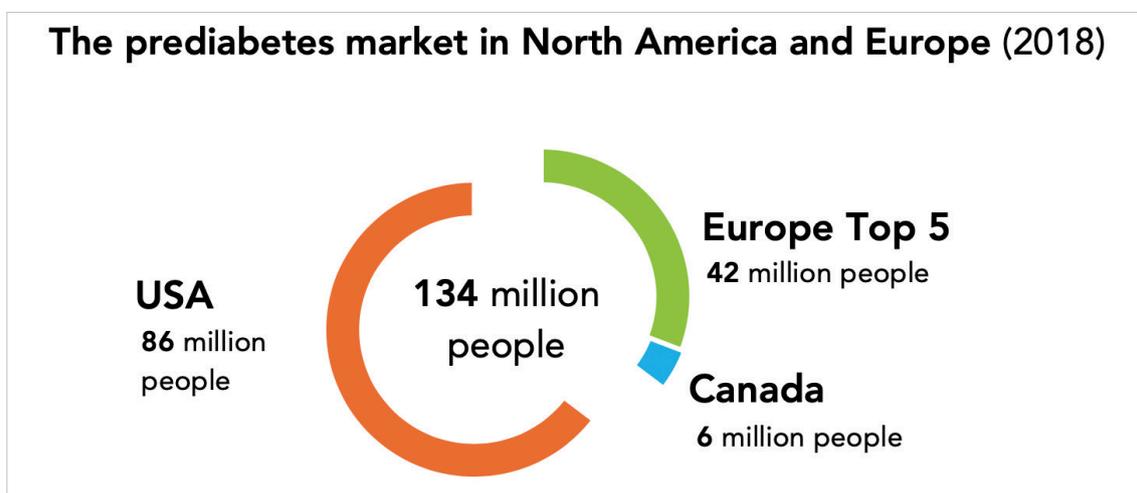
Prediabetes: a fast-growing market

The study conducted by AEC Partners, a firm specializing in life sciences for market access, licensing and strategy consulting, details the size and maturity of the key VALBIOTIS markets today: the United States, Canada and the 5 leading European countries (Germany, Spain, France, Italy and United Kingdom). In these 7 countries, the prediabetes population was estimated in 2018 to be **134 million people**, of whom 10% have already been diagnosed. The majority of the diagnosed population is American (more than 10 million in 2018, 12% of the American prediabetic population).

In the United States, the diagnosis rate has increased in recent years thanks to the mobilization of federal authorities, led by, among others, the *Center for Disease Control and Prevention*⁹. **For example, the *American Diabetes Association* recommends to screen anyone over the age of 45 or with a BMI greater than 25 kg/m² with at least one additional risk factor, for prediabetes.**⁶

In Europe, Germany and United Kingdom are particularly affected by this condition, with 14 and 12 million people being prediabetics, respectively.

A profile of the prediabetic individual has been established: over the age of 45 years, overweight, sedentary, but with no gender or ethnicity dimension.



The prediabetes market has been valued at an estimated **€600 million** in 2018 in the 7 countries studied. In 2027, with the increasing prevalence of prediabetes, a continuous increase in the diagnosis rate (**13% in 2027 against 10% in 2018**) thanks to the efforts of health authorities, the development of both prevention programs and the market of products dedicated to prediabetes, the prediabetes market could grow threefold and exceed **€1.8 billion**.

In the United States, a developing care pathway and a need for products specifically adapted to prediabetes

The AEC Partners study of the American market reveals that the management of diagnosed prediabetes is being built around health care professionals. National diabetes prevention programs focused on lifestyle changes (diet and physical activity) exist and are validated by the American health authorities. They are eligible for reimbursement by Medicare (up to €670 per followed program) and certain insurance plans. In 2012, health care expenditure related to prediabetes in the United States was already estimated at \$44 billion². Spending related to diabetes represented \$327 billion in 2017¹⁰.

The study emphasizes the prescription of an anti-diabetic drug, metformin. This prescription, off-label, remains infrequent (0.7% to 3.7% of cases^{11,12}) nonetheless representing \$170 million in annual sales. From the prediabetic consumer perspective, there is a real reluctance to use a drug without being diabetic and a preference for more natural solutions, including lifestyle changes¹³.

Furthermore, the American market for dietary supplements that may be used for prediabetes is growing and currently houses several products. None of these products benefits from a health claim acknowledged by health authorities, to reduce the risk of type 2 diabetes in the prediabetic population.

Emerging management in Europe, following the example of the United States

In Europe, prediabetes management has reached various levels of maturity depending on the country, but includes the same elements as in the United States: screening, prevention and lifestyle-dietary programs, dietary supplements and metformine. This “prediabetic journey” is currently being developed according to the same principles as in the United States.

European efforts are expected to intensify over the upcoming years, as in the United States, in light of the major health and economic challenges facing the authorities and affected populations. **Ultimately, the European market is expected to match the American market in terms of both size and maturity.**

¹AEC Partners data on key VALBIOTIS markets: the United States, Canada and the 5 primary European countries (Germany, United Kingdom, France, Spain and Italy), 2019.

²Dall TM, Yang W, Halder P, et al. The economic burden of elevated blood glucose levels in 2012: diagnosed and undiagnosed diabetes, gestational diabetes mellitus, and prediabetes. *Diabetes Care*, 2014.

³Outside consultant IZ3 Consulting

⁴Diabetes Atlas, 8th edition, International Diabetes Federation, 2018, p. 44.

⁵Ibid, p. 41.

⁶American Diabetes Association, Standards of Medical Care in Diabetes—2019, *Diabetes Care* 2019, S17.

⁷Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: Diagnosis and classification of diabetes mellitus, World Health Organization, 1999, pp. 14-15.

⁸Diabetes Atlas, 8th edition, International Diabetes Federation, 2018, p. 21.

⁹www.cdc.gov/diabetes/prevention/index.html

¹⁰American Diabetes Association, Economic Costs of Diabetes in the U.S. in 2017, *Diabetes Care* 2018

¹¹Metformin Use in Prediabetes Among U.S. Adults, 2005-2012; *Diabetes Care* 2017 Jul; 40(7):887-893.

¹²Metformin Prescription for Insured Adults With Prediabetes From 2010 to 2012: A Retrospective Cohort Study. *Annals of Internal Medicine*, April 2015.

¹³Patient Perceptions About Prediabetes and Preferences for Diabetes Prevention. *Diabetes Educ.* 2016.

¹⁴Phase I clinical trial to evaluate TOTUM-63, a botanical complex for managing prediabetes, Sirvent P. et al., Poster, American Diabetes Association, June 2016. Consultable sur www.valbiotis.com

VALEDIA®: a unique value proposition for an unmet need on the prediabetes market

All of these elements justify the value proposition of VALEDIA®, which will be launched on the market in 2021. VALEDIA® will represent a new approach, based on plants, that meets the expectations of prediabetics.

VALEDIA® will be backed by unequivocal clinical proof of efficacy in terms of reducing type 2 diabetes risk factors, based on studies conducted on prediabetics. This standard of proof will be supported by an exclusive health claim to reduce the risk of type 2 diabetes issued by the FDA, EFSA and Health Canada – a first and a real guarantee for people with prediabetes.

About TOTUM-63, the main active ingredient of VALEDIA®

TOTUM-63 is composed of a specific and patented combination of 5 plant extracts selected for their effects on metabolism. It acts on several targets involved in the physiopathology of type 2 diabetes in order to reduce the clinical risk factors of the disease. TOTUM-63 was developed to challenge perceptions of the prediabetes management and help protect the health of prediabetic patients.

TOTUM-63 has already been proven safe and effective in humans through a Phase I/II clinical study¹⁴. The results of a first Phase II European study are expected for Summer 2019, regarding the reduction of one or several risk factors for type 2 diabetes.

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.

