

# Voluntis announces its new strategic roadmap

- Strategic prioritization of the oncology business.
- Signature of a major agreement with Bristol-Myers Squibb to develop digital therapeutics based on the Theraxium Oncology platform.
- Significant contribution of the new oncology collaborations to revenues as of 2020.
- Reorientation of the diabetes business towards a new partnership strategy and discontinuation of direct commercialization.
- Reduction of operational expenses and update of the objectives communicated by the Group in line with the new roadmap.

**Cambridge, MA, and Paris, France - March 4, 2020** – Voluntis (Euronext Paris, Ticker: VTX - ISIN: FR0004183960) announces today its new strategic roadmap.

Pierre Leurent, CEO of the Voluntis Group (« Voluntis » or « the Group »): "We recently executed major new partnerships that reinforce Voluntis' lead in the field of digital therapeutics, with one of the largest portfolios of pharmaceutical collaborations. Our commercial momentum in oncology demonstrates both the relevance of our approach and the unique profile of the Group's assets. With regard to diabetes, we are suspending investments linked to direct commercialization in the United States, as their profitability horizon proves to be too distant in view of the Group's objective of financial break-even. However, Voluntis' diabetes solutions address significant unmet needs and we aim to execute new commercial partnerships that can fully exploit the potential of these assets. The primary focus on the oncology business, the renewal of the partnership approach in diabetes and the adaptation of the cost structure are the key levers of Voluntis' path to profitable growth".

## Strong commercial traction of the oncology business with new major collaborations

Voluntis recently inked two new partnerships related to its Theraxium Oncology platform with Novartis and Bristol-Myers Squibb<sup>1</sup>. In addition to these new collaborations, which complement the existing partnership with AstraZeneca, Voluntis is in discussion with several other pharmaceutical companies to improve patients' experience with many types of cancer treatments.

These commercial successes confirm, in the Group's opinion, the unique value of the Theraxium Oncology platform to accelerate the development of digital therapeutics. Indeed, the platform integrates a standard library of clinical algorithms, which can be customized with specific modules to accelerate the design, development and validation of these algorithms. Theraxium Oncology also includes modules for optimizing the ergonomics of applications, analyzing data collected from patients and operating digital therapeutics.

The new commercial partnerships signed by the Group will generate upfront and, as the case may be, milestones payments, and, in the case of a commercial rollout, annual payments linked to the number of users. These collaborations will have a significant contribution to the Group's revenues as of 2020.

<sup>&</sup>lt;sup>1</sup> Please refer to the news released today by Bristol-Myers Squibb and Voluntis

# Strategic Prioritization of the Oncology business

#### The Group's offer is perfectly adapted to the new models of cancer care.

Cancer remains one of the leading causes of death worldwide: every year, more than 14 million cancers are diagnosed<sup>2</sup>. The development of outpatient care and personalized medicine is leading to a rethinking of healthcare pathways. In addition, the symptoms associated with the disease and its treatments affect nearly 90% of patients and alter their quality of life. This can result in temporary or permanent treatment interruptions and unplanned hospitalizations. Improving the management of these symptoms is a priority in terms of clinical practice and cost optimization for healthcare teams.

Voluntis' digital therapeutics are in line with these market trends and are designed to address these challenges. They contribute to improving care by supporting personalized symptom management at home, thanks to recommendations automated by intelligent clinical algorithms. These digital therapeutics enable a collaborative approach between patient and healthcare team thanks to remote monitoring and identification of situations requiring the intervention of healthcare professionals.

Oleena, Voluntis' proprietary multi-cancer digital therapy, which targets a wide range of cancerrelated symptoms, uses the technological foundation of Theraxium Oncology. The Group plans to make Oleena available to several cancer centers in the U.S. in the first half of 2020 to generate new real-world data and reinforce its experience with integration into clinical workflows.

The Group is now prioritizing its oncology business with a view to asserting its position in this sector with high growth potential.

### Reorientation of the diabetes business towards a new partnership strategy

#### Discontinuation of investment in direct commercialization in the United States

For direct distribution of Insulia in the United States, the introduction of reimbursement schemes in January 2019 by the Center for Medicare and Medicaid Services has been a key success factor. In the second half of 2019, the Group started contracting with healthcare providers by leveraging this new framework.

However, the effective implementation of these reimbursement schemes within medical practices, which has significant operating costs, takes longer than the Group initially anticipated. Given the more distant horizon than expected for return on investment of this approach, which

undermines its financial sustainability, the Group has decided to suspend all investments related to direct commercialization in the United States of its products in the field of diabetes. These investments represent approximately 15% of the Group's operating expenses.

In this context, the Group also decided to postpone the additional developments required by the Food and Drug Administration's feedbacks on the version of Insulia adapted to insulin NPH during the process of application of this product in the United States. The Group reserves the right to file a new application of this version of the product at a later stage.

#### Evolution of the partnership with Sanofi

With regards to Insulia, the scope of the global distribution contract with Sanofi has been refocused on the French territory only, in line with Sanofi's new strategic directions in diabetes. The partnership related to Diabeo, a solution developed with Sanofi France and CERITD, will end in

<sup>&</sup>lt;sup>2</sup> <u>https://www.cancer.gov/about-cancer/understanding/statistics</u>

December 2020, in accordance with its contractual term. The results of the Telesage study, conducted in France, were also the subject of a first communication at the last ATTD congress in the form of abstracts.

#### Prioritizing a new partnership approach to roll out the Group's diabetes solutions at scale

The Group intends to establish new privileged partnerships to distribute its Insulia solution on a large scale, primarily in North America and Europe. The Group has already initiated new discussions to this end.

In the event of a new partnership, the Group may contemplate the development of a version of Insulia extended to patients treated with a combination of basal and bolus insulin, as well as integrating NPH insulins for the US market.

# Reduction of operational expenses and update of the objectives communicated by the Group in line with the new roadmap

In view of the priority allocation of resources to oncology and the projected operating loss for the 2019 financial year, which is of a similar order of magnitude to 2018, the Group is contemplating the implementation of a significant cost reduction plan in order to achieve its objective of financial break-even in 2021<sup>3</sup>. The information and consultation process starting with the work council in the coming days will enable the Group to present its proposals for achieving this objective.

Voluntis therefore confirms its objective of financial break-even (EBITDA) in 2021, for invoiced revenues in 2021 ranging between Euro 8 and 12 million and an annual cost base of the same order, following the prioritization of the oncology business and the adaptation of the cost structure.

#### **About Voluntis**

Voluntis creates digital therapeutics that empower people suffering from chronic conditions to selfmanage their treatment every day, thus improving real-world outcomes. Combining mobile and web apps, Voluntis' solutions deliver personalized recommendations to the patient and the care team so that they can, for example, adjust treatment dosage, manage side effects or monitor symptoms. These real-time recommendations are based on digitized clinical algorithms. Leveraging its Theraxium technology platform, Voluntis has designed and operates multiple digital therapeutics, especially in diabetes and oncology. Voluntis has long-standing partnerships with leading life science companies. Based out of Boston and Paris, France, Voluntis is a founding member of the Digital Therapeutics Alliance. For more information, please visit: www.voluntis.com

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<sup>&</sup>lt;sup>3</sup> See section 12.2 of Voluntis reference document registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.19-013 on April 26, 2019 (in French) (stating an objective of financial break-even (EBITDA) reached in 2021 on the basis of 2021 revenues of Euro 40 million).

#### Disclaimer

This press release contains certain forward-looking statements concerning Voluntis group and its business, including its prospects and product candidate development. Such forward-looking statements are based on assumptions that Voluntis considers to be reasonable. 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 Voluntis registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.19-013 on April 26, 2019 (a copy of which is available on www.voluntis.com) and to the development of economic conditions, financial markets and the markets in which Voluntis operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Voluntis or not currently considered material by Voluntis. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Voluntis to be materially different from such forward-looking statements. Voluntis expressly declines any obligation to update such forward-looking statements.