

## Launch of Dal Lab, Europe's first and only Med Tech for smoking cessation

- **Smoking, a major public health problem that kills 700,000 people a year in Europe.**
- **Existing smoking cessation solutions are inadequate to meet needs.**
- **Dal Lab is developing the first and only electronic nicotine substitute that delivers a high dose of nicotine and will be sold exclusively in pharmacies.**
- **A potential pharmacy market worth an estimated €1 to 1.5 billion in Europe.**

**Dal Lab**, a medical device technology company specialised in smoking cessation, has announced it will be launching in France with the ultimate goal of serving the whole of Europe and the UK.

Dal Lab was created in 2019 by Alexandre Lenormand, David Martin Diaz and Léon Chen, all three entrepreneurs from the world of e-cigarettes.

Given the issues arising from tobacco use and the needs that smoking cessation solutions have so far failed to address, Dal Lab, the Med Tech specialised in smoking cessation, has set itself the task of developing and marketing the first ever high-dose electronic nicotine substitute, available exclusively in pharmacies on the pharmacist's advice or on prescription, and delivering nicotine replacement without requiring smokers to change their habitual behaviour; a combination that increases the success of smoking cessation and therefore reduces tobacco-related morbidity/mortality.

To achieve its goals, Dal Lab has enlisted the help of an eminent Scientific Committee and well-known leading experts, who are supporting it through the various phases of its development.

### Smoking, a major public health problem

Nearly **30%** of Europeans are smokers. Smoking is responsible for **700,000 deaths** a year in Europe. On average, every year, a third of smokers try to quit. Unfortunately, the majority fail, and most smokers have to try several times before stopping for good. Only 7% of smokers who have tried to quit have managed to stop for 6 to 12 months.

"I'm delighted that new options are becoming available in the fight against smoking. I agreed to advise Dal Lab on how to improve smoking cessation success in smokers who wish to quit. What they are doing is remarkable, and I'm sure that the long pharmaceutical approval process they have embarked upon will culminate in success for the millions of smokers who wish to wean themselves off tobacco under medical supervision," says Prof. Philippe Maincent, Professor Emeritus of Biopharmacy at the Nancy School of Pharmacy, former vice-president of the French Marketing Authorisation Commission (ANSM, Paris), and member of Dal Lab's Scientific Committee.

### **Existing smoking cessation solutions are inadequate to meet needs**

Smoking is a complex behaviour, every aspect of which must be considered in the cessation process. Smokers who are trying to quit must deal not only with the pharmacological aspect of nicotine dependence, but also with the psychological (cognitive, social and behavioural) factors associated with tobacco addiction. In fact, smoking entails far more than the addictive effect of nicotine; it is also a set of rituals that every smoker associates with their habit, including body language and postures. When the smoker stops smoking, the need for these rituals continues and is a major cause of relapse.

On the other hand, high doses of nicotine coupled with prolonged treatment (> 14 weeks) are a useful strategy for highly dependent smokers.<sup>(1)</sup>

The nicotine substitutes currently available in pharmacies increase the chances of smokers who are determined to quit, but they lack medium- and long-term efficacy, especially in real-world conditions. The nicotine patch is the most widely used treatment, but it is not very effective in heavy smokers ( $\geq 20$  cigarettes/day).

"The randomized study published by Peter Hajek et al (2019) in the famous New England Journal of Medicine (NEJM) compared e-cigarettes to other nicotine substitutes. The results of this study showed that e-cigarettes were more effective, with the rate of smoking abstinence at one year nearly twice as high in vapers than in those using nicotine replacement therapy. Why? Most likely because e-cigarettes not only address nicotine dependence, but also the psychological factors associated with smoking dependence. Unlike nicotine substitutes, it can replace some of the rituals associated with smoking," says Prof. Daniel Marzin, Emeritus Professor of Toxicology at the Lille School of Pharmacy and member of Dal Lab's Scientific Committee.

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The British Medicines and Healthcare Products Regulatory Agency (MHRA) encourages e-cigarettes to be licensed as medicines and wants to help companies apply for marketing authorisations (MAs) for these products.

In a report published in May 2021, the European Commission acknowledged that e-cigarettes are effective aids to smoking cessation and that, as such, they should be regulated in the same way as pharmaceutical products.

In France, the National Institute for Health Prevention and Education (INPES) recognises that using e-cigarettes reduces smoking by 8.9 cigarettes per day on average.

The National Academy of Medicine, meanwhile, points out that e-cigarettes – which are less dangerous than cigarettes – help to reduce and stop tobacco consumption, and that 700,000 smokers have already quit thanks to them.

To address the still unmet medical needs involved in smoking cessation, Dal Lab is developing its electronic nicotine substitute in line with the strict quality and efficacy standards required for medicines.

It carried out pharmacological and toxicological tests on its electronic nicotine substitute in 2021.

Studies on the stability of the nicotine solution and the development of the administration device (e-cigarette) are currently in progress, with a view to obtaining CE marking. Pharmacokinetic studies in humans will soon be carried out, demonstrating that the new product is an effective nicotine substitute and enabling Dal Lab to apply for marketing authorisation in Europe and the UK within the next three years.

**A potential pharmacy market worth an estimated €1 billion to €1.5 billion in Europe**

The European market for smoking cessation aids, including e-cigarettes, is expected to be worth US\$18.63 billion by 2028, compared with US\$7 billion in 2021; it is expected to grow by 14.8% per year from 2021 to 2028. <sup>(2)</sup> E-cigarettes account for just over 50% of this market<sup>(3)</sup>.

“Pharmacy sales of our electronic nicotine substitute could initially reach €1 to 1.5 billion in Europe,” says David Martin Diaz, co-founder and COO of Dal Lab.

**Dal Lab raised €915,000 in 2020 from private equity.**

**It plans to raise around €3 million from private and public funds in 2022 to finance its development.**

See this press release on our website at <https://www.dal-lab.tech/communiqués-de-presse/>

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