



## Klaria Pharma initiates clinical program for Naloxone Alginate Film to prevent opioid overdose

**Klaria Pharma Holding AB (publ) announces that the Naloxone Alginate Film has entered into clinical phase of development. GMP production of the product has been initiated and the first clinical studies developing Naloxone Alginate Film as a co-prescription to opioids for patients at high risk of opioid use disorder. Klaria estimates the total addressable market for co-prescription of naloxone is worth 1.9 billion USD in the United States alone.**

“After having secured a financing round of 27 MSEK, we are now expanding Klaria’s operations and launching the clinical program for Naloxone Alginate Film to prevent opioid overdose. The US Department of Health and Human Services (HHS) views co-prescription of naloxone with opioid based pharmaceuticals as a prioritized area to reduce the risk of opioid overdose. Today, however, Naloxone is only being co-prescribed in a few percent of all cases, as the nasal sprays available on the market are not fit for purpose while also being too expensive, bulky and burdened with other disadvantages. Naloxone Alginate Film addresses these challenges,” says Klaria’s CEO Jesper Wiklund.

“We are planning to apply for market approval in Europe and the United States in 2023. We see a substantial value in this clinical program and expect a significant interest from healthcare authorities and pharmaceutical companies that are eager to reduce the number of human tragedies as well as the substantial societal costs associated with the use misuse of opioid-based pharmaceuticals,” says Jesper Wiklund.

With today’s announcement, Klaria will initiate two clinical studies in the second half of 2020. The second study is a pivotal bioequivalence study with Sumatriptan Alginate Film for migraine which is financed by the EU Horizon 2020 program. Preparations for the initiation of this clinical study during the latter part of 2020 are proceeding according to plan.

### **Co-prescription of naloxone with opioid-based pharmaceuticals**

The United States and several other countries have been severely affected by addiction problems and overdoses associated with the use of opioid-based pharmaceuticals for pain. In 2018, 168 million prescriptions for these pharmaceuticals were dispensed in the United States. About half of all persons receiving these pharmaceuticals are at risk of complications, and US authorities recommend that co-administration with naloxone should be made in these cases. However, this is done in only a few percent of all relevant cases, despite the fact that the HHS views this as a high priority issue. This is partly due to the fact that the leading nasal spray offered today costs about 140 USD for two units. Nasal sprays are also bulky and take up a lot of space when kept in stock in large volumes at the pharmacies. Klaria expects to be able to offer Naloxone Alginate Film at around one sixth of the price of the leading nasal spray on the market, corresponding to an addressable market of 1.9 billion USD. At the same time, a package of Alginate films does not take up much more space than a stamp, making it possible to store the product in large volumes.

A presentation on the potential of Naloxon Alginate Film has been published on Klaria’s website, and can be reached via this link: [https://www2.klaria.com/wp-content/uploads/2020/06/Klaria-Naloxone-Intro\\_Summer-2020.pdf](https://www2.klaria.com/wp-content/uploads/2020/06/Klaria-Naloxone-Intro_Summer-2020.pdf)

**For more information, visit the Klaria Pharma Holding website [klaria.com](http://klaria.com) or contact:**

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### **This is Klaria Pharma Holding AB**

Klaria (Klaria Pharma Holding AB) is a Swedish listed pharmaceutical company that develops innovative, rapid-acting products. By combining patented technology of a film that attaches to the oral mucosa and well proven pharmaceuticals, the company has developed a drug distribution concept with many benefits and potential uses. Klaria is listed on Nasdaq First North Growth Markets under the short name KLAR. FNCA Sweden is Certified Advisor ([info@fnca.se](mailto:info@fnca.se), +46(0) 8-528 00 399) for Klaria Pharma Holding AB. For more information, see [www.klaria.com](http://www.klaria.com).