

Emplicure announces results from the exploratory clinical PK study of its drug candidate Empli03

Emplicure, the company that combines proprietary technology with tried and tested substances and ingredients to develop new consumer and pharmaceutical products, today announces top-line results from an exploratory pharmacokinetic study with Empli03 in healthy volunteers.

Empli03 is an oral buccal tablet containing the opioid buprenorphine for the treatment of moderate to severe chronic pain. Empli03 was well tolerated with no local irritation. However, the desired plasma concentrations did not reach the target profile for a controlled-release oral buccal tablet.

The objectives of this exploratory study were to examine the safety and tolerability of Empli03, and to analyze the plasma concentrations of buprenorphine. Twelve healthy volunteers were dosed with a single oral buccal tablet placed under the upper lip for six hours and blood samples were collected throughout the study. All healthy volunteers completed the study, and no local irritation was observed in the oral mucosa. The tablet was easy to keep in place and was well accepted by the volunteers.

“The pharmacokinetic results are somewhat disappointing but give us valuable information in the continued development of Empli03 for the treatment of moderate to severe chronic pain,” said Håkan Engqvist, CEO of Emplicure. “Our preliminary judgement is that the ceramic platform still is a potent tool for controlled release of buprenorphine. It is important to strike the right balance between the abuse-deterrent properties and the clinically effective release profiles.”

Pain is a major health issue globally and, in the US, as many as 20% of the population are estimated to suffer from chronic pain and to need long-term pain relief. Widespread moderate to severe pain is a problem that is associated with high costs for society and individual patients. Opioids are, and will continue to be, an important part of pain treatment.

Buprenorphine is approved to treat opioid use disorder and pain in major markets, including the US and EU. It is a partial agonist at the mu receptor, which results in a lower risk of respiratory depression compared with full agonists, such as oxycodone and fentanyl. The US Department of Health and Human Services recommends buprenorphine over full agonists for patients who suffer from pain and need treatment with opioids.

The safety profile of buprenorphine together with properties that limit abuse are important features that can contribute to a safer medical treatment of pain.

This information is information that Emplicure AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons above, on December 22, 2022 at 13:32 CET.



Emplicure develops new and innovative products by combining existing and approved active substances with advanced materials science within ceramic biomaterials. The product portfolio is focused on chronic pain and on abuse-deterrent formulations. The subsidiary Amplicon AB develops consumer products with oral nicotine as the first product. The share is listed on Nasdaq First North Growth Market (EMPLI). Read more at www.emplicure.com

For more information, please contact:

Håkan Engqvist
CEO
Phone: +46 (0)702 569 500
Email: hakan.engqvist@emplicure.com

Certified Adviser

Certified Adviser is Erik Penser Bank.



Emplique develops new and innovative products by combining existing and approved active substances with advanced materials science within ceramic biomaterials. The product portfolio is focused on chronic pain and on abuse-deterrent formulations. The subsidiary Amplicon AB develops consumer products with oral nicotine as the first product. The share is listed on Nasdaq First North Growth Market (EMPLI). Read more at www.emplicure.com