

Emplicure to advance Empli03 formulation to boost initial release profile

Emplicure has decided to move forward with formulation development to increase the initial release profile of buprenorphine in Empli03. The decision was taken after final results from the exploratory pharmacokinetic study showed a steady extended release profile.

Empli03 is an oral buccal tablet containing the opioid buprenorphine for the treatment of moderate to severe pain. The exploratory clinical PK study is the first to investigate delivery of buprenorphine under the lip and final results demonstrate an extended release profile.

"The results show that our ceramic platform is a potent tool for controlled release of buprenorphine," said Håkan Engqvist, CEO of Emplicure. "This gives us the confidence to advance formulation development to increase the initial release profile. We believe Empli03 can play an important role in the treatment of moderate to severe pain, and potentially opioid use disorder."

After further positioning and formulation, Emplicure intends to find a partner for early-stage co-development of Empli03.

About the study

The objectives of the exploratory study were to examine the safety and tolerability of Empli03, and to analyze 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. The tablet was easy to keep in place and was well-accepted.

Buprenorphine

Buprenorphine is approved to treat opioid use disorder and pain in major markets, including the US and EU. The safety profile of buprenorphine together with properties that limit abuse are important features that can contribute to safer medical treatment of pain..

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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