

EMPLICURE'S APPLICATION OF A CLINICAL PK STUDY OF EMPLI03 HAS BEEN APPROVED

The UK authorities have approved Emplicure's application to conduct a clinical pharmacokinetic study of Empli03, a drug candidate for chronic pain.

The purpose of the study is to document the safety profile and pharmacokinetic properties of Empli03 in humans. Empli03 is an oral buccal tablet containing the opioid buprenorphine. The tablet can be placed under the upper lip to achieve stable pain relief using a controlled release of buprenorphine. The risk of serious side effects if the user swallows the tablet is low due to buprenorphine being broken down and inactivated in the upper part of the intestine. Empli03 also has properties that make abuse more difficult.

Chronic pain is a growing health problem globally and in the United States, as many as 20 percent of the population is estimated to suffer from chronic pain and be in need of long-term pain relief. Widespread chronic pain is a problem associated with high costs for society and individual patients. Opioids are, and will continue to be, an important class of treatments for moderate to severe chronic pain.

The results from this first clinical study will provide valuable information for the next step in the development of Empli03 and are also important for Emplior as a platform. The company's CRO Quotient Sciences, is now starting recruitment and screening of the subjects to be included in the study, a total of twelve healthy volunteers. The subjects are dosed with one tablet and the concentration in blood of the active substance will be measured. Initial results will be available towards the end of the year.

"With this positive news, Emplicure is driving the clinical development of Empli03 further. It is an important milestone on our journey forward and I am proud of the focused and hard work that has made this possible." says CEO Torbjörn Walker Larsson.

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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. Wholly owned 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