Klaria Pharma receives approval to initiate clinical Phase 1 trial of Naloxone Alginate Film

UPPSALA, 2 December, 2021. Klaria Pharma AB (Nasdaq Stockholm: KLAR) announces today that is has received approval from the regulatory authorities in the United Kingdom (MHRA) to carry out a clinical Phase 1 study with Naloxone Alginate Film, a new treatment of opioid overdose. With a more patient friendly formulation that is being specifically developed to meet the needs of patients and caregivers today, Naloxone Alginate Film has the potential to be significantly superior to all Naloxone nasal sprays currently in use.

Naloxone Alginate Film is addressing a market with significant unmet medical needs. This is especially true in the United State where in 2019 there were 168 million prescriptions written for opioids and where more than 50.000 deaths from opioid overdose occurred. Opioid overdose continues to be a significant medical and humanitarian challenge, with a steadily increasing number of deaths every year. To help address this issue, the Biden Administration has officially recommended an increase in so called co-prescription, whereby a Naloxone product will be prescribed together with an opioid.

Klaria Pharma is developing Naloxone Alginate Film specifically for co-prescription with opioids. This is a very large commercial opportunity due to the large number of opioid prescriptions. For example, a share of 5% of the addressable market for opioid co-prescription would translate into annual sales for Naloxone Alginate Film in excess of USD 1 billion per year. Naloxone Alginate Film is protected in the United States by approved patents until 2038, as communicated in a Klaria Pharma press release dated 22 October, 2021.

The aim of the planned Phase I study is to evaluate the pharmacokinetic effects and the safety profile of Naloxone Alginate Film. Klaria Pharma will conduct the study in collaboration with an experienced clinical research organization based in the United Kingdom that has extensive expertise in clinical studies.

“The regulatory go-ahead to start the Phase 1 study with Naloxone Alginate Film constitutes an important step forward for Klaria Pharma. This is the company’s second clinical program. We now broaden our clinical pipeline and continue our mission of developing products addressing high unmet medical needs using our proprietary, patented technology platform. The goal of the Naloxone Alginate Film program is to bring to market a novel and superior solution for the administration of Naloxone to aid all those who are currently suffering through the devastating suffering and death

brought by opioid overdose” said Scott Boyer, CSO, Klaria Pharma.

About Naloxon Alginate Film (KL-00514)

KL-00514 is an alginate-based oral trans-mucosal film. KL-00514 is the first oral trans-mucosal opiate overdose product and is designed to be a significant improvement to all available acute nasal spray treatments available to patients today, particularly in the co-prescription market. KL-00514 is a unique molecular dispersion of naloxone. The KL-00514 film presents naloxone to the oral mucosal surface in a unique way to allow rapid, consistent absorption superior to that of present nasal spray-based products. The base film-forming alginate and the naloxone-containing films have been the subject of comprehensive intellectual property protection, thus ensuring prolonged market exclusivity.

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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, +46(0) 8-528 00 399) for Klaria Pharma Holding AB. For more information, see www.klaria.com.