

PRESS RELEASE

Stockholm, 31 August 2017

Karessa has today submitted an application for clinical trial for project K-03 to the Medical Products Agency

Karessa Pharma Holding AB announces today that an application for a clinical trial with Vardenafil within the project K-03 has been submitted to the Swedish Medical Products Agency.

The study is a Phase I, open, randomized, single-center study on healthy male subjects in order to determine the PK profile in the body (pharmacokinetic profile) of Vardenafil given as K-03/1 buccal film. The study consists of comparing the PK profile of four different variants of K-03/1 buccal film. Except for the evaluating of PK profile, the safety and tolerability of Karessa's K-03/1 buccal film will also be investigated. The study comprises a total of 16 male volunteers and is scheduled to start and complete during the fourth quarter 2017.

Karessa Pharma's pharmaceutical project K-03 is based on the drug molecule Vardenafil and is a so called phosphodiesterase type 5 inhibitor. Vardenafil is a well-proven molecule for treatment of erectile dysfunction and is the active substance in the impotence drug Levitra®. The sales of Levitra, owned by Bayer AG, amounted to approximately SEK 2.4 billion in 2015.

About Karessa's pharmaceutical projects for treatment of erectile dysfunction

Current treatment of impotence is well proven and has a favorable safety profile, but many patients are bothered by the delayed onset and that it may vary depending on food intake. These problems are a consequence of the drug being given as tablets and thus has to pass the stomach and liver before reaching the right place in the body. Karessa has developed a buccal film with the active substance Vardenafil (K-03). The film is small and is placed on the inside of the chin where it dissolves as the drug is delivered directly into the bloodstream via the oral mucosa. By this way the drug is delivered into the body and a quick and reliable onset is achieved. This completely regardless of whether you just have been eaten a good dinner.

Impotence affects many middle-aged men and has an increased prevalence of age. The global market for impotence drugs is estimated to a value of approximately SEK 40 billion.

This information is such information that Karessa Pharma Holding AB (publ) is obliged to disclose public according to the European Union's Market Abuse Regulation. The information was provided by the contact person below for publication on 31 August 2017, 14.00 CET.

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About Karessa Pharma Holding AB

Karessa develops new pharmaceuticals based on a patented drug delivery technology and proven pharmaceutical substances in order to offer men with impotence problems a fast and more reliable effect. Karessa is listed on Nasdaq First North and has Remium as Certified Advisor. For more information, please visit karessa.se