

PRESS RELEASE

Stockholm, 16 October 2017

Karessa Pharma Holding AB announces today that they have been approved by the Medical Products Agency to start a clinical study with K-03 Vardenafil buccal film

Karessa submitted an application to the Swedish Medical Products Agency on 31st of August to perform a Phase I study on healthy volunteers of male subjects. Today, the Medical Products Agency announced that they approved the application.

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 in November and be completed during 2017.

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 October 16, 09.30 CET.

FOR MORE INFORMATION, PLEASE CONTACT:

Michael Brobjer, CEO, Karessa Pharma Holding AB (publ)

Tel: +46 8-768 22 33

Email: michael.brobjer@karessa.se

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.

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 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 35 billion.

For more information, please visit karessa.se