

PRESS RELEASE

Stockholm, 12 October 2017

Update and status of Karessa Pharma's project K-03

Karessa Pharma Holding AB is working actively to operate the most advanced project, K-03 Vardenafil buccal film, through its various development phases as effectively as possible.

Status project K-03 Vardenafil buccal film

Karessa submitted an application for a clinical trial with K-03 Vardenafil buccal film to the Medical Products Agency on 31st of August, which the market has previously been informed of. The company has received questions from the Medical Products Agency that has been answered and an approval is expected to arrive in late October. The project is proceeding according to plan, with a great focus on ensuring that everything is ready in order to start the clinical trial. GMP manufacturing at our CMO, Recipharm, has been on schedule and the drugs for the trial are scheduled to be released in good time for the study. The study is scheduled to start the first week in November and be completed this year. According to the plan, the final report of the study will be reported early in Q2 2018.

Identification of potential partners are in progress. Karessa has today ongoing dialogues with a handful of companies about the K-03 project. During the autumn further activities will be taken to interest more companies for the project.

Provided that clinical data are positive, a pivotal study can start in the winter 2018/2019.

FOR MORE INFORMATION, PLEASE CONTACT:

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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.

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