



## **Peptonic Medical submits 510k application for VagiVital® in the US**

Stockholm, 25th February, 2020 – Peptonic Medical (publ) ("Peptonic" or "Company") today announced that it has submitted a so called 510k application to the US Food and Drug Administration (FDA) to obtain approval to market and sell VagiVital® in the USA.

*- USA is the single largest market for vaginal atrophy products in the world, and we believe that VagiVital® is well positioned to successfully enter the self-care market segment thanks to its unique clinical proof of efficacy and safety, and for its effective symptom relief, says Johan Inbarr, CEO of Peptonic Medical.*

The Company is now prepared to answer any questions or requests for complementing documents before the review process starts. Recently, FDA has switched to become 100 per cent digital, which has delayed the submission of the VagiVital® application.

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*This information is information that Peptonic Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 25th February 2020.*

### **About VagiVital®**

VagiVital® is a patent pending hormone free self-care product for the treatment of vaginal atrophy and vaginal dryness. The product has been tested in randomised clinical studies (vaginal atrophy) with very positive results both for objective (vaginal pH and proportion of superficial cells in the vaginal mucosa) and subjective (most bothersome symptoms, such as vaginal dryness, vaginal irritation/itching, dyspareunia and dysuria) parameters. The magnitude of symptom relief is on par with that demonstrated with e.g. prescription estrogen based products on the market today. It was very well tolerated and caused no serious adverse effects.

VagiVital® was launched in Sweden as a non-prescription self-care product in July 2018 (see [www.vagivital.com](http://www.vagivital.com)).

### **About Peptonic Medical**

Peptonic Medical is an innovative Swedish medical development company. Its vision is to offer safe and effective treatments and relief for women specific diseases and medical conditions.

VagiVital® is a registered trademark of Peptonic Medical. The product is hormone free and is being commercialised for the non-prescription use for the treatment of vaginal atrophy (VA) and vaginal dryness. The pipeline of Peptonic Medical also includes Vagitocin®, which is an oxytocin-based vaginal gel for the treatment of VA. This product candidate is in clinical development phase 2. The development of Vagitocin® is on hold pending additional data on i.a. the mechanism of action.

Since July 2014, the Peptonic Medical share has been traded on the Spotlight Stock Exchange ([www.spotlight.se](http://www.spotlight.se), ticker: PMED) in Stockholm, Sweden.

For more information: [www.peptonicmedical.com](http://www.peptonicmedical.com)