



Klaria Pharmaceuticals enters into Agreement with FluiMed GmbH to develop Sirolimus Alginate Film for prevention of Organ Transplant Rejection

Uppsala, 30 March, 2020. Sirolimus has an [immunosuppressant](#) function and is used to prevent the rejection of organs in Solid Organ Transplantation (SOT) procedures. However, both the efficacy and safety of Sirolimus varies greatly between individual patients. This variability is due to how the treatment is metabolized. An Alginate Film that delivers Sirolimus directly into the blood stream via the oral mucosa would not be subject to this variability. The result would be a treatment that would make life-saving Solid Organ Transplant procedures both less dangerous and more likely to succeed.

Formulating Sirolimus in Klaria's patented Alginate Film potentially offers a creative and innovative solution to one of the most important problems in transplantation medicine, "how to better prevent the rejection of transplanted organs". Klaria's technology could create a more precise treatment. Application of Sirolimus on the oral mucosa could abolish first-pass metabolism, enzymatic degradation during GI passage and food effect problems which translate into a higher and more predictable bioavailability of the API. This would result in reduced intra – and interpatient variability of Sirolimus which translates into a better safety profile of the drug and creates added value for the patient. Given that this is the most important issue today with Sirolimus treatment using available formulations, this has the potential to bring a dramatic improvement to the entire solid organ transplantation (SOT) area.

In the first stage of the collaboration, Klaria will conduct formulation development as well as pre-clinical development to create a drug candidate that is ready to undergo clinical testing in preparation for filing with both the EMA and the FDA. As part of the agreement, Klaria will receive upfront payments of ca SEK 10 million.

"A Sirolimus Alginate Film that would deliver a rapid and precise dose of Sirolimus across the oral mucosa would create a significant clinical added value in the SOT therapy. This would mark a significant innovation in transplantation medicine, and it would be an important step forward for transplantation patients world-wide." said Wolfgang Beier, Managing Partner of FluiMed GmbH.

Scott Boyer, CSO of Klaria added "The development of Sirolimus Alginate Film is perfectly in line with Klaria's strategy of developing treatments where our technology has the potential to solve important medical problems and in so doing, addressing high unmet medical needs. We also note that Nucleus Medicine identified our Alginate Film

Technology as being the one with the highest probability of successfully achieving oral transmucosal delivery and creating a product that meets the needs of transplantation patients. This shows us that our diligent work and success in developing various Alginate Films is acknowledged in the wider drug development community.”

For more information, visit the Klaria Pharma Holding website klaria.com or contact:

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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.