Press release November 8, 2019

AcuCort gives an update on the continued work concerning the bioequivalence study for US registration

AcuCort AB (Spotlight Stock Market: ACUC) gives further information on the results from the second bioequivalence study for a US registration, and reports on the efforts to establish the causes of non-achieved bioequivalence and to develop options for the continued work with registration and commercialization of the company's drug candidate ISICORT®.

AcuCort has previously reported positive results from the first of the two studies for registration in the US, and from the bioequivalence study on which the company's submitted application for marketing authorization in Sweden is based.

The present study was performed with non-fasting participants, comparing ISICORT® 6 mg fast-dissolving oral film with an already approved reference product, West-Ward Pharmaceuticals' Dexamethasone 6 mg tablets USP. The criteria for bioequivalence mean that the tested product should be within a certain range of the reference product's value for three parameters.

ISICORT® met the criteria for the two parameters that describe the total absorption of active substance in the study participants, AUC (Area Under the Curve). The third parameter, called Cmax, describes the maximum amount of active substance (Dexamethasone) measured in plasma. ISICORT® did not meet the Cmax requirement, as the value was lower than for the reference product. A further parameter called Tmax is not a requirement for bioequivalence but is regarded as an important parameter. It concerns the time it takes to reach the maximum amount of active substance in plasma. Tmax was reached later with ISICORT® than with the reference product. The study results demonstrate a stronger absorption impact related to food intake on ISICORT than on that of the reference product.

After the report of the results, AcuCort has appointed an expert group with competences in amongst others pharmacokinetics, clinical study design and gastroenterology. The group has the tasks to:

- Confirm the cause of the results.
- Present options for courses of action to enable continued registration and commercialization of ISICORT® on the US market.
- Evaluate the consequences of the various options.

The group has started its work. Possible causes for the results have been established and the work to confirm these is in progress.

On September 30, 2019 AcuCort announced that the company has filed an application for marketing authorization of ISICORT® with the Swedish Medical Products Agency. The Swedish application is based on approved results on bioequivalence in a study with fasting participants and another reference product than the one used in the study for a US application. Any possible consequences of the results of the US study will not be known until the Medical Products Agency submits questions to AcuCort, which is expected to happen in the first quarter 2020, at the earliest.

"AcuCort's objective to register and commercialize ISICORT® remains unchanged. We have great confidence in the expert group and will give status updates as their work progresses," says Mats Lindfors, CEO of AcuCort.

For further information, please contact

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About AcuCort AB

AcuCort develops and commercializes ISICORT®, a new fast-dissolving oral film to put on the tongue, based on a well-known cortisone substance containing – dexamethasone. ISICORT® is a smart product in a new, innovative, patented and user-friendly dosage form primarily for the treatment of severe and acute allergic reactions, croup in children and Chemotherapy-Induced Nausea and Vomiting (CINV). The bioequivalence study that forms the basis of the application for marketing approval in Europe was carried out with positive results and a national hybrid application has been submitted to the Swedish Medical Products Agency. Taken together, this strengthens the company's assessment that the time until commercialization of ISICORT® may be relatively short. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market in Sweden. Learn more at www.acucort.com.