

Iconovo's partner Amneal has taken the next important step in the clinical development of ICORES[®] budesonide/formoterol

Iconovo AB (publ), a leader in the development of inhalable drugs based on proprietary inhalers and dry powder formulations, today announces that the company's development partner Amneal Pharmaceuticals has completed a clinical pharmacokinetic pilot study comparing ICORES[®] budesonide/formoterol and Symbicort[®] Turbuhaler[®]. The results from the study indicate that ICORES[®] budesonide/formoterol will meet the criteria for demonstrating bioequivalence in an appropriately designed and powered study. The study represents an important step ahead of the initiation of a registration study of the product and Iconovo will proceed according to plan.

In this exploratory pharmacokinetic study, comparing two ICORES[®] budesonide/formoterol product variations with the reference product, Symbicort[®] Turbuhaler[®], the comparative bioavailability of all three products was shown to be very similar. Given this successful outcome, ICORES[®] budesonide/formoterol is expected to meet the strict criteria for demonstrating bioequivalence in an appropriately designed and powered study.

The study was conducted in 24 healthy individuals with a single-dose crossover design. In order to more effectively identify which formulation composition is needed to achieve bioequivalence in a registration study, two arms with different compositions were investigated. The different compositions in the ICORES[®] inhaler were compared with those of a control arm with Symbicort[®] Turbuhaler[®].

"We are pleased that our partner, the publicly listed U.S. pharmaceutical company Amneal Pharmaceuticals, has taken this important step forward in the clinical development of ICORES[®] budesonide/formoterol. The results from this study have provided the final piece of the puzzle to move forward with a pivotal study according to plan," says Iconovo's CEO, Johan Wäborg.

ICORES[®] budesonide/formoterol is based on Iconovo's innovative proprietary dry powder inhaler. It is being developed by Amneal Pharmaceuticals as a generic version of Symbicort[®] Turbuhaler[®], a well-established treatment for asthma and COPD. Symbicort[®] had sales of USD 2.4 billion in 2023 of which 60-70% is derived from the Turbuhaler inhaler. Amneal has in-licensed the global rights to ICORES[®] budesonide/formoterol, while Iconovo intends to market the product in the Nordic region. Iconovo's royalty on Amneal's sales of ICORES[®] budesonide/formoterol amounts to between 5 and 10 percent.

The clinical development of ICORES[®] budesonide/formoterol encompasses a number of pilot pharmacokinetic studies that are performed sequentially to optimize the product for a final registration study, a pivotal pharmacokinetic study, with the potential to demonstrate its equivalence to Symbicort[®] Turbuhaler[®]. When positive results have been achieved from such a pivotal pharmacokinetic study, the product can enter the regulatory approval process.

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About Iconovo

Iconovo (Nasdaq First North Growth Market: ICO) develops new inhaled medicinal products in collaboration with international pharmaceutical companies. The company provides several types of patent-protected inhalers that can generate significant commercial opportunities in the development of novel pharmaceuticals and vaccines and at patent expirations for established pharmaceuticals. The most advanced project is a generic version of the asthma and COPD product Symbicort® which is expected to reach the market in 2026. Iconovo plans to market this product in the Nordic region through its subsidiary Iconovo Pharma, while the company's partner Amneal Pharmaceuticals has the rights in other parts of Europe and the United States. Certified Adviser is Carnegie Investment Bank AB (publ).

This information is information that Iconovo is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-10-30 15:57 CET.

Attachments

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