

Iconovo announces completion of comparative clinical study of ICORES budesonide/formoterol and Symbicort Turbuhaler

Iconovo AB (publ), a company developing complete inhalation products for a global market, today announces that a clinical pilot pharmacokinetic study, comparing the pharmacokinetic profile of ICORES budesonide/formoterol and Symbicort® Turbuhaler®, has been successfully concluded. The study, which was carried out by Amneal Pharmaceuticals, has provided valuable data that supports continued development of ICORES budesonide/formoterol as a potential generic substitution of Symbicort® Turbuhaler® for the management of asthma and COPD.

ICORES is an innovative proprietary dry powder inhaler developed by Iconovo. ICORES budesonide/formoterol is being developed by Iconovo under a license agreement with Amneal Pharmaceuticals as a generic version of Symbicort Turbuhaler, a well-established treatment of asthma and COPD with sales of approx. USD 2.7 billion in 2020. Amneal has licensed the global rights to ICORES budesonide/formoterol, and Iconovo intends to market the product in the Nordics following a potential regulatory approval.

The clinical development of ICORES budesonide/formoterol contains a series of pilot pharmacokinetic studies. These studies are carried out sequentially, to optimize the product prior to a final registration study with statistical power to prove bioequivalence with Symbicort Turbuhaler.

In 2020, a first clinical pharmacokinetic study demonstrated that the ICORES dry powder inhaler functioned as intended when used in clinical practice. The objective of the second study, that has now been completed, was to further establish the in vivo and in vitro correlation of the pharmacokinetic properties of ICORES budesonide/formoterol compared to Symbicort Turbuhaler. Two batches of ICORES budesonide/formoterol and one batch of Symbicort Turbuhaler were investigated in a single-dose cross-over design in 30 healthy individuals.

The obtained relative bioavailability results support the continued development of ICORES budesonide/formoterol and provides valuable information that will be used to optimize the product for the next study. The development program is still on track to allow a filing for market approval in the EU during 2023, potentially allowing a product launch in 2024.

“We are pleased to have taken another important step forward in the development of ICORES budesonide/formoterol. Albeit the limited size of this pilot trial, the data gathered is very helpful in the process of optimizing the product. Iconovo is now looking forward to support Amneal in further progressing the development of ICORES budesonide/formoterol,” said Johan Wäborg, CEO Iconovo.

“The results from this pharmacokinetic study have given us valuable information on how to further optimize the product. Amneal is firmly committed to bringing this strategically important and complex generic product to the market as soon as possible. We look forward to completing development, collaborating closely with Iconovo, and ultimately making our product available for patients around the world,” said Gregory Sgammato, Head of Global Corporate Development at Amneal Pharmaceuticals, Inc.

Contacts

Johan Wäborg, CEO

+46 707 78 51 71

johan.waborg@iconovo.se

About Iconovo

Iconovo was founded in 2013 by people with long experience in inhalation development. The company develops inhalers and associated drug preparations that are used to treat asthma and COPD. However, Iconovo also has the competence to develop products for new types of inhaled drugs such as vaccines.

By working with Iconovo, pharmaceutical companies and generic companies can access a complete pharmaceutical product, thereby eliminating the complex and costly early stages of the development phase. Iconovo licenses its patented products to customers and offers a faster way to the inhalation market with lower risk and at a lower cost.

More information about the company can be found at www.iconovo.se.

Iconovo is based in Lund and its share (ticker ICO) is listed on Nasdaq First North Growth Market, Stockholm since April 6, 2018. The Company's Certified Adviser is Erik Penser Bank AB, Box 7405, SE-103 91 Stockholm, phone +46 8 463 80 00, email: certifiedadviser@penser.se.

Attachments

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