PRESS RELEASE
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Iconovo receives positive guidance from FDA regarding substitutability for ICOpre®

Iconovo AB (publ), which develops inhalation products for a global market, today announces that the US Food and Drug Administration (FDA) has issued a positive guidance regarding the generic substitutability of the company's proprietary inhaler ICOpre® with the original drug Breo Ellipta with respect to external design and operating principles.

The FDA's preliminary view is that ICOpre with its current external design attributes and operating principle is appropriate for submission in an Abbreviated New Drug Application (ANDA) for a generic Breo product. In addition, the FDA provides guidance regarding the configuration of the final ANDA to be able to provide substitutability.

The feedback from the FDA on the external design and operation and how a final application should be structured is important knowledge. It is also confirmation that the development is on the right track towards an approved generic variant of this well-established asthma and COPD drug.

"We are very pleased to have received this important guidance regarding ICOpre from the FDA. The FDA assesses that ICOpre with its current design can be used in an ANDA process in the US. This is another positive message that we will take with us in the negotiations. Advisory feedback from the FDA is an important competitive advantage in this situation," says Johan Wäborg, CEO of Iconovo.

The design of the inhaler ICOpre® has been successfully optimized during the summer based on previous guidance from the FDA and input from a comparative human factors study regarding the inhaler's user-friendliness. The statement from the FDA shows that ICOpre can be handled by patients in a way that is very similar to the original in a patient-safe manner, which is a prerequisite for getting an approval of the product through an *Abbreviated New Drug Application* (ANDA) and achieving generic substitutability, so-called AB rating.

The next step in the development of a generic Breo/Relvar in ICOpre® will be to conduct a pharmacokinetic study together with a partner company. The work of finding a partner company has taken more time than Iconovo initially estimated but continues with constructive negotiations and due diligence around all steps in the development towards a final product. Recently, an additional company of significant size has contacted us, which we must leverage in the best possible way in the process.

About ICOpre®
ICOpre® is a pre-filled multidose inhaler that can be adapted to any type of inhalation powder and offers the user convenience in line with the well-known Ellipta inhaler from GSK. ICOpre® can be loaded with up to three different drug substances for simultaneous inhalation. The inhaler has an accurate dose counter that shows how many doses remain. ICOpre® is based on a unique, patent-pending principle that minimizes the risk of infringement of other inhalers' intellectual property rights. Global sales of inhaled medicines in the Ellipta portfolio amounted to approximately USD 5 billion in 2023.

Currently, a global structured out-licensing process for ICOpre® is underway and is expected to be completed in 2024, which means good opportunities for ICOpre® to become the first challenger to Ellipta in both the EU and the US. The first opportunity for launch within the portfolio is expected to be for a generic version of Relvar in 2027.

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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 2025. 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).

Attachments

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