PRESS RELEASE
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Iconovo meets US Quality System regulation for medical devices

Iconovo AB (publ), that develops complete inhalation products for a global market today announces that the company's Quality Management System (QMS) has been upgraded to meet the US Quality System Regulation (QSR 21 CFR 820) for medical devices. The company's development and documentation process must comply with this FDA regulation to enable registration and marketing of medical device products in the US.

This achievement is a crucial step to obtain future US market access for all Iconovo drug device combination products including ICOres, ICOpre, ICOone and ICOcap.

In 2020, Iconovo's QMS became compliant with the international ISO 13485:2016 standard for medical devices. Thus, the QMS also complies with the EU Medical Device Regulation. This has enabled Iconovo to develop drug device combination products that will be ready for registration on the European market.

"Iconovo have global ambitions for our inhalation platforms and US is the biggest pharma market in the world. Compliance with the US regulations is a key component to advance existing projects and will unlock even more opportunity in our partnering and business development process," said Johan Wäborg, CEO for Iconovo.

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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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