

Iconovo signs agreement for development of inhaled oxytocin in ICOone for maternal health

Lund, December 21, 2020. Iconovo AB (publ) today announced that the company has signed a development agreement with Monash University for the development of inhaled oxytocin in ICOone®. The agreement verifies the suitability of ICOone for use with innovative pharmaceuticals. Monash University's Institute of Pharmaceutical Sciences (MIPS) is leading the development project supported by a research agreement with Janssen Pharmaceutica N.V., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, and ongoing support from long term partner GSK.

The agreement gives Monash an exclusive global right to use ICOone with oxytocin to prevent postpartum haemorrhage in women giving birth. The agreement has a staged technology access fee of €900,000 that will be triggered by milestones in the clinical trial stage of the project where the first out of three milestones will be paid as an exercise fee to license the device subject to a positive Phase 1 trial that is planned for 2021. In addition, Monash will pay Iconovo for commissioned development work through milestones that are yet to be defined. Royalties from sales over a 20-year period from launch will be in the 5 – 10 % range, as previously communicated for similar agreements.

“We are excited to be contributing with ICOone and our inhalation know-how to such an important medical innovation. There is a huge need to ease administration of oxytocin so that these unnecessary and tragic deaths can be reduced all over the globe. In this project, we all come together to make great things happen,” said Johan Wäborg, CEO of Iconovo.

“For Iconovo, this project will broaden our experience to include innovative development and we look forward to many more such projects where we can use our inhalation experience. It sends a clear signal that these innovation-focused partners see ICOone as a promising inhaler for innovative applications. We are very pleased that we now have commercial royalty bearing agreements for all Iconovo's three platforms,” continued Johan Wäborg.

Currently, injectable oxytocin is used to prevent postpartum hemorrhage (PPH) after childbirth. It is recommended by the WHO that women should receive an injected dose of oxytocin during the third stage of labor to prevent PPH. An inhaled formulation can provide important advantages such as ease of use, cheaper transport and storage without cold chain and no handling of used needles and syringes. It is particularly important in parts of the world where infrastructure is less developed, like in rural parts of Africa or Asia. To remove the need for a cold-chain and the management of hazardous waste will be a great cost reduction and potentially help eliminate disease spreading by infected needles. Iconovo estimates that there are 115 million live births in the region of interest, whereof 65 million are in rural areas with the greatest need. Iconovo believes that the product will be used in 15 – 20 % of live births in rural areas. In the future there is a possibility that also other markets like USA and Europe will open for inhaled oxytocin as a safer, non-invasive alternative to injections.

“This is an exciting opportunity to expand this collaboration between industry and academia to develop an important healthcare innovation that aims to address a critical unmet medical need,” said Monash University's Professor Michelle McIntosh, who has pioneered the inhaled delivery of oxytocin. “There is a massive ripple effect when a mother dies – it's a very significant burden for these families and communities, and we are committed to bringing gold-standard care to all mothers.”

ICOone is a single-dose inhaler designed for ultra-low manufacturing cost and easy operation. In these areas, ICOone is particularly suitable since it can deliver one dose at a low price-point and with a mode of operation that requires a minimum of training. Therefore, ICOone supports the potential of delivering an inhaled oxytocin product at an affordable price point comparable to other uterotonic options available in low- and middle-income countries.

About PPH

PPH, a condition of excessive blood loss after birth, is the leading cause of maternal mortality globally, resulting in an estimated 60,000 deaths per year, overwhelmingly in resource-limited countries. Most deaths resulting from PPH could be avoided if access to suitable medical innovation were available. It is effectively managed in developed countries using the gold standard therapy, oxytocin, a manufactured form of a natural hormone. Accessibility to quality oxytocin in resource-poor countries is, however, limited as current products are only available in an injectable form requiring supply and storage under refrigerated conditions and trained personnel to administer the product safely.

About ICOone®

ICOone is a unique, patented dry powder inhaler for single use. The smart design generates an ultra-low manufacturing cost combined with simple and discreet use. It is particularly suitable for short-term treatment and as-needed use as it provides an unsurpassed low treatment cost and price point for treatments with a low number of doses. The simple design also enables patients and caregivers to learn how to handle the inhalers with minimal training. ICOone can deliver large inhalation doses that are well protected against moisture, an important factor for many biomolecules.

About Monash University's Institute of Pharmaceutical Sciences (MIPS)

MIPS has formed an alliance with a number of industry partners, including Janssen Pharmaceutica N.V., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, and GSK, as well as philanthropic organisations such as the McCall MacBain Foundation, to develop a novel, temperature-stable formulation of oxytocin. The 2020 QS World University Rankings by Subject ranked Monash University number two in the world for Pharmacy and Pharmacology. The University has also retained a long-held position as Australia's and the Asia-Pacific's number one University for Pharmacy and Pharmacology, and since the subject rankings were introduced in 2011 has consistently ranked in the most elite group of Pharmacy and Pharmacology programs worldwide with an average top ten ranking.

For further information, please visit <https://www.monash.edu/pharm/research/pharmaceutical-sciences>.

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.

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 2020-12-21 07:30 CET.

Attachments

[Iconovo signs agreement for development of inhaled oxytocin in ICOone for maternal health](#)