



## PRESS RELEASE

2019-08-27

# Sales of Miris Human Milk Analyzer in the U.S. increasing

**As milk analyzer company Miris received clearance by US Food and Drug Administration (FDA) to market its Miris Human Milk Analyzer™ (Miris HMA™) in December last year, clinicians in the U.S. for the first time have access to a test to analyze the nutrients in breast milk. With the FDA clearance Miris has seen an increased demand for the instrument and the development of target fortification strategies.**

During the first half of 2019, Miris has focused on entering the U.S. market. During the first six months of 2019 Miris sold and installed two HMA units for clinical use in the U.S. Now, in August alone, four additional units has been sold. The instruments sold since the FDA clearance will be in use at Neonatal Intensive Care Units in; California, Texas, New York state, Tennessee and North Carolina.

*"Sales processes for capital equipment in hospital care are slow as funding always needs to be approved in their budgets, says Marie Ekholm, Sales Director Miris. We are now experiencing more and more NICUs receiving approved budgets for the purchase of HMA equipment and sales are picking up in US. Also, several of the units sold to date are installed at university hospitals and will in addition to standard care also be used in clinical studies of the benefits of target fortification. More studies on this topic are very important for continuous growth of this market and means more babies will in the future benefit from target fortification", she said.*

The Miris HMA™ measures the concentration of macronutrients in breast milk, to ensure that premature and sick babies get the best possible nutrition and start in life. The interest for optimizing nutrition for preterm babies is growing in the U.S. and with the FDA clearance, Miris is in the forefront of this development. In total Miris now has 32 HMA units in U.S.

*- "Throughout 2019, we will continue to see consistent growth in the numbers of customers benefitting from Miris HMA™ to analyze the nutrients in breast milk since more and more hospitals in the U.S. are receiving funding and an increasing number of NICUs are changing to target fortification strategies, says Camilla Myhre Sandberg, CEO Miris. The increased level of orders received over the past few weeks is in line with our original expected timeline and we anticipate that the number of orders will continue to increase going forward", commented Camilla Myhre Sandberg*

## Miris helps Neonatal Intensive Care Units and research institutes

The Miris Human Milk Analyzer™ uses an infrared spectroscopy system to analyze samples of human milk and provide a quantitative measurement of fat, protein and total carbohydrate content as well as calculations of the total solids and energy content contained in the milk. Data reviewed by FDA showed that the Miris Human Milk Analyzer test was effective at determining levels of protein, fat and carbohydrate in the milk. This is a prescription device intended for use by trained health care personnel at clinical laboratories.

### For more information:

Camilla Myhre Sandberg, VD Miris Holding AB

Cell phone: +46 18-14 69 07, E-mail: [camilla.sandberg@mirissolutions.com](mailto:camilla.sandberg@mirissolutions.com)

### About Miris

Miris is a global MedTech company who develops and sells instruments and solutions for human milk analysis. The products are used at neonatal intensive care units, milk banks and research centers worldwide. The purpose is to enable clinicians to practice individualized nutrition of human milk using target fortification, thus giving preterm babies the best possible start in life. Miris received FDA clearance for the Human Milk Analyzer™ for the US market in December 2018. The mission is to make individualized nutrition, based on breast milk, available globally to improve neonatal health. Miris Holding AB is listed on the Spotlight Stock Market in Sweden.

This information is the information that Miris Holding AB is required to disclose under the EU Market Abuse Regulation. The information was provided by the above contact person for publication on Aug 27, 2019.