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October 26, 2023 - Avelo, VIVOLTA, and BLINK today announced they have won a €1.5M Eurostars grant to develop a new solution for diagnosing lower respiratory tract infections (LRTIs).

The three companies, based in Switzerland, the Netherlands and Germany – are joining forces in the BreathCounts consortium to create an innovative, non-invasive system to diagnose lower respiratory tract infections (LRTIs) using a patient’s breath as sample material. LRTIs are currently the fourth most lethal disease worldwide, causing more than 2.5 million deaths annually, and insufficient diagnostic methods for these infections is a major problem.

The companies will aim at developing a disposable breath collection device, incorporating an electrospun filter, as well as a high-throughput diagnostic assay capable of screening multiple pathogens at the point-of-need. The project will span two years and lay the foundation for market launch in 2027.

The solution will be the world’s first breath-based system capable of fast, accurate, and specific diagnosis of LRTIs, and will be simple-to-use for maximum adoption around the world. Using this system, clinicians will be able to distinguish between viral and bacterial infections, specifying the underlying cause of infection and drug resistance genes, thus informing the best possible treatment. Particularly, as bacterial resistance from the overuse and misuse of antibiotics for non-bacterial infections grows in significance, providing an accurate, fast, and specific diagnosis will help clinicians prescribe the right medication and help combat this major global health problem.

Melanie Aregger, co-founder and CEO of Avelo, commented: “We are thrilled about this opportunity. Joining forces with VIVOLTA and BLINK will help us to develop and validate our AveloCollect breath sampling kit, which has the potential to revolutionize the field of respiratory medicine. This consortium is highly synergistic, and its expertise will greatly support our journey towards improving the diagnosis of LRTIs and clinical outcomes, as well as combatting antimicrobial resistance.”

Ramon Solberg, CTO and CEO ad interim of VIVOLTA, said: “Joining the BreathCounts consortium is a great opportunity for VIVOLTA and we are delighted to help bring this exciting diagnostic solution to the millions of patients worldwide who need it. We particularly look forward to demonstrating the full potential of our MediSpin platform, the world’s first and only fully automated medical electrospinning manufacturing system, for the mass-production of the AveloCollect device’s filter. Together with Avelo and BLINK, we believe this is a winning product coupled with a winning team.”

The LRTIs solution consists of two products used in conjunction: (1) AveloCollect, a novel breath sampling device capturing the infection-causing pathogen(s) directly from exhaled breath through its proprietary aerosol filter technology, and (2) Respirex, a unique molecular diagnostic test using the world’s first digital PCR point-of-care analyzer for sensitive detection of LRTIs.

The AveloCollect breath collector, developed by Avelo, represents a breakthrough in LRTI sample collection because current methods are a major limiting factor for diagnosis: they miss LRTIs (swabs or

saliva), are hard to obtain (sputum), or are highly invasive (bronchoalveolar lavage), leaving up to 50% of patients without an accurate diagnosis. In contrast, AveloCollect captures biological sample material, including the infection-causing pathogens, from the patient's breath in a non-invasive and fast manner.

The AveloCollect device also incorporates a high-efficiency filter material, created by a specialized manufacturing process called electrospinning. Vivolta, a world leading company in medical electrospinning, will be responsible for optimizing and scaling this process up for commercial phase by leveraging its proprietary MediSpin platform, which is the world's first and only fully automated, mass production system qualified for electrospun medical products.

Respirex , developed by BLINK, is a specialized LRTI test can rapidly identify multiple pathogens at once, measured from a single AveloCollect breath sample. The Respirex assay, which identifies a pathogen's specific DNA/RNA fingerprint, is based on BLINK's proprietary digital PCR technology. It enables highly precise and extremely broad molecular analysis of a single sample via nanoreactor bead technology, enabling dozens to hundreds of tests in one. The Respirex assay will be produced in the form of a cartridge, containing all reagents necessary for the test, greatly reducing time and variability of other systems where reagents must be added separately by a technician. After adding the breath sample from the AveloCollect device, the Respirex cartridge can be rapidly analyzed in BLINK's first-of-its-kind point-of-care analyzer, the BLINK ONE.

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About Avelo

Avelo, the Swiss breath aerosol diagnostic company, aims to revolutionize the diagnosis of Tuberculosis and lower respiratory tract infections (LRTIs) causing pneumonia. Their breath collector enables non-invasive collection of pathogens from breath and works in combination with existing PCR tests. The collector is designed for broad utility, similar to other sample collection technologies such as blood tubes. Avelo has a talented team with experience in functional materials, IVD product development, clinical research, molecular diagnostics, and business development working from their R&D facilities in Zurich-Schlieren.

About VIVOLTA

VIVOLTA is a world leader in the development and manufacturing of electrospun medical products. Utilizing its proprietary, fully automated MediSpin™ production platform, VIVOLTA supports its clients in realizing electrospun medical solutions that guide the body to heal itself. These medical products restore and cure damaged and diseased tissues, with the aim of improving patients' lives while minimizing complications. VIVOLTA's solutions are applicable to a broad array of high-value therapeutic areas with

unmet clinical need, such as cardiovascular implants, soft tissue repair, orthopaedic sports medicine, and drug delivery. The company, formerly IME Medical Electrospinning, is a pioneer and global leader in the electrospinning sector, having contributed significantly to the first ASTM (American Society for Testing and Materials) standard for fiber-based medical scaffolds (F3519-21), published in 2021.

About BLINK

BLINK is a German SME that was founded in 2015 with a mission to revolutionize the development and application of molecular assays across a range of fields. With the goal of extending the power of molecular analysis tools to more areas of life sciences, biotechnology, environmental testing, agriculture, veterinary medicine, and in vitro diagnostics, BLINK has developed a revolutionary digital PCR technology using proprietary hydrogel beads alongside a modular integrated technology package that allows them to develop tailor-made assays. BLINK has a talented team of over 60 employees and operates an extensive R&D operation in Jena, Germany, where it is part of the InfectoGnostics Research Campus.

About the Eurostars grant

Eurostars is part of the European Partnership on Innovative SMEs. The partnership is co-funded by the European Union through Horizon Europe. It's the largest international funding program for SMEs wishing to collaborate on R&D projects that create innovative products, processes or services for commercialization. <https://www.eurekanetwork.org/countries/spain/eurostars/>

For more information, please contact:

VIVOLTA

Ramon Solberg, CTO, CEO a.i.
Noel Davison, Director of Business Development

Tel: +31 (0) 40 282 7956
Email: BD@vivolta.com

VIVOLTA – Instinctif Partners (Media)

Melanie Toyne-Sewell / Giulia Lasagni / Batoul Ali

Tel: 0207 457 2020
Email: vivolta@instinctif.com

Avelo

Melanie Aregger, CEO

Tel: +41 43 588 33 44
Email: hello@avelolife.com

BLINK

Eugen Ermantraut, CEO

Tel: +49 3641 5542 100
Email: contact@blink-dx.com