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Mount Sinai Medical Center's Comprehensive Cancer Center Leads International Clinical Trial On The Early Detection Of Breast Cancer By Examining Organic Compounds In Breath

MIAMI BEACH, FL, and TEL AVIV, ISRAEL — June 22, 2023 — Steven N. Hochwald, MD, MBA, FACS, Director of the Comprehensive Cancer Center and Chief of Surgical Oncology at Mount Sinai Medical Center, is a lead investigator on an international clinical trial that examines organic compounds in the breath to detect breast cancer.

Cancer is a leading cause of death worldwide. It accounted for nearly 10 million deaths in 2020, or nearly one in six deaths. The most common cancers are breast, lung, colon and rectum, and prostate. Breast cancer is known as the most prevalent malignancy among women and the primary cause of female cancer deaths worldwide. In fact, in 2018, over 2 million new cases were diagnosed and 626,679 deaths due to breast cancer occurred worldwide.

In the United States, an estimated 249,260 new cases of breast cancer were diagnosed in 2018. The prognoses in patients with breast cancer depended mainly on the stage of the disease at diagnoses.

Early diagnosis and appropriate therapy can effectively reduce the mortality of breast cancer. There are several adjuvant screening methods (e.g., mammography, ultrasonography, digital breast tomosynthesis [DBT], and magnetic resonance imaging [MRI]) for breast cancer. However, the accuracy of these methods largely relies on the physicians' experience, stage of disease, and the tumor's histopathologic features. Therefore, there may be a misinterpretation or a missed diagnosis.

Furthermore, it is estimated that only 60% of women follow the established guidelines for breast cancer screening, with a large percentage of women choosing not to get screened. This is due to discomfort with the mammography, ultrasound, or MRI exam; lack of privacy; excessive cost; and inconvenience.

"Exhaled breath analysis has increasingly been adopted for early diagnosis of several disease states, including diabetes, explains Dr. Hochwald. "With the rapid development of exhaled breath metabolomics in recent years, the association between volatile organic compounds (VOCs) of exhaled breath and cancer has attracted increasing attention."

Breath VOC analysis is appropriate for disease screening because it is noninvasive, portable, inexpensive, and easy for patients to accept. The technique also has the potential for early diagnosis.

The planned clinical trial will evaluate the exhaled breath of patients with precancerous conditions of the breast (carcinoma in situ) and those with biopsy-proven breast cancer and compare the presence and type of organic compounds in the breath to those patients who have normal mammography examinations and no evidence of breast cancer.

Enough patients will be enrolled to determine if different breast cancer subtypes and whether the breast cancer stage at diagnosis correlates with specific signatures of organic compounds in the exhaled breath. The goal is to develop an exhaled breath test that can detect precancerous conditions of the breast as well as breast cancer type and stage.

The breath sample is collected in an aluminum bag, then processed by reducing the temperature to minus 20 degrees Celsius for at least three minutes, eliminating approximately 80% of the liquids. The bag is then processed using their aerosol generator, which generates droplets of 5 to 15 microns that go through the optical gas cell. The original detection is 200 parts per billion, but the company has managed to reduce it to one part per trillion.

Breath of Health's machine is a standalone system and requires only electricity to perform its analysis of breath and delivery of results, meaning its services can be of great benefit to those in remote areas without access to hospitals with Mammography units.

"We are not motivated by monetary benefits. The technology is inspired by Breath of Health's focus on humanity. Our technology is capable of detecting breast cancer at an early stage, which can lead to considerable life-saving benefits. We believe that the breath-based technology for early detection of cancer is a significant breakthrough in healthcare. With its non-invasive screening platform and low-cost testing, we aim to improve existing cancer screening programs and save lives", says Arie Laor, Founder of [Breath of Health](#).

To schedule an interview with Dr. Hochwald, please email Erica.Corsano@msmc.com.

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About Mount Sinai Medical Center

*Founded in 1949, Mount Sinai Medical Center is the largest independent, private, not-for-profit teaching hospital in South Florida. Mount Sinai's mission is to provide quality health care to a diverse community enhanced through teaching, research, charity care, and financial responsibility. Mount Sinai's Centers of Excellence combine technology, research, and academics to provide innovative and comprehensive care in cardiology, neuroscience, oncology, urology, and orthopedics. One of the original statutory teaching hospitals in the state of Florida, Mount Sinai is the hospital of choice for those who seek the level of expertise and care that only a teaching hospital can offer. Mount Sinai currently offers nine convenient locations in Miami-Dade County, including three emergency centers, and two specialty care offices and a primary care office in Monroe County. For more information on Mount Sinai Medical Center, visit msmc.com or call **305.674.CARE** (2273).*

About Breath of Health

[Breath of Health](#), an Israel-based healthcare technology company, is beginning clinical studies of its proprietary breath-based technology for the early detection of cancer. The company, founded in 2020, has been developing quick and accurate breath-based diagnostics for early life-saving detection of cancer, Alzheimer's, and other diseases. Their mission is to improve existing cancer screening programs through the widespread adoption of their proven disease detection method.

Utilizing AI to detect a broad range of cancerous biomarkers, Breath of Health aims to provide a non-invasive screening platform to save lives. Through molecular analysis, the technology can detect early responses in the immune system, even in asymptomatic stages.