

Ikonisys & Sheba Medical Center-ARC Partner to Detect & Target Cancer with Novel Technology

- **Circulating Tumor Cells (CTC) analysis has great potential to transform the cancer diagnostic landscape**
- **Ikoniscope® platform allows to find extremely rare cells**
- **Partnership with world-leading medical center further validates Ikonisys' technology**

Tel Aviv/Israel, New Haven, CT/USA & Milan/Italy - November 14, 2019 – Sheba Medical Center, the largest hospital in the Middle East, which is based in metro Tel Aviv, Israel, and Ikonisys Inc., a cell-based diagnostic company located in New Haven, Connecticut, USA and Milan, Italy, announced today the signing of a partnership agreement for the development of novel proprietary Circulating Tumor Cells (CTCs) tests, targeting specific cancers. The tests and applications will be aimed at a variety of potential clinical purposes, including treatment monitoring (the detection of disease recurrence) and companion diagnostics. Ikonisys will play an integral role within Sheba's ARC innovation hub, which is accelerating and redesigning global healthcare through collaboration.

Prof. Iris Barshack, Head of the Institute of Pathology at Sheba Medical Center, commented, "We are excited to begin using the Ikoniscope® system provided by Ikonisys. Together, we aim to improve the detection of disease recurrence and clinically validate applications for various types of cancers while contributing to Sheba Medical Center's mission to deliver excellent, highly innovative comprehensive diagnoses and care management to patients."

Michael Kilpatrick, Chief Scientific Officer of Ikonisys, added, "We are proud to cooperate with one of the world's leading medical centers in developing innovative tests for the diagnosis and monitoring of cancers. This partnership validates our proprietary Ikoniscope® technology and coincides with the launch of our second-generation system. The cooperation also enables us to further expand Ikonisys' product portfolio, strengthening our commitment in the world of CTCs to continuously improve cancer treatment."

The circulating tumor cells detection test possesses the ability to detect, quantify, and analyze tumor cells in the blood of cancer patients. With application in determining disease status, rate of disease progression and predicting the likely efficacy of a particular therapy or treatment, CTC analysis has great potential to transform the cancer diagnostic landscape. However, it has been limited so far by the difficulty in finding these extremely rare cells, that can be as few as 10 out of millions in a typical 10ml blood sample. The automated scanning and analysis capabilities of the Ikoniscope® platform allow the efficient screening of a much larger number of cells than would be possible by manual analysis, allowing the identification and enumeration of CTCs in the blood of cancer patients with high sensitivity and specificity.

Sheba's research team, led by Prof. Iris Barshack, will identify and propose biomarker panels for specific cancers of particular interest that will be evaluated as potential new Ikoniscope® CTC tests. All available clinical data will be collected for the patient samples being tested, including, for example, other available liquid biopsy data. This will allow evaluation of the potential complementary nature of cell-based CTC tests, such as performed on the

Ikoniscope[®], for characterization of individual tumor cells, compared to circulating DNA-based tests that provide global tumor genotype information.

About Ikoniscope[®]: Through its breakthrough fluorescence microscopy platform, Ikonisys continues to develop a stream of oncology tests for a variety of cancers. At the center of the platform is the Ikoniscope[®], a robotic, high-throughput, microscopy system that provides a true “walk away” automated solution. In addition to providing high quality cell images, the platform analyzes the cells of interest, offering an interpretation of the analysis, to facilitate the quick, accurate reporting of the test result. Implementation of the Ikonisys platform provides the ability for a laboratory to both expand their test volume capacity and standardize their diagnostic procedures, thus enhancing their ability to economically deliver accurate, fast, personalized results. In addition to automating traditional FISH-based tests, the rare cell detection and analysis capabilities of the platform, that facilitates the examination of large complex samples for the clinically relevant cells, make it particularly suitable for circulating tumor cell-based testing. The next generation of the Ikoniscope[®] launched with this project provides an improved performance, in a system of minimal size and weight and a modular design allowing for laboratory specific customization.

About Ikonisys Inc.: Ikonisys is a privately held cell-based diagnostics company based in New Haven, Connecticut (USA) and Milan, Italy. The company develops, produces and markets the proprietary Ikoniscope[®] platform, designed to deliver highly accurate and reliable detection of rare cells. Utilizing advanced molecular and immunological markers, Ikoniscope-built applications are extensively used in the US and Europe for the diagnosis of a variety of cancers. Ikonisys has received FDA clearance for several automated diagnostic applications also marketed in Europe under CE certification. More information at www.ikonisys.com

About Sheba Medical Center: Established in 1948, Sheba Medical Center is the leading medical center in the Middle East and an internationally recognized healthcare facility. In 2019, Newsweek magazine ranked Sheba on their prestigious list of the top ten hospitals in the world. Located on a comprehensive campus, Sheba offers a wide range of medical divisions and specialties. Highly qualified doctors are involved in many innovative treatments and cutting-edge research programs to advance the clinical care of patients. Sheba also functions as a tertiary care center and accepts referrals of complex cases from throughout the region and the world. **Sheba's ARC innovation hub** brings together clinicians, startups, industry leading medical centers, and national partners to transform healthcare delivery and improve patient care through innovation. More information at www.eng.sheba.co.il

Picture: *Prof. Iris Barshak (Sheba Medical Center, Head of the Institute of Pathology) and Mario Mauri (Ikonisys, Member of the Board of Directors) at the ARC Innovation Center, November 2019.*

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