Press release

Ikonisys successfully completed its ISO certification reaffirming its ability to continuously meet quality international standard requirements

Paris, October 16, 2023 – 6:00 pm CEST - Ikonisys SA (ISIN Code: FR00140048X2 / Ticker: ALIKO), a company specializing in the early and accurate detection of cancer with a unique fully-automated solution for medical diagnostic labs, today announces the successful completion of its triennial Registration Renewal ISO Audit by its US subsidiary.

Ikonisys, Inc. has completed a three-day ISO recertification audit leading to the revalidation of the ISO 13485. This standard indicates that the company is following a procedure recognised by an independent body that audits it regularly. Certification also simplifies the CE marking of products marketed by a company. Concretely this obtention validates the conformity of the following strategic items:

- compliance with regulatory requirements,
- control of special processes,
- risk analysis throughout product development,
- organisation of material vigilance,
- traceability of the configuration of each medical device delivered.

Dr. Michael Kilpatrick, Chief Scientific Officer of Ikonisys, stated: "*We are very pleased to announce this highly successful audit which resulted in zero non-conformances. Such an impressive result ensures that the company meets or exceeds all of the rigorous quality elements required by this international standard. Completing the audit so successfully indicates the ability of Ikonisys to continue to meet FDA requirements in the USA. In addition, it allows Ikonisys to continue to provide CE marking for its products, as we work toward full conformance with the IVDR, the new EU regulation on medical devices*".

About Ikonisys

Ikonisys SA is a cell-based diagnostics company based in Paris (France), New Haven (Connecticut, USA) and Milan (Italy) specialized in the early and accurate detection of cancer. The company develops, produces and markets the proprietary Ikoniscope20® platform, a fully-automated solution designed to deliver accurate and reliable detection and analysis of rare and very rare cells. Ikonisys has received FDA clearance for several automated diagnostic applications, which are also marketed in Europe under CE certification. Through its breakthrough fluorescence microscopy platform, the company continues to develop a stream of new tests, including liquid biopsy tests based on Circulating Tumor Cells (CTC).

For further information, please go to www.Ikonisys.com

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