Press release

Successful 2024 ISO 13485 Certification Maintenance Strengthening Ikonisys' Strong Market Position and Growth Potential

Paris, France – October 3, 2024 – 6:00 pm CEST – Ikonisys SA (Euronext Growth Paris: ALIKO), a company specializing in the early and accurate detection of cancers through a unique, fully automated solution for medical analysis laboratories, today announces the successful maintenance of its ISO 13485 certification. This milestone strengthens the Company's QMS (Quality Management System) and enhances its competitive edge in global markets, driving confidence in both operational excellence and future growth potential.

ISO 13485 is an internationally recognized standard for quality management systems in the medical device industry, ensuring that products meet customer and regulatory requirements throughout their lifecycle.

Following a thorough audit conducted by Ikonisys' U.S. subsidiary, passed with zero non-compliances, major or minor, this ongoing certification confirms the Company's full compliance with the internationally recognized ISO 13485 standard for medical devices. The latter is key to maintain CE marking, ensure access to European markets, and meet stringent FDA requirements in the U.S., as an FDA Registered Medical Device Manufacturer with FDA clearances for the Ikoniscope instrument and cancer tests, a critical foundation for scaling operations globally. Ikonisys is thus well-positioned to accelerate its expansion strategy, including further penetration into key global markets.

The audit validated Ikonisys' performance across strategic areas, including:

- Strict regulatory compliance, ensuring risk mitigation,
- Efficient management of specialized processes to enhance product reliability,
- Comprehensive risk assessment throughout product development, safeguarding innovation,
- Robust material vigilance protocols, supporting supply chain stability, and
- Detailed traceability for each medical device, driving customer trust.

Dr. Michael Kilpatrick, Chief Scientific Officer of Ikonisys, commented: *"Maintaining ISO 13485 certification, with zero non-conformances, evidences Ikonisys' commitment in exceeding the highest standards required for long-term success in the medical device industry. This certification strengthens our ability to deliver on regulatory expectations, securing our establishment in both U.S. and European markets, while positioning us for significant growth under the new EU IVDR (In Vitro Diagnostics Regulation) framework. We believe that all our efforts put to maintain it reinforces Ikonisys' competitiveness and provides a strong foundation for future growth and value creation both for the Company and shareholders."*

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

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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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