

Revolutionary AI Algorithm «Prostate.Carcinoma.ai» Achieves EU MDR Class IIa Registration

Zurich, 18th of December 2023: Xlife Sciences AG (SIX: XLS) achieves EU MDR Class IIa registration with the portfolio company FUSE-AI GmbH and reaches a milestone for medical technology. The AI algorithm «Prostate.Carcinoma.ai» from FUSE-AI GmbH can analyze a multitude of radiological images in a very short time with a lower error rate than the human eye.

The AI-based assistance diagnostic software «Prostate.Carcinoma.ai», developed for prostate gland segmentation and lesion detection, has been awarded the prestigious EU MDR Class IIa registration in December 2023. This registration marks a significant milestone in the journey of «Prostate.Carcinoma.ai», which began with the initial investment by Xlife Sciences AG in FUSE-AI GmbH in October 2019.

This is not only a success for FUSE-AI GmbH and Xlife Sciences AG, but also a milestone for the technological development in radiology and the quality of radiological diagnostics in Europe. The software «Prostate.Carcinoma.ai» is the result of interdisciplinary collaboration between scientists, AI developers and radiologists. The timing of this milestone goes along with the global medical image analysis software market being projected to achieve a value of \$4.545 billion by 2023, growing at a compound annual growth rate (CAGR) of 9.9%.

«Prostate.Carcinoma.ai» not only promises a 30% time saving per patient but also matches the accuracy of experienced radiologists in prostate volume determination. Its ability to predict and segment lesions as malignant or benign significantly assists radiologists in MRI analysis for prostate diagnosis. The objective is to decrease the error rate in this process from 14% to 1%.

The registration of «Prostate.Carcinoma.ai» is a crucial step towards a transformative era in global healthcare, as it enables the initiation of its market rollout. This significant development means that preliminary agreements will now evolve into binding contracts, and the pre-installed or test installations of the software in various medical facilities will become fully operational, paving the way for revenue generation. Strategically, «Prostate.Carcinoma.ai» is not just an isolated solution but a critical component of a broader ecosystem. FUSE-AI GmbH is committed to obtaining registrations for additional areas, thereby positioning «Prostate.Carcinoma.ai» as a vital part of a comprehensive plug-in solution. This approach is expected to establish FUSE-AI's presence in hospitals worldwide, making it an indispensable tool in the medical field.

Matthias Steffen, CEO of FUSE-AI GmbH, commented, *«Two factors guarantee a positive continuation of our path: an interdisciplinary team that develops AI tools close to the needs of radiologists and a global sales structure that takes into account the regional macroeconomic conditions of the individual healthcare industries.»*

Oliver R. Baumann, CEO of Xlife Sciences AG, stated *«We are more than proud to see our portfolio company FUSE-AI not only contributing to but leading the AI-based assistance diagnostic software field. This will have a positive effect on many patients with radiology being only the beginning.»*

As we celebrate this achievement, we look forward to the continued advancement of «Prostate.Carcinoma.ai» and the FDA approval in Q1 2024.

Financial calendar

Annual Report 2023	23 April 2024
Annual Shareholders Meeting 2024	20 June 2024
Half-Year Report 2024	19 September 2024

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About Xlife Sciences AG (SIX: XLS)

Xlife Sciences is a Swiss company focused as incubator and accelerator on the value development and commercialization of promising research projects from universities and other research institutions in the life sciences sector, with the aim of providing solutions for high unmet medical needs and a better quality of life. The goal is to bridge research and development to healthcare markets. Xlife Sciences takes carefully selected projects in the four areas of technological platforms, biotechnology/ therapies,

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medical technology, and artificial intelligence/digital health to the next stage of development and participates in their subsequent performance. For more information, visit <https://www.xlifesciences.ch/en/home>

About FUSE-AI GmbH

FUSE-AI GmbH is an e-health company that has set itself the goal of improving medical care with intelligent software solutions, i.e., AI-supported software, for radiology. The AI algorithm 'prostate.Carcinoma.ai' analyzes a multitude of radiological images in a very short time with a lower error rate than the human eye. The algorithm is designed in such a way that it can be applied to other areas of image recognition, even outside the medical field. For more information, visit: <https://fuse-ai.de/>

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