

SMAIO signs a new distribution agreement for its open platform KEOPS-4ME with Orthofix in the U.S.

- + Orthofix is a global medical technology company focused on healing musculoskeletal pathologies
- + The distribution arrangement is part of SMAIO's collaborative strategy aimed at deploying its new open platform for customized implant solutions in the U.S. market

Dallas (United States) and Lyon (France), October 22, 2025 – 7:00 am CEST – SMAIO (Software, Machines and Adaptative Implants in Orthopaedics – Euronext Growth Paris, ISIN: FR0014005180 / Ticker: ALSMA), a French-American player specialized in complex spine surgery with a global offer comprising software, adaptative implants and related services, today announces the signing of a distribution agreement with Orthofix (Lewisville, Texas), a leading global medical technology company focused on healing musculoskeletal pathologies.

Orthofix offers a comprehensive portfolio of spinal hardware, bone growth therapies, specialized orthopedic solutions, biologics and enabling technologies, including the 7D FLASH[®] Navigation System. By providing medical technologies that heal musculoskeletal pathologies, Orthofix delivers exceptional experiences and life-changing solutions to patients around the world.

Within the framework of this strategic collaboration, Orthofix's network of surgeons in the U.S. will gain access to SMAIO's comprehensive spinal realignment planning solutions, as well as the ability to integrate SMAIO's technology with their existing implant systems. This collaboration marks a new milestone in the rollout of SMAIO's open platform, KEOPS-4ME, designed to deliver a personalized and data-driven approach to complex spine surgery. The platform combines advanced data analysis, 3D surgical planning through the KEOPS Balance Analyzer 3D and use of the patient-specific K-Rods.

This strategic collaboration will enable SMAIO to leverage Orthofix's hospital network, streamline implant registration processes and accelerate clinical adoption of joint solutions in the United States.

Philippe ROUSSOULY, Chairman and CEO of SMAIO, stated: *"We are proud to enter a second collaboration with such an important company in the field of spinal surgery as Orthofix. SMAIO's unique spine realignment planning and patient specific technologies will perfectly fit with Orthofix's innovative product portfolio, including the 7D FLASH[™] Navigation System, and are fully aligned with Orthofix's vision for the future of spine surgery. This rapid succession of collaborations confirms the strong interest in our open platform KEOPS-4ME and highlights its potential in addressing the needs of surgeons and healthcare providers. We are confident that this momentum will support our continued expansion in the U.S. market and facilitate the creation of additional strategic collaborations. Our goal remains to position SMAIO as a pioneer in data-driven innovative solutions that improve surgical planning, patient outcomes, and the overall efficacy of spinal care."*

Max Reinhardt, President, Orthofix Global Spine, said: *"At Orthofix Global Spine Solutions, we are deeply committed to advancing clinical outcomes in complex spine surgeries. Our strategic collaboration with SMAIO marks a significant milestone in our innovation journey. We are proud to join forces with the Roussouly family and the SMAIO team, whose deep expertise in spinal deformity has led to the development of a truly differentiated solution. Their approach to pre-operative planning and the creation of patient-specific rods aligns perfectly with our mission to deliver meaningful, patient-centered innovation."*

SMAIO intends to build on its position as a trusted, innovative commercial partner to major surgical companies and to develop future collaborations around its open platform.

Upcoming financial events:

- **Full year 2025 sales:** Tuesday, January 20, 2026 (after market close)

About Orthofix

Orthofix is a global medical technology company headquartered in Lewisville, Texas. By providing medical technologies that heal musculoskeletal pathologies, Orthofix delivers exceptional experiences and life-changing solutions to patients around the world. Orthofix offers a comprehensive portfolio of spinal hardware, bone growth therapies, specialized orthopedic solutions, biologics and enabling technologies, including the 7D FLASHb Navigation System.

For further information, please visit www.orthofix.com.

About SMAIO

A precursor in the use of clinical data and imaging of the spine, SMAIO designs global solutions for spine surgery specialists. The Company has recognized expertise thanks to KEOPS, its Big Data management software that has become a global reference with more than 100,000 patient cases documented.

SMAIO offers spine surgeons a comprehensive platform, I-Kontrol, incorporating planning, implants and related services, enabling them to treat spinal pathologies in a safe, effective and lasting way.

The Company's open platform deployed in the United States, KEOPS-4ME, is designed to deliver a personalized and data-driven approach to complex spine surgery, enabling SMAIO to partner commercially with major U.S. surgical companies and provide their surgeon clients with patient-specific implants.

Based in Dallas (United States) and Lyon (France), SMAIO benefits from the skill and expertise of more than 40 highly specialized staff.

For further information, please visit our website: www.smaio.com

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