

SMAIO receives FDA 510(k) clearance for customized surgery planning software co-developed with NuVasive

Lyon (France), June 8, 2023 – 7:00 am CEST – SMAIO (Software, Machines and Adaptive Implants in Orthopaedics – Euronext Growth Paris ISIN: FR0014005180 / Ticker: ALSMA), a French player specializing in transforming vertebral fusion with breakthrough innovation, today announced that it has received FDA 510(k) clearance for the customized surgery planning software co-developed with NuVasive¹.

Obtaining FDA 510(k) clearance for this customized version of the surgery planning software represents a key milestone in the partnership and licensing agreement signed in Q1 2022 between SMAIO and NuVasive, a global leader in spine technology innovation. This customized surgery planning software is based on SMAIO's previously released vertebral realignment planning technology, "Balance Analyzer 3D".

Philippe ROUSSOULY, CEO of SMAIO, stated: *"This 510(k) clearance represents a major step towards the commercialization of our joint planning platform and innovative services to NuVasive customers. We believe that with our technology, surgeons will soon benefit from our cutting-edge solution for planning and performing spine surgery, considering individual morphological specificities and ultimately, for improving patient outcomes".*

The achievement of this first milestone, in line with the roadmap presented by SMAIO at the time of its IPO in April 2022, triggers a \$3 million payment by NuVasive to SMAIO. As part of the previously announced partnership, an additional milestone payment will be triggered after further integration of the Balance Analyzer 3D into the NuVasive platform, as well as additional technical capabilities.

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.

SMAIO is positioned at the forefront of innovation with the ambition of providing surgeons with the first active robotic solution enabling a high level of performance and repeatability to be achieved.

Based in Lyon, France, SMAIO benefits from the skill and expertise of more than 30 highly specialized staff.

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

Next financial events:

- **Annual General Meeting:** June 20, 2023
- **H1 2023 sales:** July 18, 2023 (after market)
- **H1 2023 results:** October 18, 2023 (after market)

¹ On February 9, 2023, Globus Medical, a U.S.-based company that manufactures and markets a full range of spinal devices and implants, signed an agreement to acquire NuVasive in an all-stock transaction valued at approximately \$3.1 billion. As of the date of the publication of the annual financial report and the information available to SMAIO, NuVasive owns 15.55% of the Company's share capital.

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