PRESS RELEASE

Carvolix Takes a Key Step Toward Commercial Launch of TAVIPILOT Software in Europe with Regulatory Submission for CE Marking

- EU CE marking dossier for TAVIPILOT Software was submitted in August 2026, clearing key regulatory milestone; certification expected by year-end.
- TAVIPILOT Software European launch is now targeted for early 2027, alongside ongoing US commercialization.
- Strong early feedback from first US commercial contract, with 10 patients successfully treated at Rush University Medical Center in Chicago.

Aix-en-Provence, September 9, 2026 – 5:45 pm CET – Carvolix (formerly Affluent Medical) (ISIN: FR0013333077 – Ticker: CVX), a French medical technology company at the commercial and clinical stages, specializing in the development, industrialization and international commercialization of AI-powered mini-robots and innovative biomimetic implants, announces a new major milestone in the development of TAVIPILOT Software, its artificial intelligence software for intraoperative guidance of transcatheter aortic valve replacement (TAVI) procedures.

Submission of the European regulatory dossier in August 2026

Having completed the main stages of its clinical and regulatory development in the United States, Carvolix submitted the TAVIPILOT Software regulatory dossier in August 2026 to obtain CE marking. Subject to completion of the regulatory review process, CE marking is expected by year-end 2026, opening the way to the European commercial rollout of TAVIPILOT Software.

"*We now have a clear path to CE marking for TAVIPILOT Software and to its commercial rollout across Europe, expected in early 2027*," **said Sébastien Ladet, CEO of Carvolix**. "*The successful showcase of the TAVIPILOT platform at the EuroPCR congress in May 2026, together with our early commercial experience in the United States, gives us renewed confidence as we enter this new phase — confidence in TAVIPILOT's ability to bring a new dimension to the guidance of TAVI procedures.*"

Targeted European commercial launch from early 2027

Carvolix plans to start the commercial launch of TAVIPILOT Software in early 2027, initially focusing on France and Germany, two of the largest European markets for TAVI procedures.

This gradual development strategy aims to support the adoption of the technology by medical teams, to document its use in real-world conditions and to progressively build a community of reference user centers. In parallel, Carvolix has begun strengthening its commercial resources, with the recruitment of a team dedicated to European market development.

This organization will support the first centers in integrating TAVIPILOT Software into their clinical practice and prepare, in Europe for the second half of 2027, the launch of the platform including the robot. This AI-driven robotic platform will serve as the foundation for additional features designed to augment the interventional cardiologist in treating more patients while improving clinical outcomes.

Growing US track record

The commercial deployment of TAVIPILOT Software also benefits from the experience being built up in the United States. The first US commercial contract was established with Rush University Medical Center in Chicago.

Prof. Hussam Suradi, MD, interventional cardiologist, and his team recently treated ten patients successfully, providing an initial experience of the solution in a leading US Hospital.

"*TAVIPILOT brings an exciting new level of real-time visualization to TAVI. By providing AI-guided visualization during valve deployment, it gives operators greater confidence in achieving the intended final valve position and has the potential to make valve deployment more precise and reproducible*" **said Prof. Hussam Suradi.**

These real-world experiences gained during US commercialization complement the clinical data previously obtained in Australia and France and progressively strengthen the health & economic evidence supporting the benefits of the TAVIPILOT platform.

About TAVIPILOT Software

TAVIPILOT Software is an AI-powered real-time intra-procedural guidance software for percutaneous aortic valve implantation (TAVI). It provides automatic real-time detection of anatomical landmarks (aortic annulus plane, non-coronary cusp, transcatheter valve position) as well as continuous depth assessment during valve deployment. The software was developed and validated on a database of more than 5,000 TAVI patients from US and European populations, achieving non-coronary cusp detection within 2 mm in 100% of patients and transcatheter valve detection within 1 mm in 100% of cases. TAVIPILOT Software received FDA 510(k) clearance (K243884, July 2025) and is protected by seven patents. Commercial deployment in the United States began in H2 2025 as part of a targeted customer launch.

About the SAITO clinical program

The SAITO clinical program is a first-in-human post-marketing study of TAVIPILOT Software in patients undergoing transfemoral TAVI. It comprises three prospective cohorts of 10 patients each (n=30 total): SAITO 1A (Clinique Pasteur, Toulouse, October 2025), SAITO 1B Australia (Macquarie University Hospital, Sydney, November-December 2025) and SAITO 1B France (Clinique Pasteur, Toulouse, March 2026). Primary endpoints are procedural success, procedural time, fluoroscopy time, contrast volume and implantation accuracy. The SAITO 1B pool (Sydney + Toulouse R2, n=20) serves as the current benchmark for comparison against the pivotal PARTNER 3 and SMART trials.

About Carvolix

Carvolix is a French medical technology company at the commercial and clinical stages, founded by Truffle Capital (also founder of the leading European biotechnology company), with the ambition of becoming a global leader in the treatment of structural heart diseases and strokes, the leading causes of mortality and disability worldwide. According to the Truffle 10 MedTech Index, Carvolix ranks first in Europe and fifth worldwide. Carvolix develops novel AI- and imaging-powered mini-robots that make complex procedures accessible to interventional cardiologists, as well as biomimetic heart valves.

For more information: www.carvolix.eu

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Forward-looking statements

This press release contains forward-looking statements regarding Carvolix's clinical development, regulatory pathway, commercial plans and market estimates. These statements are based on current expectations and assumptions and involve known and unknown risks and uncertainties — including, but not limited to, those related to clinical trial results, sample sizes, follow-up data, regulatory approvals and market conditions — that could cause actual results to differ materially. The clinical results described concern a limited number of patients and remain subject to longer-term follow-up and publication following peer review. Forward-looking statements speak only as of the date of this press release, and Carvolix undertakes no obligation to update them, except as required by law.

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