PRESS RELEASE

Carvolix presents promising clinical data on the TAVIPILOT platform at New York Valves 2026

- TAVIPILOT Software, a commercial intraoperative AI guidance solution for aortic valve positioning, shows excellent results in the post market clinical study: 100% procedural success with no device related safety events.
- Accurate positioning: all valves were accurately implanted within a millimeter of the targeted range of implantation depth.
- Promising insights with observed reduction of procedure duration, fluoroscopy time and contrast agent usage to the benefit of the healthcare system and the patients.
- TAVIPILOT Robot — first 9 patients of Cohort 1 of the first-in-human program were presented. 100% procedural success with no device related safety events. The robotic platform enhances catheter stability and allows millimetric movement.

Aix-en-Provence, July 6, 2026 – 7:00 am CET – Carvolix (formerly Affluent Medical) (ISIN: FR0013333077 – Ticker: CVX), a French commercial and clinical-stage medical technology company specializing in the international development, industrialization and commercialization of breakthrough AI-driven mini-robots and biomimetic implants, today announces that detailed clinical results for both the TAVIPILOT AI software and the TAVIPILOT Robot were presented at New York Valves: The Structural Heart Summit, held June 24–26, 2026, at the Jacob K. Javits Convention Center in New York.

The data were presented by Professor Stephen Worthley, MD PhD, Interventional Cardiologist at Macquarie University Hospital, Sydney, Australia. The studies were conducted at Macquarie University Hospital, Sydney (Pr Stephen Worthley) and at Clinique Pasteur, Toulouse, France (Dr Didier Tchétché).

"TAVIPILOT is a robotic platform driven by AI, not a single-feature product. Precision positioning is the first commercial feature we deliver, but the same software and robotic architecture is designed to host additional intra-procedural capabilities — supervised autonomy positioning, commissure alignment, valve expansion guidance and further features currently in development. Building a platform, not a single product, is how we scale value delivery to each cath-lab we will equip," **said Sébastien Ladet, Chief Executive Officer of Carvolix.**

TAVIPILOT Software — detailed results

The SAITO clinical program comprises three prospective cohorts of 10 patients each (total n=30) with severe symptomatic aortic stenosis undergoing transfemoral TAVI. All three cohorts achieved 100 % procedural success, with no device-related adverse events or software incidents. Real-time anatomical landmark detection was reliable across all procedures, and implantation depth was within the operator-planned target range in all patients.

Overall clinician satisfaction ranged from 8.7 to 10 out of 10 across participating centers.

The 20 patients enrolled in the SAITO 1B pool (Macquarie University Hospital, Sydney, and Clinique Pasteur, Toulouse) represent a patient population with a mean risk profile of 5.70 (± 4.91 STS-PROM) — materially higher than the low-risk population in reported in the literature in PARTNER 3 study and higher than the SMART trial

cohort. Despite this greater clinical complexity, TAVIPILOT-assisted procedures were shorter and more predictable than the validated pivotal trial benchmarks:

Parameter	SAITO 1B Pool (n=20)	PARTNER 3 (n=496)	SMART BEV (n=361)	Δ vs Benchmark
Clinical risk profile (STS-PROM)	5.70 ± 4.91	1.9 ± 0.7	3.2 ± 1.7	3× higher
Procedure time (min)	31.0 ± 17.1	58.6 ± 36.5	105.6±42.8	−47 % / −53 % SD
Fluoroscopy time (min)	10.4 ± 5.4	13.9 ± 7.1	Not reported	−25 % / −24 % SD
Contrast volume (mL)	70.3 ± 27.5	Not reported	94.9 ± 42.5	−26 % / −35 % SD
Procedural success	20/20 (100 %)	—	98%	—

Sources: PARTNER 3 (Mack MJ et al., NEJM 2019, Supplementary Appendix Tables S3, S9, S17); SMART BEV (Herrmann HC et al., NEJM 2024, Supplementary Appendix Tables S7, S14).

"The software is quick to adopt as it is easy to use, it is dynamic, it avoids some extra fluoroscopy, it guides us to the right position, and it reduces procedural time, so integrating it into the workflow is very easy," **said Professor Stephen Worthley.**

The first day of use at Macquarie University Hospital, 6 patients were treated with the guidance of TAVIPILOT Software and the observed duration of the procedure was significantly decreased illustrating the short learning curve of the software.

TAVIPILOT Robot — first clinical results and platform vision

In the dedicated robotics session, Professor Worthley reported the first-in-human clinical experience with the TAVIPILOT Robot, the world's first AI-driven robotic platform for transcatheter aortic valve implantation. Data on the first 9 patients enrolled in Cohort 1 of the ongoing first-in-human program were presented.

The clinical program is structured in three sequential cohorts of 10 patients each, evaluating the robot in tele-operated mode (Cohort 1), then in combination with the TAVIPILOT software (open-loop AI-guided, Cohort 2), and ultimately in supervised autonomy (closed-loop robotic positioning under clinician supervision, Cohort 3).

Procedures were performed with Edwards SAPIEN 3 and SAPIEN 3 Ultra valves, with high procedural success and no device related complications in the initial cohort. Early operator feedback centers on two consistent observations: the robot brings marked intra-procedural stability during valve deployment and enables catheter positioning with millimeter-by-millimeter precision under direct operator control.

"I was pleasantly surprised by the accuracy and stability that the robot provides. Being able to control the catheter movement millimetre by millimetre changes what we can achieve at the moment of valve deployment. I think this can improve reproducibility and reduce procedural time in the future," **said Professor Stephen Worthley.**

About TAVIPILOT Software

TAVIPILOT Software is an AI-driven live intra-procedural guidance software for transcatheter aortic valve implantation (TAVI). It provides automated real-time detection of anatomical landmarks (aortic annular plane, non-coronary cusp, transcatheter valve position) and 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 is 510(k)-cleared by the US FDA (K243884,

July 2025) and is protected by seven patents. Commercial deployment in the US began in H2 2025 through a targeted customer release program.

About TAVIPILOT Robot

TAVIPILOT Robot is the world's first AI-driven robotic platform for TAVI, designed to operate together with the TAVIPILOT Software. The robot enables sub-millimetric catheter navigation and, in supervised (closed-loop) mode, automated valve positioning at the AI-computed optimal depth under clinician supervision. The clinical program is structured in three sequential cohorts of 10 patients (n=30 total). FDA clearance is targeted for the coming months, with commercial launch of the integrated platform planned for 2027.

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, procedure time, fluoroscopy time, contrast volume and implantation precision. The SAITO 1B pool (Sydney + Toulouse R2, n=20) provides the current benchmark reference against the pivotal PARTNER 3 and SMART trials.

About Carvolix

Carvolix is a French medical technologies company, commercial and clinical stage, founded by Truffle Capital (also founder of the top European biotech company), that aims to become a global leader in the treatment of structural heart diseases and brain strokes, the world's leading causes of mortality and disability. According to the Truffle 10 MedTech Index, Carvolix ranks number one in Europe and number six worldwide. Carvolix develops novel AI and imaging driven mini robots that make complex procedures doable by interventional cardiologists, as well as biomimetic heart valves.

For more information: www.carvolix.eu

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