PRESS RELEASE

Carvolix Announces Positive Results of the Post-marketing Clinical Program Evaluating the TAVIPILOT AI Software

- **Completion of three post-marketing clinical studies with a total of 30 patients in France and Australia.**
- **Excellent results with 100% procedural success and high clinician satisfaction.**
- **Targeted Commercial launch in the US progressing well**
- **Publication of the 2025 Universal Registration Document (URD).**

Aix-en-Provence, May 4, 2026 – Carvolix (formerly Affluent Medical) (ISIN: FR0013333077 – Ticker: CVX – "Carvolix" or the "Company"), 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 announced the successful completion of the post-marketing SAITO clinical program evaluating the TAVIPILOT AI-driven software during Transcatheter Aortic Valve Implantation (TAVI) procedures.

TAVIPILOT Soft is easy-to-use, AI-driven intra-operative software that tracks real-time anatomical and prosthesis landmarks. It enables precise and accurate heart valve positioning. Following FDA clearance in H2 2025 for commercial use in the US, the solution is being commercially deployed in the US through a targeted customer release.

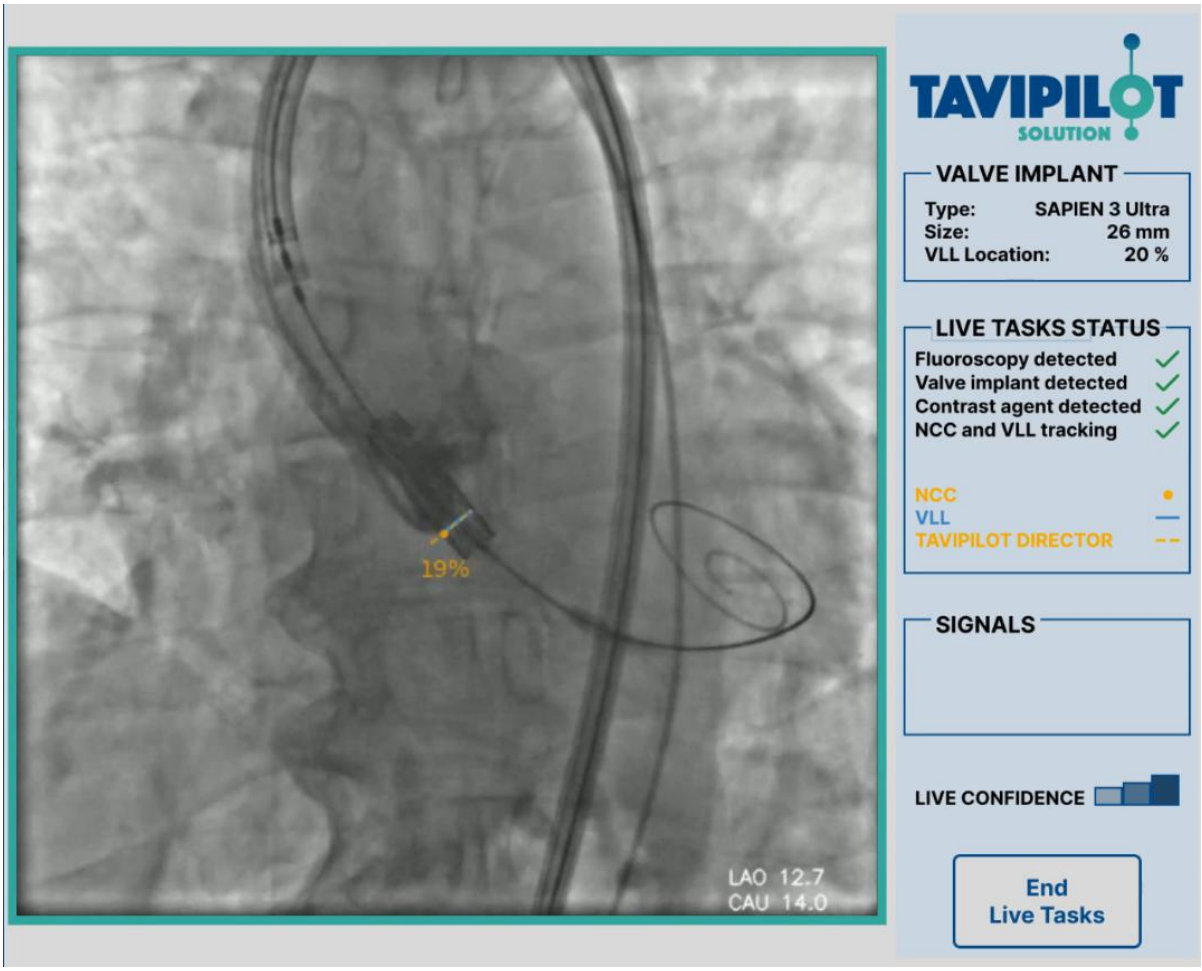
The SAITO clinical program, aiming at generating clinical evidence to support market acceptance in the US and CE mark registration in Europe, consisted of three prospective studies conducted in France and Australia, enrolling a total of 30 patients suffering from severe symptomatic aortic stenosis and undergoing transfemoral TAVI. The studies were performed at leading centers, including Clinique Pasteur in France (world leader for TAVI) and Macquarie University Hospital in Australia, by experienced interventional cardiology teams.

"*By delivering accurate, real time anatomical landmark visualization throughout TAVI procedure, TAVIPILOT SOFT empowers clinicians to make more confident decision during valve positioning. The result is a measurable improvement in care quality and standardized, optimized approach to procedural outcomes*" says **Dr. Didier Tchétché**, Interventional Cardiologist at Clinique Pasteur, Toulouse, France.

Across all studies, procedural success was achieved in 100% of cases, with successful navigation, positioning, and deployment of the valve prosthesis and no procedural mortality. All procedures were performed under local anesthesia, with no conversion to general anesthesia.

The TAVIPILOT AI-software was used throughout all procedures and operated without technical incidents, with no crashes, delays, or unexpected behaviors reported. Initially evaluated in a passive mode, the system was subsequently used in real time to actively assist valve positioning, under clinician supervision. It provided autonomous anatomical landmark detection and

continuous assessment of implantation depth, **supporting precise valve positioning** while maintaining full clinician control.



Analyses across the three studies confirmed accurate and consistent valve positioning across centers and operators.

Investigators consistently reported clear visualization of anatomical and valve markers, accurate depth measurements, and ease of use of the AI-driven TAVIPILOT software. The system demonstrated seamless integration into the procedural workflow and was associated with a reduction in operator workload.

Safety outcomes were consistent with routine TAVI practice, with no device-related adverse events reported across the program.

The results of the SAITO clinical program represent a significant milestone in Carvolix's commercial and clinical development strategy and support the continued evaluation and broader clinical adoption of TAVIPILOT as a real-time guidance solution for TAVI procedures.

Although Transcatheter Aortic Valve Implantation (TAVI) has become a well-established therapy over the past two decades, it remains a complex manual procedure with significant variability depending on operator experience and procedural conditions. While approximately 300,000 TAVI

procedures are performed each year in the United States and Europe, a large proportion of eligible patients—estimated at 1.7 million—still do not have access to this treatment. The current TAVI market, valued at around $8 billion according to Frost & Sullivan, continues to expand rapidly. In this context, Carvolix technologies are being developed to improve procedural consistency and facilitate broader adoption across large and smaller centers.

TAVIPILOT AI-Soft is designed to support clinicians during transcatheter aortic valve replacement procedures and is designed to be compatible with all cardiac imaging systems and with all the main TAVI heart valves available on the market.

UNIVERSAL REGISTRATION DOCUMENT AND FUNDRAISING UPDATE

The Company announces the publication of its 2025 Universal Registration Document (URD) and the approval of the financial statements by the board of directors. Its cash runway has been extended through the end of June 2026 by means of a current account advance from Truffle Capital, to provide Carvolix with additional time to finalize the second tranche of the €30 million fundraising round announced upon the Company's formation on January 30, 2026.

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 biomimetics heart valves.

Contacts:

CARVOLIX

Sébastien LADET
CEO
investor@carvolix.eu

SEITOSEI.ACTIFIN
Financial communication / Financial press relations
Ghislaine GASPARETTO / Jennifer JULLIA
+33 (0)6 85 36 76 81 / +33 (0)6 02 08 45 49
ghislaine.gasparetto@seitosei-actifin.com / jennifer.jullia@seitosei-actifin.com

PRIMATICE
Media relations France
Thomas ROBOREL de CLIMENS
+33 (0)6 78 12 97 95
thomasdeclimens@primatice.com

MC SERVICES AG
Media relations Europe
Maximilian SCHUR / Julia BITTNER
+49 (0)211 529252 20 / +49 (0)211 529252 28
carvolix@mc-services.eu