PRESS RELEASE

Carvolix announces positive 3-years clinical results for Kalios™, the only adjustable mitral ring

100% of patients met primary endpoint for mitral regurgitation

Kalios™ adjustable ring for mitral valve repair with positive 3-year results:

- Pivotal Optimise II study confirms efficacy and excellent safety profile at 3 years in 15 patients
- No device-related adverse events and all patients with mitral regurgitation ≤2+ at 3 years
- Company strategy to submit to FDA for potential commercialization in 2027.

Aix-en-Provence, June 15, 2026 - 5:45 pm 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 positive long-term clinical results from a pivotal study with its mitral ring Kalios™.

The company previously reported the 1-year results from the Optimise II study on 20 patients treated with the Kalios™ adjustable mitral annuloplasty device in patients with both degenerative (58%) and functional (42%) mitral regurgitation (MR), including 6 patients who underwent peri-operative or later adjustment without cardiopulmonary bypass. As the cohort matures, follow-up is now available in 20 patients at 2 years and 15 patients who reached 3 years of follow-up.

At 3 years, the results confirm both the safety and efficacy of the implant:

- No adverse events related to the device were reported up to 3 years;
- All evaluated patients have mitral regurgitation grade ≤2+ at 3 years which meet the primary endpoint of the study. Mitral regurgitation is evaluated by echocardiography with an independent core lab, confirming sustained long-term efficacy.
- The mitral valve leaflet coaptation length improved from 3.9 mm at baseline to 6.4 mm at 3 years, demonstrating significant and sustained improvement in structural valve function.

These long-term results confirm and consolidate the previously reported 1-year interim data and continue to validate the value proposition of Kalios™ mitral ring.

"The three-year data showing sustained efficacy in all patients including the adjusted ones is a promising outcome. The ability to downsize the ring on a beating heart is a new paradigm for mitral repair. It allows better sizing with a very easy step of adjustment available to all cardiac surgeons increasing the likelihood of a durable mitral repair" **said Sébastien Ladet, Chief Executive Officer of Carvolix.**

The analysis of the primary efficacy endpoint at 3 years of the adjustable mitral ring has been submitted to a peer-reviewed journal, and a related abstract is submitted for scientific communication.

About Kalios™

Kalios™ is the only mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral insufficiency at any time after implantation, repeatedly and with a beating heart, thereby avoiding a repeat open-heart operation. Carvolix estimates that Kalios™ would prevent repeat surgery for potentially 30-40% of patients within 5 years. The market for mitral valve repair surgery is estimated to be worth $1.5 billion in the US-Europe region, growing at 3.5% per year.

About the Optimise II Pivotal Clinical Study

The European Optimise II pivotal study on Kalios™ has been designed to assess the medical device's safety and efficacy in the surgical treatment of mitral regurgitation with catheter-based adjustment. In September 2023, the Company presented interim data on 20 patients treated in five clinical centers in Europe after one year of implantation. After one year, none of the patients had mitral regurgitation >2+, which met the study's primary objective. Up to 100 patients are to be enrolled to obtain 62 evaluable patients at 1 year. Treated patients will be followed for 5 years post-surgery.

Primary endpoints are the success rate of annuloplasty surgery defined by absence of MR of grade >2 and the safety at 1 year.

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.

For more information: www.carvolix.eu

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