PRESS RELEASE

Carvolix SA announces the incorporation of its subsidiary Carvolix Saudi LLC in Riyadh with the objective of building a potential MedTech manufacturing facility to serve the Saudi, European, Asian and potentially North American markets

- **Carvolix SA, founded by Truffle Capital, is an interventional MedTech company ranked No. 1 in Europe and No. 5 worldwide[1]**
- **Potential establishment of its state-of-the-art MedTech manufacturing facility in Saudi Arabia**
- **Five interventional medical devices developed by Carvolix for heart valve replacement and brain stroke treatment, using AI-guided mini-robotics and biomimetic valves for interventional cardiologists: a market estimated over €23 billion by 2030**
- **A flagship Saudi-French cooperation project aligned with the Kingdom's Saudi Vision 2030 and France's technological excellence**
- **Philippe Pouletty, M.D., founder of Carvolix and CEO of Truffle Capital, attends this Monday evening the official dinner hosted at the Élysée Palace by French President, Emmanuel Macron in honor of His Royal Highness the Crown Prince of Saudi Arabia.**

Aix-en-Provence / Riyadh, 24 August 2026 – Carvolix (ISIN: FR0013333077; CVX–Euronext), a French clinical- and early commercial-stage MedTech company specialising in the development of AI-guided mini-robots and biomimetic heart valves, today announces, on the occasion of the visit to Paris of His Royal Highness Prince Mohammed BIN SALMAN BIN ABDULAZIZ AL-SAUD, Crown Prince and Prime Minister of the Kingdom of Saudi Arabia, the potential establishment of its state-of-the-art industrial manufacturing facility in Saudi Arabia to serve the Saudi, European, Asian and potentially North American markets.

This initiative represents the first step in a long-term Saudi-French BioMedTech partnership led by Truffle Capital, founder and majority shareholder of Carvolix, with the ambition of potentially building a state-of-the-art facility in Saudi Arabia dedicated to the manufacture and quality assurance of medical devices for interventional cardiologists, and in the future establish biotechnology companies.

A world-class MedTech manufacturing facility

Carvolix Saudi LLC, the wholly owned Saudi subsidiary of Carvolix SA (France), considers potentially establishing a commercial-scale manufacturing facility dedicated to advanced, high-value cardiovascular and neurovascular medical devices, designed in accordance with international quality standards.

TAVIPILOT Software, Carvolix's first product, is used for autonomous aortic valve replacement and has already been cleared by the FDA (US Food and Drug Administration). Its commercial launch in the United States is under way, supported by Carvolix SA's pilot facility in Aix-en-Provence.

The Carvolix Saudi manufacturing facility would be developed in two potential phases:

- Phase I: manufacture of TAVIPILOT Robot, its sterile single-use cassettes and the KALIOS adjustable mitral ring; commercial production in Saudi Arabia is scheduled to begin in 2028.
- Phase II: expansion of the manufacturing facility to include ARTEDRONE, MITRAPILOT and other Carvolix products, together with an increase in international production capacity.

At full capacity, the facility could create approximately 250 highly skilled jobs in the manufacture of high-end medical devices, quality control, regulatory affairs and engineering. The majority of the production is expected to be exported, making Saudi Arabia a leading manufacturing and export hub for these state-of-the-art MedTech products.

"We are very excited about the opportunity for a long-term collaboration with Saudi Arabia, beginning with the potential establishment of a state-of-the-art manufacturing facility dedicated to innovative medical devices, to meet medical needs and supply markets worldwide. We will also explore other avenues of cooperation with a view to establishing Saudi–French biotechnology companies in the Kingdom,

[1] Truffle MedTech 10, 24 August 2026: Among listed companies at the *early commercial stage*

particularly to develop mRNA-based therapies for rare diseases and highly potent monoclonal antibodies," **said Philippe Pouletty, M.D., founder of Carvolix and CEO of Truffle Capital,** on the occasion of his attendance this Monday evening at the official dinner hosted at the Élysée Palace by the President of the French Republic in honor of His Royal Highness the Crown Prince of Saudi Arabia.

"Our mission is to democratize access to complex cardiovascular and neurovascular procedures by making them more predictable, standardized and accessible to interventional cardiologists and patients worldwide. Manufacturing to the highest international standards is an intrinsic part of the regulatory and clinical definition of a medical device. The establishment of our operations in Saudi Arabia is part of a long-term vision," **added Sébastien Ladet, CEO of Carvolix.**

Dr Mirvat Alasnag, Chair of the Saudi Advisory Board and member of the Carvolix SA Advisory Board said: *"There is a gap between the number of patients eligible for advanced interventional procedures and the number of patients who actually have access to them–a gap that will require not only increased capacity, but also the introduction of advanced technologies that shorten the learning curve. I see Carvolix's innovations as a transformation similar to those that have redefined standards of cardiac care over the past two decades."*

Five devices to democratise access to complex, life-saving procedures

Protected by more than 50 patent families, Carvolix's portfolio comprises five synergistic medical devices:

- TAVIPILOT Software: AI-guided intraoperative software for aortic valve replacement (TAVI), already cleared by the FDA and being commercialised by Carvolix in the United States;
- TAVIPILOT Robot: a mini-robot designed to autonomously perform the TAVI procedure, thereby increasing the number of clinical teams able to perform these complex procedures and the number of eligible patients;
- KALIOS: an adjustable mitral valve repair device;
- ARTEDRONE: a mini-robot designed to autonomously remove clots obstructing the cerebral arteries in the event of a stroke (the 2nd-leading cause of death and the 2nd-leading cause of acquired disability);
- MITRAPILOT: a biomimetic mitral valve and autonomous implantation system for the treatment of mitral regurgitation.

These advanced medical devices address major unmet medical needs and sizeable markets in which patient access to care remains constrained by procedural complexity, a shortage of highly specialized operators and variability in clinical outcomes. The objective is to enable many more interventional cardiologists to perform complex procedures more easily, extend access to these techniques to smaller centres, and provide effective emergency care for stroke patients, who remain largely undertreated today, whether or not they are in major urban centers. Carvolix's ambition is to become the global leader in interventional medical technologies in the field of AI-guided autonomous robotics for interventional cardiologists and specialized clinical teams, a market estimated at €23 billion by 2030.

Ranked No. 1 in Europe and No. 5 worldwide among interventional MedTech companies at early commercial stage[2], and the only French company in the "Top 10", Carvolix benefits from the support of Edwards Lifesciences, the global leader in heart valves (market capitalisation of approximately US$50 billion) and a minority shareholder in the company.

A strong and enduring institutional and scientific presence in Saudi Arabia

The project benefits from high-level Saudi and institutional interest from key stakeholders, including Saudi Arabia's Ministry of Investment (MISA), Ministry of Industry and Mineral Resources (MIM), Ministry of Health (MOH), Saudi Authority for Industrial Cities and Technology Zones (MODON), Saudi Industrial Development Fund (SIDF) and SFDA. The industrial site is currently being selected, and the project's financing structure is being developed through a combination of equity, debt and grants.

To support its expansion in Saudi Arabia, Carvolix has established a Saudi *Advisory Board* chaired by Dr Mirvat Alasnag, an internationally renowned interventional cardiologist at King Fahd Armed Forces Hospital in Jeddah. This *Advisory Board* brings together eminent Saudi cardiologists and surgeons to

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[2] Truffle MedTech 10, 24 August 2026: Among listed companies at *early commercial stage*

support the project's clinical, scientific and training components. She is also a member of the Carvolix SA *Advisory Board*.

A flagship Saudi-French cooperation project

Carvolix and Truffle Capital's establishment in Saudi Arabia forms part of efforts to strengthen economic and technological ties between France and the Kingdom. For France, it showcases national excellence in interventional cardiology, AI, robotics and state-of-the-art medical devices. For Saudi Arabia, it contributes to the emergence of a new world-class medical device sector, the creation of highly specialised local jobs and the strengthening of local content, fully aligned with Saudi Vision 2030.

This project forms part of a very long-term vision and will be accompanied by the SAF-MD training programme for Saudi talent, in collaboration with universities, training centres, hospitals and clinics in France and the Kingdom.

SAF-MD is the Saudi-French medical exchange and cooperation programme launched by Truffle Capital, Carvolix SA and Carvolix Saudi LLC and co-chaired by Prof. Stéphan Haulon and Dr Mirvat Alasnag. Built around training, professional immersion and scientific exchange, SAF-MD will provide medical teams from both countries with a framework for sharing experience in complex cardiovascular and neurovascular procedures. Technologies developed by Carvolix–TAVIPILOT Software, TAVIPILOT Robot, KALIOS, ARTEDRONE and MITRAPILOT–combining artificial intelligence, mini-robotics and biomimetic heart implants, will naturally be at the heart of these exchanges and open up new opportunities for medical and scientific cooperation.

About Carvolix

Carvolix is a French medical technology company at the commercial and clinical stages, founded by Truffle Capital (which also founded Europe's leading biotechnology company, ranked third worldwide), with the ambition of becoming a global leader in the interventional treatment of heart disease and stroke. Carvolix develops novel AI-powered mini-robots and biomimetic heart valves for interventional cardiologists. According to the Truffle 10 MedTech Index, Carvolix ranks first in Europe and fifth worldwide. For more information: www.carvolix.eu

About Truffle Capital

Founded in 2001, Truffle Capital is an independent European venture capital firm specialising in disruptive technologies in the life sciences (MedTech and Biotech) and information technology (Fintech and Insurtech) sectors. Truffle Capital's mission is to support the creation and development of innovative companies capable of becoming the leaders of tomorrow. It notably founded Abivax (market capitalisation: US$11 billion).
Led by Philippe Pouletty, M.D. and Bernard-Louis Roques, co-founders and co-CEOs,Truffle Capital manages €500 million in assets. The firm has raised more than €1.2 billion since inception and has backed more than 124 companies in life sciences and digital technology sectors. For more information, visit www.truffle.com

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