Compelling FIH Study results for CathRx's ElectroPulse™ PFA (pulsed field ablation) System in atrial fibrillation (AF) patients

- **Compelling mid-term ElectroPulse PFA first-in-human (FIH) Study results**
- **Progressing plans to commence CE Mark Pivotal Trial**
- **PFA system designed for electrophysiologists (EPs) as a new standard for precision and safety in AF ablation therapy**
- **FIH Study results presented in a late-breaking clinical trial session at APHRS November 14, 2025, in Japan**

Sydney, Australia - 14 November 2025; CathRx Ltd (**CathRx** or the **Company**), an Australian developer and manufacturer of cardiac electrophysiology catheters, is pleased to report mid-term results from its First-in-Human **(FIH)** study evaluating the company's ElectroPulse pulsed-field ablation **(PFA)** System for the treatment of symptomatic atrial fibrillation **(AF)**.

ElectoPulse PFA System - designed for EPs as a new standard for precision and safety in AF ablation

CathRx's ElectroPulse PFA System is designed to deliver controlled, non-thermal electrical pulses to create precise cardiac lesions to treat abnormal electrical signals responsible for AF. Developed over a 4+ year period, the system comprises the ElectroPulse PFA Variable Loop Catheter and Generator and is purpose-engineered to improve on first-generation PFA systems being rapidly adopted worldwide.

At 8 Fr (2.66 mm) in diameter, the PFA Variable Loop Catheter is one of the smallest ablation catheters in its class, developed to enhance safety by reducing the risk of perforation, bleeding and vascular access complications as well as providing more control over ablation areas. Designed as a multi-functional mapping and ablation catheter, it allows cardiac electrophysiologists (**EPs**) to perform the entire procedure with a single device streamlining workflow, lowering procedural time and cost, and improving efficiency.

The ElectroPulse PFA Generator is approximately 50% more powerful than first-generation PFA systems and incorporates an innovative real-time tissue contact sensing module. This provides instant feedback on electrode-to-tissue contact, allowing EPs to deliver energy precisely where needed, resulting in improved lesion accuracy, better durability, while reducing risks of unintended ablation.

Compelling FIH Study results support progressing to Pivotal Trial

The 60-patient study enrolled real-world Paroxysmal AF (**PAF**) and Persistent AF **(PersAF)** patients with significant co-morbidities.

Participants were divided into two cohorts:

- Cohort 1 (n=30, 40% PersAF patients): **Initial energy protocol**
- Cohort 2 (n=30, 57% PersAF patients): **Modified high-energy protocol**

All patients underwent pulmonary vein isolation **(PVI)** and posterior wall isolation **(PWI)** using the ElectroPulse System.

Safety Results:

- 0% device-related serious adverse events or complications
- 0% acute kidney injury, or phrenic nerve injury
- 0% primary safety endpoint events
- Median procedure time of 63 minutes and fluoroscopy exposure of 7 minutes

Repeat ablation and durably isolated Pulmonary Veins (PV):

- Cohort 1: 63.4% freedom from repeat ablation; 27.0% durable PV isolation.
- Cohort 2: 90.0% freedom from repeat ablation;100.0% durable PV isolation.

Effectiveness - freedom from AF recurrence:

Cohort 1: Initial energy protocol	18 Paroxysmal AF patients	**75.1% free from documented AF/AFL/AT** recurrence at 365-day follow-up.
	12 Persistent AF patients	**30.3% free from documented AF/AFL/AT** recurrence at 365-day follow-up.
Cohort 2: High energy protocol	13 Paroxysmal AF patients	**92.3% free from documented AF/AFL/AT** recurrence at median 272-day follow-up.
	17 Persistent AF patients	**72.5% free from documented AF/AFL/AT** recurrence at median 272-day follow-up.

Effectiveness - Symptomatic AF Recurrence

- **Cohort 1: 16.6%** of participants experienced symptomatic AF recurrence
- **Cohort 2: 3.3%** of participants experienced symptomatic AF recurrence

Although based on a relatively small FIH sample size, the Study findings demonstrate substantial improvements in efficacy, durability, and safety under the modified high-energy protocol, highlighting ElectroPulse's potential to significantly reduce repeat procedures.

CathRx is now progressing plans to commence patient enrolment in a CE Mark Pivotal Trial in Q4 2025 incorporating a larger, statistically significant sample size and the modified high-energy protocol.

Presentation of FIH Study results at APHRS 2025

The FIH study results were presented in a Late-Breaking Clinical Trial session at the Asia Pacific Heart Rhythm Society **(APHRS)** Scientific Meeting in Japan on 14 November 2025.

Professor Prash Sanders, the study's Principal Investigator and Director of the Centre for Heart Rhythm Disorders at the University of Adelaide and Royal Adelaide Hospital, commented on the FIH Study saying:

"This new device is far more precise and targeted than existing treatment options. The real-time feedback enables clinicians to create highly accurate lesions, improving efficacy and reducing the risk of unintended ablation. If this device can help clinicians treat AF successfully the first time and reduce repeat ablations, it will be a game changer."

Professor Sanders noted that up to half of Australian AF ablation patients require repeat procedures, costing the domestic healthcare system an estimated A$1.25 billion annually. *"Improving first-time success rates would not only transform patient care but also significantly reduce the economic burden of AF,"* he said.

CathRx's Managing Director, Ian Fong commented on the announcement saying:

"This study represents a major milestone for CathRx and an encouraging validation of our design philosophy. The ElectroPulse PFA System leverages our modular catheter platform technology platform which has been developed over a 10-year period and utilises novel and proprietary functions designed to improve on the performance of first-generation PFA systems, including: one of the smallest catheter in class for improved safety; a generator approximately 50% more powerful with contact sensing for greater efficacy; and dual mapping and ablation for improved procedural efficiency and cost savings. These promising FIH results demonstrate the system's potential to improve long-term patient outcomes and transform the way atrial fibrillation is treated worldwide."

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About CathRx Ltd

CathRx Ltd is an Australian medical device company developing next-generation electrophysiology technologies. Its patented modular ablation platform has been designed in collaboration with world-leading cardiologists and developed in Sydney. CathRx's mission is to make advanced, safer, and more efficient cardiac ablation accessible globally - improving outcomes for patients and families living with cardiac rhythm disorders.