BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

World’s smallest heart pump ready for human trial

11 June 2020 | News

FDA Approves Abiomed’s investigational device exemption application to start an early feasibility study with a first-in-human trial of the 9 French (Fr) Impella ECP™ heart pump

The United States Food and Drug Administration (FDA) has approved of the world’s smallest heart pump. The regulatory agency approved US based Abiomed’s investigational device exemption application to start an early feasibility study with a first-in-human trial of the 9 French (Fr) Impella ECP™ heart pump. Impella ECP (expandable cardiac power) will be studied in high-risk percutaneous coronary intervention (PCI) patients.

This is the world’s smallest heart pump. It achieves peak flows greater than 3.5 L/min and is delivered through a slender-profile sheath. It is un-sheathed in the descending aorta and expands to approximately 18 fr. Using a specifically designed pigtail, it crosses the aortic valve without a wire, backdown to 9Fr and removed with that same profile.

Michael R. Minogue, Chairman, President and Chief Executive Officer of industry sponsor Abiomed, declared that this is a “breakthrough technology” advancing “the field of heart recovery.” The company chief emphasized that the firm making substantial investments in pursuit of “smaller, smarter and more connected technology that forms the foundation of the company’s continued leadership in the field of mechanical circulatory support.”

Impella ECP includes a unique feature in that it sits across the valve with a soft atraumatic polyurethane cannula that opens only when the pump is flowing. If the pump stops for any reason, this cannula relaxes allowing the valve leaflets to close around it, maintaining valve competency.

Impella ECP is intended for short-term mechanical support in patients undergoing a high-risk PCI, to provide both circulatory support and left ventricular unloading. Hence, such a device potentially is of importance for interventional cardiologists, vascular access and closure are critical to the success of PCI procedures with mechanical circulatory support.

Typically these procedures require placement of sheaths or cannulas ranging from 13-24 Fr to perform the intervention. According to hypothesize this investigational product allows for a smaller access site, which could possibly increase adoption.

A prospective, multi-center, non-randomized early feasibility study will allow the sponsor (Abiomed), the study investigators and the FDA to make qualitative assessments about the safety and feasibility of the investigational product use in high-risk patients. Study investigators will commence this first-in-human trial later in the calendar year.