SMT announces positive results of Hydra™ Transcatheter Aortic Heart Valve published in *JACC: Cardiovascular Interventions*

Release Summary

- The results of the Hydra CE study are published in *JACC: Cardiovascular Interventions*
- The study evaluated 30-day and 1-year safety and performance of Hydra™ Transcatheter Aortic Heart Valve in the treatment of patients with symptomatic severe aortic stenosis who are at high or extreme surgical risk

19th January 2022, Mumbai, India

SMT (Sahajanand Medical Technologies Limited) today announces the publication of Hydra Transcatheter Aortic Heart Valve CE study data in the reputed JACC (Journal of American College of Cardiology) Cardiovascular Interventions journal[1]. This study was evaluating 30-days and 1-year safety and performance of the Hydra™ transcatheter aortic heart valve in the treatment of symptomatic severe aortic stenosis in cardiac patients at high or extremely high surgical risk.

The Hydra Valve system is approved in Europe (CE mark) and several other countries in Asia to treat people with symptomatic, severe aortic stenosis who are at high or extreme risk for open-heart surgery. Aortic stenosis is one of the most common and life-threatening heart valve diseases. It occurs when the aortic valve's opening narrows and restricts blood flow from the left ventricle to the aorta.[1] Patients with the disease can experience breathlessness, chest pressure or tightness, fainting, palpitations, fatigue, and heart murmurs. The condition can ultimately lead to heart failure.[2] While many people don't have noticeable symptoms, more than one in eight aged 75 and older has moderate or severe aortic stenosis, which reduces the heart's pumping ability.[3] Prior to TAVR, the standard of care for severe aortic stenosis was surgical aortic valve replacement, but not all patients were candidates for open-heart surgery. The Hydra Valve system provides a robust solution due to its flexible delivery system and supra annular leaflets and it can specifically become a good choice for patients who may have -

a) the risk of patient prosthesis mismatch
b) the risk of new conduction abnormalities
c) a tortuous anatomy including horizontal aorta due to flexible delivery system
d) or a need for future coronary interventions

In early 2021, the Genesis study on safety and performance of Hydra valve system which included 40 patients across 11 centres of India was published in the journal *Catheterization and Cardiovascular Interventions*[3]

The "*30-Days and 1-year Outcomes of TAVI with the novel Hydra THV – The Hydra CE study*"[1] published now in *JACC: Cardiovascular Interventions* is again a multicentre study conducted across 18 medical centres in European and Asia-Pacific countries led by Prof. Dr. Lars Sondergaard from Rigshospitalet in Copenhagen, Denmark which included as many as 157 patients with a mean age of 80 years.

The Hydra CE study has demonstrated that transcatheter aortic valve replacement with Hydra valve offered favourable efficacy at 1 year, providing a large effective orifice area and low transvalvular gradient as well as acceptable complication rates.

Elaborating more about the findings of this study, Prof. Dr. Lars Sondergaard said, "The Hydra THV system is designed to overcome some of the limitations of existing devices for TAVI. The delivery system has a low profile and is very flexible, which allows for transfemoral access even in challenging

anatomies. Furthermore, the THV is based on self-expanding technology with supra-annular leaflet position, which provides optimal hemodynamic performance. And the stent frame design with large cells allows for easy access to the coronary arteries, and the part in the left ventricle outflow tract has little interference with the conduction system. In addition, it is possible to re-sheath and re-position the THV, which allows for more accurate deployment. Therefore, the Hydra THV system offers several advantages compared to existing systems."

About Hydra

Hydra is re-sheathable, re-positionable and retrievable self-expanding transcatheter aortic valve ensuring patient safety and good results during deployment. It has advanced features like markers on the frame for accurate guidance while deploying the frame. Hydra has a supra-annular design which helps in larger aortic valve area and best-in-class hemodynamic performance post procedure.
Hydra has less metal in the outflow portion which in turn helps in flexibility and ease of delivery of the frame which reduces the chance of trauma to the aortic root while delivering the valve to the aortic annulus and the sealing skirt mitigates paravalvular leak. Non-flared inflow part of stent frame reduces interference with the conduction system. Large open cells facilitate easy future coronary access.

About SMT

Sahajanand Medical Technologies Ltd is a leading medical devices company that researches, designs, develops, manufacturers and markets vascular devices globally. SMT has the leading market share in the drug eluting stent ("DES") market in India, with a market share of 31% as of March 31st, 2021 of the total DES sales volume in India. SMT is also among the top five companies in terms of market share (by sales volume of DES) in each of Germany, Netherlands, Italy and Poland, as of March 31, 2021 (Frost & Sullivan). SMT has a sales presence in more than 69 countries including direct presence in 10 countries such as Germany, Poland, Spain, France, UK and Brazil. SMT offers products that are used in: (i) interventional cardiology, i.e., devices used for the treatment of blockages in heart vessels (coronary artery disease), such as coronary stents and catheters; (ii) structural heart therapy, i.e., devices used for treatment of abnormalities in the tissues, walls, and valves of the heart, such as transcatheter aortic valve implants ("TAVI") and occluders; and (iii) peripheral intervention, i.e., devices used for treatment of blockages in the blood vessels other than those of the heart, such as renal stents.

Reference:

1. https://www.jacc.org/doi/abs/10.1016/j.jcin.2021.09.004
2. https://onlinelibrary.wiley.com/doi/10.1002/ccd.29733

*The CE Mark indicates that the product satisfies requirements of EU Directives (EU : The European Union) and all products need to be CE certified to be sold in Europe.

Disclaimer

*SAHAJANAND MEDICAL TECHNOLOGIES LIMITED is proposing, subject to applicable statutory and regulatory requirements, receipt of requisite approvals, market conditions and other considerations, to make an initial public offering of its Equity Shares and has filed the draft red herring prospectus ("**DRHP**") with the Securities and Exchange Board of India ("**SEBI**") on September 27, 2021. The DRHP is available on the website of SEBI at www.sebi.gov.in, websites of the Stock Exchanges i.e. BSE Limited and National Stock Exchange of India Limited at www.bseindia.com and www.nseindia.com, respectively, and is available on the websites of the BRLMs, i.e. Axis Capital Limited, BofA Securities India Limited, Edelweiss Financial Services Limited and UBS Securities India Private Limited at www.axiscapital.co.in, www.ml-*

india.com, www.edelweissfin.com and www.ubs.com/indianoffers, respectively. Investors should note that investment in equity shares involves a high degree of risk and for details relating to such risk, please see the section titled "Risk Factors" of the RHP, when filed. Potential investors should not rely on the DRHP filed with SEBI for making any investment decision.

The Equity Shares offered in the Offer have not been and will not be registered under the U.S. Securities Act of 1933, as amended (the "Securities Act") or any other applicable law of the United States and, unless so registered, may not be offered or sold within the United States, except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and applicable state securities laws. Accordingly, the Equity Shares are only being offered and sold outside the United States in offshore transactions in reliance on Regulation S under the Securities Act and pursuant to the applicable laws of the jurisdictions where those offers and sales are made. There will be no public offering of the Equity Shares in the United States.

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