

CARDIONOVUM / China Grand Pharmaceutical and Healthcare Holdings Ltd Press Release:

RESTORE[®] Drug-Coated Balloon receives first Chinese FDA medical device registration certificate for two indications

For immediate release

Beijing, China and Bonn, Germany, October 28th, 2019.

RESTORE[®], CARDIONOVUM's innovative paclitaxel-coated balloon for coronary applications, has received market approval for China, making it the first drug-coated balloon (DCB) available in China to treat two indications: in-stent restenosis (ISR) and small vessel disease (SVD). The approval was given based on the impressive results from two solidly designed clinical studies in Chinese populations: RESTORE ISR CHINA and RESTORE SVD CHINA.

"I am extremely pleased by this approval" said Xiaojie Chen from Zhuhai Cardionovum Medical Device Co., Ltd and China Grand Pharmaceutical. "In-stent restenosis and small vessel disease are two urgent and challenging clinical areas in China. Powerful new therapies like RESTORE will help both physicians and patients."

RESTORE ISR CHINA and RESTORE SVD CHINA were both multicentre, randomised controlled trials designed and performed to the highest quality standards. RESTORE ISR CHINA included 240 subjects with coronary ISR at 12 sites in China. The performance of RESTORE matched the best-in-class Sequent[®] Please DCB on both in-segment and in-device late lumen losses at 9 months after the procedure, and on rates of target-lesion failure at one year.¹

RESTORE SVD CHINA was performed at 12 sites, enrolling 262 subjects with coronary small vessel lesions. RESTORE was non-inferior to the latest-generation Resolute[®] zotarolimus-eluting stent on percent diameter restenosis at 9 months, as well as on rates of target-lesion failure at one² and two years.³ In a substudy in patients with very small vessels (≥ 2.00 mm and < 2.25 mm) RESTORE was successfully employed with a very low procedural complication rate and no death, MI or thrombotic event. The results make RESTORE the first DCB with strong evidence in this vulnerable population.

"At CARDIONOVUM we are passionate about driving the future and RESTORE is one of our most innovative products" said Marina Izzo, CEO of CARDIONOVUM. "I am very proud of the Chinese elite investigators whose hard work laid the foundation for this

approval. RESTORE is the first and only DCB available in China to treat SVD. This is a great honour for us and a validation of our focus on performance-driven quality."

About ISR and SVD

ISR is a common problem. More than 10% of patients who receive a drug-eluting stent can expect to suffer from the complication.⁴ DCB treatment is highly appealing as a 'leave nothing behind' option that avoids introducing another layer of metal stent into the vessel. Small vessel diameter is a strong predictor of restenosis and target-lesion failure after PCI, particularly with bare-metal stent or plain old balloon angioplasty.⁵ The need for novel treatments is large: in daily practice, 30% and more of percutaneous coronary interventions (PCI) involve small coronary vessels.⁶ In these individuals, rates of repeat revascularisation can exceed 25%.

About RESTORE® and SAFEPAX® technology

RESTORE is a paclitaxel-coated balloon for coronary applications, specifically designed for ease of handling, high safety and precise drug delivery. It utilises SAFEPAX, the proprietary next-generation stable, homogeneous, paclitaxel coating. This amorphous, non-crystalline matrix is not affected by mechanical stress due to elastic, lipophilic, polymeric excipients. SAFEPAX is being investigated in a number of high-quality clinical trials.

About CARDIONOVUM

CARDIONOVUM, a medical technology company based in Bonn, Germany, develops and commercialises innovative medical devices such as new generation of DCB and drug-eluting stents for the treatment of coronary and peripheral artery disease. The company's pioneering range of DCBs is based on the SAFEPAX paclitaxel coating matrix which has the lowest wash-off rates on the market. The company's strong commitment to clinical research ensures a continually deepening and expanding evidence-base in support of the clinical benefits of our products.

About China Grand Pharmaceutical and Healthcare Holdings Ltd

China Grand Pharmaceutical and Healthcare Holdings Ltd is an investment holding company with subsidiaries principally engaged in the development, manufacture and sale of pharmaceutical preparations, medical devices, pharmaceutical intermediates, specialised raw materials and healthcare products. The company aims to become one of

the largest pharmaceutical and healthcare manufacturers in the People's Republic of China through organic growth and acquisitions.

¹ Yundai Chen et al. JACC: Cardiovascular Interventions, Volume 11, Issue 23, 10 December 2018, Pages 2368-2377

² Yida Tang et al. JACC: Cardiovascular Interventions, Volume 11, Issue 23, 10 December 2018, Pages 2381-2392

³ Jian Tian TCT (2019) 259

⁴ Cassese S, et al. Heart. 2014;100:153-159.

⁵ Price et al, JACC: Cardiovascular Interventions 10, 1381-1388 (2017).

⁶ Ho & Ong, The Lancet (2018), doi:10.1016/S0140-6736(18)31926-3.