

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

APERTO OTW® Drug Coated Balloon receives first Chinese NMPA Medical Device Registration Certificate for High Pressure DCB for Vascular Access

For immediate release

Beijing, China and Bonn, Germany - April 20, 2020

APERTO®, CARDIONOVUM's innovative paclitaxel-coated balloon for arterio-venous access, has received market approval for China, making it the first high pressure drug-coated balloon (HPDCB) available in China to treat obstructive lesions of native Arterio Venous Dialysis Fistulae. The approval was given based on the statistical superiority shown in a solidly designed clinical study in Chinese populations: APERTO AVF RCT CHINA.

"I am extremely pleased with this approval" said Xiaojie Chen from CARDIONOVUM China, also in his positions as the new CEO of CARDIONOVUM GmbH and Assistant to President of China Grand Pharmaceutical. "AVF patency is a challenging request of life-saving procedures. With the approval of APERTO®, we will be able to deliver a better clinical solution to Chinese patients, and improve their quality of life."

"APERTO AVF RCT CHINA" is a multicenter, randomized controlled trial designed and performed with highest quality standards. APERTO AVF RCT is the first AVF RCT study to archive statistical superiority vs. high-pressure POBA¹. In a population of 161 patients, treatment with APERTO® achieved superiority in freedom from restenosis at 6 months, and better intervention-free survival of both, the target lesion and target shunt at 12 months with equivalent safety. Alter, patients treated with APERTO® maintained patency for another three months¹.

"At CARDIONOVUM we are passionate about driving the future, and with APERTO® as one of our most innovative products" said Xiaojie Chen. "I am very proud of the Chinese elite investigators whose hard work laid the foundation for this approval. APERTO® is the first DCB which has been approved in China for the treatment of AVF stenosis. This is a great honor for us and a validation of our focus on performance-driven quality."

Investigators Statements



Prof. Dr. Qizhuang Jin, Peking University First Hospital, Nephrology Department,

PI of the "APERTO AVF RCT CHINA" trial, presented the study results at the Charing Cross Symposium in 2019 on behalf of the Chinese clinical research team of this project. The APERTO AVF China study is both, in line with the trend of the times and shows the level of Chinese research in the field, he said, "Compared with other countries, the work on the treatment of vascular access for hemodialysis started relatively late in China, and there is still a gap in the scientific research achievements compared to global standards. The APERTO AVF RCT CHINA study was carried out strictly following the standard of a multi-center, randomized controlled trial, which reflects the level and determination of China in this field in line with worldwide standards. I would like to see that APERTO[®] will be launched as soon as possible so that physicians can provide better long-term solutions for patients and conduct further research."



Prof. Dr. Zhengya Yu, Beijing Tong Ren Hospital, Vascular Surgery Department,

states: "Differently from the peripheral DCBs in previous studies, APERTO[®] adopts the unique patented SAFEPAX[®] coating technology. The coating is membranous, transparent, and smooth, and the amount of wash-off before reaching the target lesions and disgregation during inflation is small, so the total drug loss does not need to be high. The use of an amorphous drug realizes a rapid tissue absorption which only affects the target lesions. A higher safety outcome might be expected, but a continuous post-market observation is still needed."

About AVF

According to the article "Global, regional, and national burden of chronic kidney disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study" published in The Lancet, 2020², China had 132 millions of Chronic Kidney Disease patients, contributing 19% of the global patients. Among all CKD patients in China, around 0,45% of them were dialysis patients. With the approval of APERTO[®] we will be able to provide better clinical solutions to Chinese patients, and improve their quality of life.

About APERTO OTW[®] and SAFEPAX[®] Technology

APERTO[®] is a paclitaxel coated balloon for AVF applications, specifically designed for ease of handling, high safety and precise drug delivery. It is based on 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 is a medical technology company based in Bonn, Germany, and develops and commercializes innovative medical devices such as the new generation of drug coated balloons 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) Qizhuang Jin, Charing Cross Symposium in 2019

2) [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30045-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30045-3/fulltext)

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