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Sirtex Medical and China Grand Pharmaceutical announce SIR-Spheres® Y-90 resin microspheres milestone
SIR-Spheres® new drug application is accepted by the National Medical Products Administration of China

WOBURN, Mass. (November 25, 2020) -- [Sirtex Medical \("Sirtex"\)](#), a leading manufacturer of targeted liver cancer therapies, announced today that Sirtex with the support of its shareholder, China Grand Pharmaceutical and Healthcare Holdings Limited (CGP), has been notified of the acceptance by the National Medical Products Administration (NMPA) of the People's Republic of China of its new drug application (NDA) of SIR-Spheres® Y-90 resin microspheres.

With the NDA acceptance and according to relevant regulations on the review period for NDAs by the NMPA, Sirtex expects to receive a decision on the approval of SIR-Spheres for commercialization in China in the fourth quarter of 2021. However, the duration of approval procedures and final approval is subject to various factors. The indication included in the NDA is for the treatment of unresectable metastatic colorectal cancer (mCRC) in combination with fluorouridine adjuvant chemotherapy. In August this year, CGP and Sirtex received approval to file the NDA based on existing clinical trial data.

"We celebrate this achievement in our journey to provide a valuable treatment option to people with liver tumors from mCRC in China," said Kevin R. Smith, Chief Executive Officer of Sirtex. "We express deep thanks to the members of CGP, Sirtex China and our Global Regulatory, Quality Assurance, Operations and Medical teams as they navigated the regulatory process and secured acceptance of the NDA by the NMPA."

According to China's cancer statistics in 2015, the number of new cases of colorectal cancer in China is 376,300, of which more than half of the patients (around 188,000) are likely to have liver metastasis. In addition, the broader liver cancer treatment market is even larger, as according to the World Health Organization statistics in 2018, there were 841,000 new cases of HCC worldwide, of which 400,000 occurred in China, accounting for 47.6% of the total cases. This demonstrates the long-term prospects for the Sirtex entry of SIR-Spheres in China.

About Sirtex

Sirtex is a global healthcare business with offices in the U.S., Australia, Europe and Asia, working to improve outcomes in people with cancer. Sirtex's current lead product is a targeted radiation therapy for liver cancer called SIR-Spheres® Y-90 resin microspheres. More than 100,000 doses have been supplied to treat patients with liver cancer at more than 1,300 medical centers in over 45 countries. For more information, visit www.sirtex.com. SIR-Spheres® is a registered trademark of Sirtex SIR-Spheres Pty Ltd.

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