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Sirtex Medical and Grand Pharmaceutical Group Limited receive NDA approval of SIR-Spheres® Y-90 resin microspheres in China from the National Medical Products Administration

SIR-Spheres® Y-90 resin microspheres are the first therapeutic radiopharmaceutical approved by the NMPA in 2022

WOBURN, Mass. (February 9, 2022) – [Sirtex Medical \(“Sirtex”\)](#), a leading manufacturer of targeted liver cancer therapies, announced today with its shareholder, Grand Pharmaceutical Group Limited, that SIR-Spheres® Y-90 resin microspheres have been approved by the National Medical Products Administration (NMPA) for the treatment of patients with colorectal cancer liver metastases.

The NDA approval of SIR-Spheres for the Chinese market is the first therapeutic radiopharmaceutical approved by the NMPA in 2022 and is the only radioactive microsphere product approved by the NMPA based on clinical trial data obtained outside of China. The first procedure of selective internal radiation therapy (SIRT) using SIR-Spheres in China was successfully performed for a patient in September 2021, which at that time utilized the pilot implementation policy for commercialized medical devices in Hainan.

“We are proud to expand the reach of SIR-Spheres to China, where thousands of patients will now have access to this treatment option,” said Kevin R. Smith, Chief Executive Officer of Sirtex. “We express deep gratitude to our partners at Grand Pharmaceutical Group Limited, Sirtex China and our Global Regulatory, Quality Assurance, Operations and Medical teams for their incredible work and diligence that has allowed us to reach this goal.”

According to GLOBOCAN 2020, there were 410,000 new cases of liver cancer with 390,000 deaths in China. Additionally, in 2020, there were over 550,000 new cases of colorectal cancer with more than 280,000 deaths in China. Those morbidity and mortality rates are about twice as high as average global rates.

“The prognosis for patients suffering from liver cancer in China is poor with the five-year survival rate being roughly 12%,” notes Dr. Tang Weikun, Chairman of the Board at Grand Pharmaceutical Group Limited. “The use of SIR-Spheres to downstage liver tumors to the point where they can be surgically removed has been well documented in other countries. Our hope is that by expanding the reach of SIR-Spheres to China we will have a similar impact, with improved treatment outcomes and survival rates among patients diagnosed with liver tumors.”

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. For more information, visit www.sirtex.com. SIR-Spheres® is a registered trademark of Sirtex SIR-Spheres Pty Ltd.