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Sirtex Medical and China Grand Pharmaceutical announce landmark drug registration milestone

Approval issued to file new drug application for SIR-Spheres® Y-90 resin microspheres in China based on existing clinical trial data.

WOBURN, Mass. (August 27, 2020) — [Sirtex Medical \(“Sirtex”\)](#), a leading manufacturer of targeted liver cancer therapies, announced today that Sirtex and its shareholders, China Grand Pharmaceutical and Healthcare Holdings Limited (CGP), have been issued a “Notice of Drug Clinical Trial Approval” by the National Medical Products Administration (NMPA) of the People’s Republic of China.

The notice confirms that SIR-Spheres® Y-90 resin microspheres meet the relevant requirements for drug registration in China. With this confirmation, Sirtex is approved to file a New Drug Application (NDA) in the country.

“We are grateful to the members of CGP, Sirtex China and our Global Regulatory, Quality Assurance, Operations and Medical teams for their dedicated work in achieving this approval from the NMPA and navigating the complex regulatory process,” said Kevin R. Smith, Chief Executive Officer of Sirtex. “This is a critical milestone toward allowing us to provide a valuable treatment option to people with liver cancer in China.”

The announcement marks an important step in Sirtex’s journey to gain market entry into China, thanks to the company’s collaboration with its shareholder, CGP.

“We are proud of our team’s accomplishment and work to achieve this goal,” said Weikun Tang, Ph.D., General Manager of Sirtex China. “We are excited for the opportunity to work together with CGP to bring SIR-Spheres® Y-90 resin microspheres to our country’s patients.”

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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