

C-Ray Therapeutics Announced Approval of the First Radiation Safety License for Its Chengdu Facility in China

September 27, 2023, Shanghai C-Ray Therapeutics ("C-Ray"), an innovative radiopharmaceutical company in China, today announced the approval of the "**Class A Radiation Safety License**" of its first phase of research and manufacturing facility in Chengdu, China, from the Ministry of Ecology and Environment.

C-Ray aims to build up a total 66,600m² plant of integrated radiopharmaceutical development and manufacturing facilities, to meet the global cGMP (current Good Manufacturing Practice) standards for radiopharmaceutical manufacturing, including therapeutic and centrally distributed diagnostic products. The new facility allows the operation of α , β , and positron radioisotopes, and consists of commercial scale production suites, research space, translational research centers, multiple sterility lines, quality control, material storage, and packaging space.

In China, the Radiation Safety License is an important qualification and permission for radiopharmaceutical manufacturers, which is issued by the Ministry of Ecology and Environment. By obtaining such license, the company can properly carry out radioactivity-related work, and Class A is the highest level of this type of license. At present, very few Class A Radiation Safety License has been issued to the nuclear pharmaceutical enterprises in China, which makes C-Ray has a strategic advantage and leading position in the industry.

The first phase of the project covers a total area of 3 buildings, including 1,800m² of radiochemistry development labs, 5,000m² space for 10+ automated radiopharmaceutical production lines, as well as a 2,700m² research center for efficacy, distribution and imaging studies. The State-of-the-Art facility is designed and fully equipped to maximize the efficiency of manufacturing workflows, integrating all support areas surrounding multiply cleanroom space and multiple automatic processing production lines. The facility is also licensed to safely handle commercial scale of radionuclides.

The Facility's Chengdu location was chosen both for access to the pharmaceutical talent pool in the area and for logistical advantages of being in Sichuan province. With proximity to major transportation hubs of Chengdu Shuangliu International Airport, the facility can seamlessly manage both incoming raw material supply chains from local and overseas sources, and outgoing delivery to China and international customers on a just-in-time basis.

As a pioneer radiopharmaceutical company in China, C-Ray Therapeutics has opened its facility within two years after the project initiation. This facility, with its high capacity, automated, and intelligent equipment and product lines, makes C-Ray Therapeutics one of the first companies in the new generation of China-based radiopharmaceutical enterprises to gain capability to develop and manufacture innovative radiopharmaceuticals at a commercial scale. The Class A Radiation Safety License approval complements C-Ray's R&D, manufacturing, commercialization, and supply chain management capacities. It also marks a meaningful

milestone that C-Ray will enter a new stage of rapid growth to revolutionize the development of radioligand drugs and theragnostic marketing in China.

About Us

C-RAY THERAPEUTICS, founded in 2021, is an innovative company focusing on developing innovative, high-quality radiopharmaceuticals for oncology diagnosis and treatment in response to unmet clinical needs. The company has R&D centers and offices in Beijing and Shanghai, using the leading technology platform combined with advanced manufacturing facilities, as well as strategic cooperation with partners in innovative technology, to realize the industrial transformation of innovative radiopharmaceutical technology.