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## **CHINA ISOTOPE & RADIATION CORPORATION**

**中國同輻股份有限公司**

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

**(Stock Code: 1763)**

### **VOLUNTARY ANNOUNCEMENT**

## **CNGT Lu-177 DMF SUCCESSFULLY OBTAINED U.S. FDA FILING CLEARANCE**

This announcement is made by China Isotope & Radiation Corporation (“**China Isotope & Radiation**” or the “**Company**”) on a voluntary basis to keep the shareholders and potential investors informed of the latest business development of the Company.

The board of directors of the Company (the “**Board**”) is pleased to announce that, recently, Chengdu Gaotong Isotope Co., Ltd. (CNNC) (“**CNGT**”), a subsidiary of China Isotope & Radiation, received a confirmation letter from the U.S. Food and Drug Administration (“**FDA**”). The Lu-177 APIs DMF previously submitted by the Company successfully passed the review. This milestone signifies that the Lu-177 APIs DMF of CNGT has been recognised by the FDA with its DMF number activated, qualifying it for citation by downstream pharmaceutical formulation manufacturers. This achievement marks a crucial step in CNGT’s internationalisation strategy in core raw material sector of nuclear medicines.

The approval and activation of the Lu-177 DMF means that downstream formulation manufacturers may directly cite the relevant DMF number when submitting applications to the FDA for Lu-177-based radiopharmaceuticals, without the need to separately provide supporting documentation relating to APIs. This effectively streamlines the drug registration process, shortens regulatory review timelines and reduces application costs. For downstream partners, this establishes a more convenient and efficient compliant source of Lu-177 APIs, facilitating the acceleration of clinical research and commercialisation progress of Lu-177-based radiopharmaceutical products.

The successful completion of this DMF filing will bolster the confidence of existing and prospective customers, drive the negotiation and implementation of relevant cooperation projects, and inject new momentum into the business expansion of CNGT.

By Order of the Board  
**China Isotope & Radiation Corporation**  
*Chairman*  
**Xiao Yafei**

Beijing, the PRC, 22 September 2026

*As at the date of this announcement, the Board comprises Mr. Xiao Yafei and Ms. Huo Yingying as executive Directors; Mr. Chen Zan, Mr. Ding Jianmin, Mr. Zhang Guoliang and Ms. Chang Jinyu as non-executive Directors; and Mr. Poon Chiu Kwok, Ms. Chen Jingshan, Mr. Lu Chuang and Mr. An Rui as independent non-executive Directors.*