

## Nihon Medi-Physics Attains World’s First Manufacturing of Actinium-225 with Cyclotron on Production Scale for Investigational Drugs

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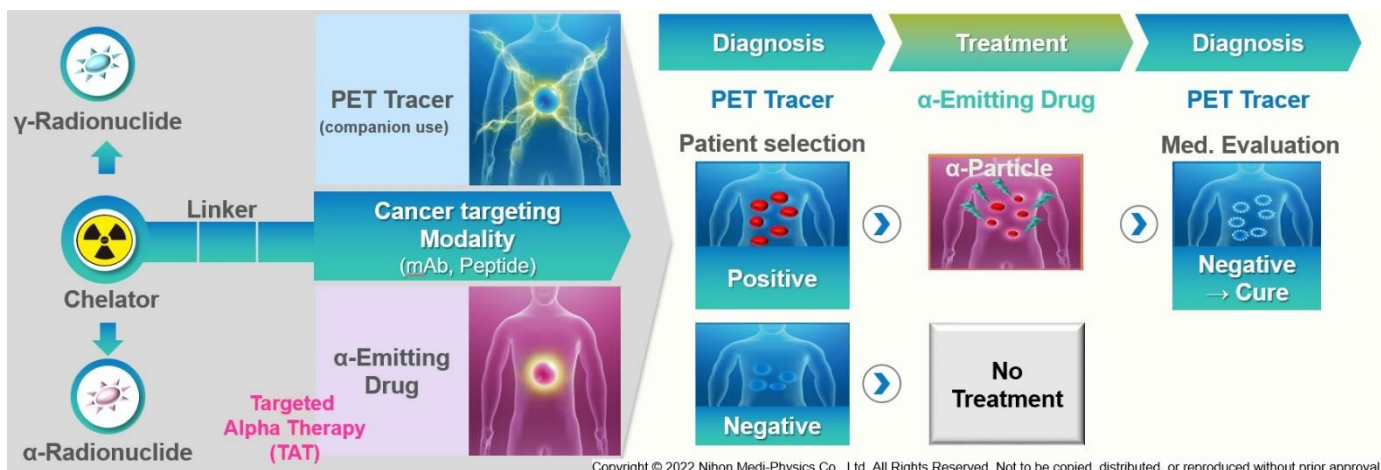
- Core Material Used for Targeted Alpha Therapy (TAT) Expected to Be Novel Treatment for Cancer -

Nihon Medi-Physics Co., Ltd. (NMP), a leading radiopharmaceutical company in Japan, announced on April 5, 2022, that the company has successfully manufactured actinium-225 (Ac-225), a core material used for Targeted Alpha (\*1) Therapy (TAT), on a GBq (\*2) scale at its drug research facility (\*3). The success represents the world’s first (\*4) manufacturing of Ac-225 with cyclotron at a quality level of materials for investigational drugs on a GBq scale.



Drug research facility “CRADLE Building”

TAT, in a form of Theranostics (\*5), is a new therapeutic concept to attack cancer cells in the body, applying a therapeutic agent in which alpha particle-emitting radionuclides that can kill cancer cells are bound to antibodies selectively accumulated in protein in cancer cells. In particular, following the report on its high therapeutic effects in patients with prostate cancer with systemic metastases in 2016 (\*6), clinical studies on TAT with alpha particle-emitting Ac-225 have been globally and increasingly conducted.



Conceptual diagram of NMP’s Theranostics

Active development and manufacturing of Ac-225, a radionuclide not naturally present, are ongoing accordingly. The manufacturing technology developed by NMP applies a commercially used small accelerator using radium-226 (Ra-226) as a material. This method using (p, 2n) nuclear reaction (\*7) is economically efficient and ensures more stable production than other methods with an electron accelerator similarly using Ra-226 as a material because the former uses less Ra-226.

NMP aims at early commercialization of Theranostics by promoting a research project (\*9) adopted in 2017 in (the second) Cyclic Innovation for Clinical Empowerment (CiCLE (\*8)) conducted by the Japan Agency for Medical Research and Development (AMED). NMP's manufacturing technology allows production of sufficient Ac-225 required for clinical development at its production facility. Thus, the company can further accelerate the research and development of TAT with collaboration among industry, academia and government.

## Notes

- \*1: Compared with other radiations, it is more biologically effective and has a shorter range. TAT is expected to become an effective treatment that intensively attacks cancer by forcefully destroying target cancer cells, while minimizing effects on healthy tissue because of its weak penetration ability.
- \*2: Gigabecquerel. A unit for measuring radioactivity. \*The article listed below (\*6) reported that each patient had received 0.1 megabecquerel of Ac-225 as a compound per kg of body mass four times.
- \*3: A research facility established in 2019 with an investment of 3.3 billion yen to promote research and development of Theranostics.
- \*4: Based on the research conducted by NMP in March 2022.
- \*5: The term "Theranostics" is a portmanteau, combining therapeutics and diagnostics. It signifies a concept that applies to therapies that convert radionuclides into therapeutic nuclides, following prevalidation with diagnoses to determine whether the drug can reach the target protein or not. Theranostics can connect therapies and diagnoses more closely, hopefully contributing to the realization of personalized medicine and effective utilization of medical expenses.
- \*6: C. Kratochwil et al., J Nucl Med. 2016, vol.57, p1941-1944.
- \*7: A manufacturing process utilizing the nuclear reaction by which two neutrons are released because of collision of the proton beam accelerated by the accelerator with radium-226 atoms and converted to Ac-225 atoms.
- \*8: CiCLE is one of the projects facilitated by AMED, aiming at utilizing government investment and supporting/arranging environment for research and development conducted with collaboration among industry, academia, and government, to develop innovative pharmaceutical products/medical devices (quoted from the AMED website).
- \*9: "Development of Antibody Labeling Therapies (with Alpha-Particle) and Companion Diagnostics, in Parallel with Maintenance of Drug Research Facilities to Embody the Concept of Theranostics."

## About Nihon Medi-Physics Co., Ltd.

Nihon Medi-Physics is engaging in ensuring stable supply and research and development of the products as a leading manufacturer of radiopharmaceuticals in Japan. Based on the technological proficiency and trust built over the years, the company is also working on research and development of "Theranostics (a combination of therapy and diagnosis)," which is a novel medical technology to provide optimal medical service to each patient, as well as on the dissemination of nuclear medicine in Asian countries by licensing its products. The company will continue contributing to society by creating values as a life science company.

Official website: <https://www.nmp.co.jp/eng/index.html>

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