

## Press Release

### PanTera Achieves Major Regulatory Milestones for its Actinium-225 Production

[Belgium, Mol], April 14<sup>th</sup>, 2026

PanTera announced today that it has reached three critical regulatory milestones in its mission to bring new hope to cancer patients by enabling the widespread use of radiopharmaceuticals for precision treatment. These achievements underscore the company's commitment to regulatory compliance, and advancing life-saving therapies, starting with the actinium-225 (Ac-225) based Targeted Alpha Therapy (TAT).

#### **c-GMP Achieved**

PanTera now operates in accordance with current Good Manufacturing Practice (c-GMP) principle, marking an important milestone in the development of its production capabilities. This advancement reflects the implementation of a robust quality system aligned with pharmaceutical standards, supporting the consistent production of pharmaceutical-grade Ac-225.

#### **Drug Master File (DMF) Submission**

In parallel, PanTera has submitted a type II Drug Master File (DMF) for its pharmaceutical-grade Ac-225 to the U.S. Food and Drug Administration (FDA). This submission provides a comprehensive dossier of the company's production process and quality controls for Ac-225 and enables streamlined regulatory access for clinical partners, supporting the integration of the company's isotope into ongoing and future clinical programs.

#### **Investigational Medicinal Product Dossier (IMPD-Q) Ready**

Finally, PanTera has developed a comprehensive quality dossier for its pharmaceutical-grade Ac-225 and is prepared to submit the drug substance quality documentation (IMPD-Q) to regulatory authorities in coordination with clinical trial applications submitted by sponsors. This milestone highlights the company's readiness to support the supply of Ac-225 for global research initiatives, facilitating the safe and standardized use of its isotope in the European scene of clinical trials. It reflects the company's ongoing commitment to accelerating the development of targeted alpha therapies for patients in need.

*"These recent milestones underscore PanTera's comprehensive expertise and technical capabilities in delivering Ac-225 that meet the most stringent compliance standards. Having demonstrated a unique ability to consistently provide high-quality products, PanTera further reinforces its commitment to supporting the advancement of clinical trials involving Ac-225."* said Sven Van den Berghe, CEO.

#### **A Game-Changer in Targeted Alpha Therapy**

Actinium-225 (Ac-225) is a promising alpha-emitting radioisotope used in Targeted Alpha Therapy (TAT) for cancer treatment. Its ability to deliver high-energy radiation directly to cancer cells while minimizing damage to surrounding healthy tissue makes it a valuable component in developing effective cancer therapies. PanTera supplies significant quantities of the material from its Early Supply today and is constructing its Commercial Scale production facility to secure access to Ac-225 for innovative cancer treatments worldwide.

## **About PanTera**

PanTera originated as a joint venture between IBA and SCK CEN, established to secure the large-scale production of actinium-225 (Ac-225), a promising alpha-emitting radioisotope for targeted cancer therapies. With a Series A funding of €95.6 million and all necessary building blocks available, PanTera is ideally positioned to develop cutting-edge production capabilities to enable the accessibility of innovative cancer treatments based on Ac-225.

PanTera's production strategy is built on two complementary approaches: an Early Supply production leveraging Thorium-229 decay, which is providing Ac-225 since May 2025, and a Commercial Supply production utilizing the Ra-226 photonuclear reaction to enable large-scale commercial production by 2028. These initiatives ensure a sustainable and scalable supply chain to meet the growing global demand for Ac-225.

### **For more information, please contact:**

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