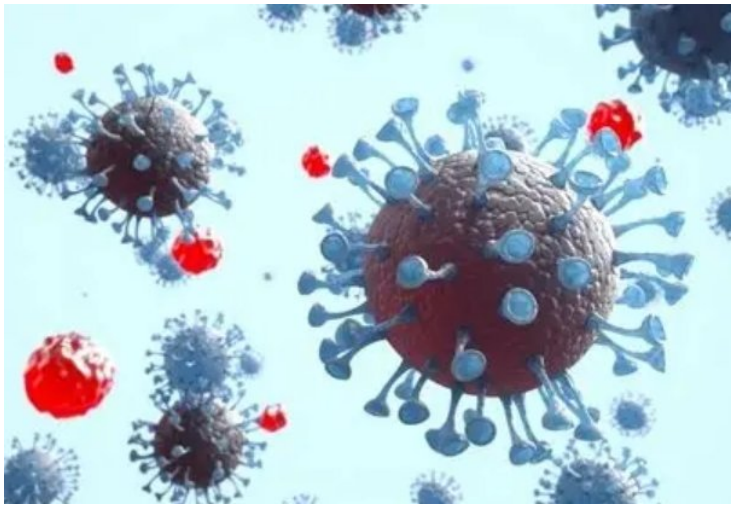
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Japan's Alpha Fusion and Kobe City Medical Center General Hospital establish At-211 investigational drug supply system

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Driving technology transfer and test manufacturing following regulatory approval to launch company-led af-001 trial



Japan's startup Alpha Fusion Inc. has announced a joint initiative with the Kobe City Medical Center General Hospital (KCGH) to establish a domestic supply system for investigational drugs utilising Astatine-211 (At-211). This collaboration significantly advances the foundational work for what is expected to be the world's first company-sponsored clinical trial using At-211.

KCGH has secured usage approval for At-211 from Nuclear Regulation Authority. The hospital is now proceeding with technology transfer and test manufacturing of the investigational drug for Alpha Fusion's lead pipeline, af-001 (targeting differentiated thyroid cancer), in preparation for clinical trial initiation. This pioneering effort is setting up a system to seamlessly translate At-211 drug discovery into clinical practice.

At-211 is recognised as an exceptionally promising radionuclide for targeted alpha therapy due to its short half-life (approx. 7.2 hours) and simple decay properties. However, a stable supply system for the investigational drug has been a major global hurdle, resulting in all clinical trials to date being academia-led.

In a breakthrough, the partnership with KCGH has established the crucial supply chain necessary to conduct clinical trials in Japan. KCGH operates a radioactive investigational drug GMP manufacturing facility. The hospital's extensive experience in manufacturing investigational drugs using short-lived radionuclides for PET (Positron Emission Tomography) will be adapted for At-211 formulations. Establishing this supply system represents a landmark achievement for global therapeutic development using At-211.

Alpha Fusion has already formed a network with Japanese academic cyclotron facilities capable of At-211 production. By incorporating the hospital's GMP manufacturing facility into the system, Alpha Fusion is building the world's first multi-site supply chain for an At-211 radiopharmaceutical, connecting radionuclide production, drug manufacturing, and clinical trial sites.