

## Chinese startup Norroy Bioscience receives US FDA approvals for kidney cancer imaging product

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### First China-originated innovative radiopharmaceutical to receive FDA Breakthrough Therapy Designation



Norroy Bioscience, a China-based clinical-stage biotechnology startup focused on innovative targeted radiopharmaceuticals, has announced that the US Food and Drug Administration (FDA) has granted both Breakthrough Therapy and Fast Track designations to  $^{68}\text{Ga}$ -NYM096, a potential radiopharmaceutical imaging agent targeting carbonic anhydrase  $\alpha^*$  (CA $\alpha^*$ ) for PET imaging of clear cell renal cell carcinoma (ccRCC).

$^{68}\text{Ga}$ -NYM096 is the first China-originated innovative radiopharmaceutical to receive FDA Breakthrough Therapy Designation. It is being developed as a non-invasive PET imaging agent to enable the characterisation of indeterminate renal masses identified by Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) and support the differentiation of ccRCC from non-ccRCC lesions.

The Fast Track designation is designed to facilitate the development and expedite the review of  $^{68}\text{Ga}$ -NYM096 by enabling more frequent interactions with the FDA, enhanced regulatory guidance throughout the clinical development process, and potential eligibility for rolling review of a New Drug Application (NDA).

Clear cell renal cell carcinoma is the most common subtype of renal cell carcinoma (RCC), accounting for approximately 70%–80% of RCC cases. According to the American Cancer Society, in 2026, an estimated 80,450 new cases of kidney (renal) cancer will be diagnosed in the US, and 15,160 people will die from the disease.