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Australia's Illuccix receives approval for prostate cancer imaging in Brazil

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First marketing authorisation in Latin America



Australia-based Telix Pharmaceuticals has announced that the Brazilian Health Regulatory Agency (Agencia Nacional de Vigilancia Sanitaria or 'ANVISA') has approved Illuccix (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), the company's lead prostate cancer imaging agent. Illuccix is the first and only PSMA-PET prostate cancer imaging agent to receive full regulatory approval in Brazil.

Illuccix, after radiolabeling with ^{68}Ga, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer.

The marketing authorisation is granted to Telix's partner R2PHARMA, Brazil's leading cold kit manufacturer, nuclear pharmacy and cyclotron network, and a subsidiary of GSH Corp Participações S.A. (Grupo GSH). Telix has provided Grupo GSH with an exclusive license to manufacture, distribute and market Illuccix® in Brazil.

PSMA-PET is a diagnostic technology demonstrated to detect advanced prostate cancer. ANVISA becomes the latest regulatory body worldwide to approve Illuccix®, which is already commercially available in Australia, Canada, New Zealand and the United States, and has recently been approved in the United Kingdom and in multiple countries within the European Economic Area (EEA).

Telix has also announced a joint venture (JV) with R2PHARMA to commercialise and distribute Telix's therapeutic and diagnostic radiopharmaceutical products in Brazil, building on the existing partnership established in 2019.