BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Australiaâ??s Telix Pharma receives US FDA Fast Track Designation for BiPASS Pre-Biopsy Prostate Cancer Imaging

September 30, 2026 | News

Evaluating 68Ga-PSMA-PET imaging alongside MRI in the pre-biopsy prostate cancer setting



Australia-based Telix Pharmaceuticals has announced that the United States (US) Food and Drug Administration (FDA) has granted Fast Track designation for the company's BiPASS® programme. BiPASS (Biopsy of the Prostate Avoidance Stratification Study) is evaluating gallium-68 (68Ga) PSMA-PET imaging in combination with MRI for the detection of prostate cancer prior to biopsy.

Biopsy can be stressful and painful for patients and may provide no meaningful diagnostic benefit, highlighting the importance of improved diagnostic tools earlier in the patient journey.

Telix recently completed enrollment in the Phase 3 BiPASS study of its proprietary 68Ga-PSMA-PET agents, Illuccix® and Gozellix® for pre-biopsy prostate cancer diagnosis. The ompany has positively engaged with the FDA on a new drug application (NDA) pathway and is planning its submission. The NDA pathway supports registration as a new product which, if approved, would broaden access to 68Ga-PSMA-PET imaging for a substantially larger patient population.

BiPASS builds on the clinical foundation established by the PRIMARY and PRIMARY2 studies. These studies demonstrated that combining 68Ga-PSMA-PET imaging with MRI can significantly improve detection of clinically significant prostate cancer while reducing unnecessary biopsies by almost 50 percent. BiPASS is not intended to replace biopsy when it benefits the patient but rather aims to improve the diagnostic pathway by helping clinicians determine which patients would benefit from biopsy and where biopsy should be targeted.