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PORTLAND LIFE SCIENCES ALTERNATIVE FUND

NEWS UPDATE

Telix Provides Updates on BLA Filing for Renal Cancer Imaging Agent TLX250-CDx

- The FDA identified a filing issue with sterility assurance, which Telix plans to address within ~90 days.
- The FDA did not note any issues with the safety or efficacy data for TLX250-CDx, which met all endpoints in its pivotal clinical trial.
- Telix confirms that the delay will not impact revenue and R&D expenditure forecasts for 2024.

Telix Pharmaceuticals (Telix) announced that the Food and Drug Administration (FDA) has not accepted its Biologics License Application (BLA) for TLX250-CDx, an investigational imaging agent for clear cell renal cell carcinoma. In providing transparency, Telix highlighted that the FDA decision was due to a filing issue related to the Chemistry, Manufacturing, and Controls (CMC) package, specifically concerning sterility assurance in the radiopharmacy production environment. Beyond the mentioned concern, the FDA has not indicated any deficiencies in the clinical or nonclinical data relating to the safety or efficacy of TLX250-CDx.

In response, Telix expects to complete remedial actions within approximately 90 days and resubmit the BLA, following which a discussion on decision outcomes could be requested with the FDA within 30 days. Dr. Christian Behrenbruch, Managing Director and Group Chief Executive Officer at Telix, noted that Telix has been collaborating closely with the FDA through a rolling review process due to the innovative nature of the product, expressing confidence in meeting the FDA's requirements and anticipating a clear path to product commercialization in 2025.

Having met all primary and secondary endpoints in its pivotal Phase III trial, TLX250-CDx represents a significant advancement as it could become the first targeted imaging agent for non-invasive detection of renal cancer, pending approval. The company expects the delay to be non-material, with no impact on revenue forecasts or research and development (R&D) expenditure for 2024.

For further details, please refer to the press release.

Telix is an investment currently held in the Portland Life Science Alternative Fund (the Fund); please visit the Fund's website for further information.

The Fund's objective is to provide positive long-term total returns by investing primarily in a portfolio of securities focused on companies active in the healthcare sector. The investment strategies focus on the area of precision oncology.

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RISK TOLERANCE

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