

FDA GRANTS ORPHAN DRUG STATUS TO RAD'S DUNP19 FOR OSTEOSARCOMA

- **Excellent recognition of the potential of DUNP19 to treat a rare bone cancer**
- **The FDA designation derives several benefits including tax breaks, user fee exemption and seven years market exclusivity post approval**
- **RAD acquired the DUNP19 technology from UCLA in April 2022**
- **Osteosarcoma has a significant unmet need with surgery and chemotherapy the current standard of care**

Radiopharm Theranostics (ASX:RAD, "Radiopharm" or the "Company"), a developer of a world-class platform of radiopharmaceutical products for both diagnostic and therapeutic uses, is pleased to announce that the US Food & Drug Administration (FDA) has granted Orphan Drug Designation for its DUNP19 technology for the treatment of osteosarcoma.

Orphan Drug Designation can be granted by the FDA for a drug or biologic product with the potential to diagnose, prevent or treat rare diseases and conditions. Recipients of the designation receive benefits and incentives including tax credits for qualified clinical trials, exemption from user fees and a potential seven years of market exclusivity following the drug's approval.

Radiopharm signed an exclusive licensing agreement with University of California Los Angeles (UCLA) Technology Development Group (UCLA-TDG) for the promising LRRC15 antibody "DUNP19" in April 2022.

LRCC15 expression is produced by cancer cells and the surrounding tumour microenvironment, but not by healthy normal tissues, and LRRC15 production is very high in aggressive and treatment-resistant tumours.

While currently available antibodies for cancer treatment omit tumour micro-environment (TME) cells, such as stromal and immune cells, which comprise >50% of tumour masses, the DUNP19 antibody has a unique ability to effectively find, internalize and destroy both cancer-, and TME cells. DUNP19 is a first-in-class therapy thanks to its unique dual action tumour targeting and to its fast internalization.

Osteosarcoma is a type of bone cancer that primarily affects children, adolescents and young adults, with surgery and chemotherapy the only currently available treatments. As aggressive osteosarcoma has one of the highest expressions of LRRC15, it's an ideal candidate for proof-of-concept testing.

Riccardo Canevari, CEO and Managing Director of RAD, said: "This is a very positive development for one of the latest additions to RAD's portfolio of assets, and demonstrates independent validation of the potential we saw in the DUNP19 technology. The resulting benefits of orphan designation will allow us to continue the development work of DUNP19's inventor Dr David Ulmert with an even greater level of confidence."

Authorised on behalf of the Radiopharm Theranostics board of directors by Chairman Paul Hopper.

**ASX ANNOUNCEMENT
9 SEPTEMBER 2022**



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