

FDA GRANTS RARE PEDIATRIC DISEASE DESIGNATION FOR RAD'S DUNP19 FOR OSTEOSARCOMA

- Further recognition of DUNP19's potential in a rare disease impacting children
- The RPD designation allows companies to receive a priority review voucher (at the time of marketing authorization) that can expedite approval or be transferred/sold to another company
- Follows Orphan Drug Designation announced 9 September 2022
- 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 Rare Pediatric Disease (RPD) Designation for its DUNP19 technology for the treatment of osteosarcoma.

The RPD program is aimed at advancing development of drugs with the potential to treat serious, rare pediatric diseases.

RPD allows companies to receive a priority review voucher (PRV) from the FDA at the time a marketing authorization is granted. A PRV can be used by the Company to expedite approval, or can be transferred/sold to other companies for use in the same manner. The price of two recent examples of PRVs sales have ranged from US\$105,000¹ to US\$110,000².

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 again excellent recognition of the work to date by Dr David Ulmert and his team and the potential for DUNP19 to make a significant difference to young patients in need. The RPD and associated PRV can be incredibly

¹ 7 Sep 2021, <https://ir.albireopharma.com/news-releases/news-release-details/albireo-sells-priority-review-voucher-prv-105-million>

² 9 Feb 2022, <https://investors.biopharm.com/2022-02-09-BioMarin-Sells-Priority-Review-Voucher-for-110-Million#:~:text=SAN%20RAFAEL%2C%20Calif.%2C%20Feb,lump%20sum%20payment%20of%20%24110%2C000%2C000>

valuable and we look forward to progressing the DUNP19 program and eventually taking advantage of this.”

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

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