ASX ANNOUNCEMENT
9 JUNE 2022

RAD adds brain tumor technology to portfolio

- Sublicensing of promising imaging & therapeutic radiopharmaceutical from leading US university, Case Western Reserve University (CWRU), Ohio
- PTPμ (PTPmu), the target, is a unique biomarker present only in tumor cells but not healthy cells
- The radionuclide carrying PTPμ-targeting agent holds the potential of *first in class* therapy in a range of tumor types
- Phase 1 brain tumor imaging study to commence in approx. 12 months
- Attractive commercial terms with modest cash obligations & low single digit royalties

Radiopharm Theranostics (ASX:RAD, "Radiopharm" or the "Company"), a world-class developer of cutting-edge radiopharmaceutical products for both diagnostic and therapeutic uses, is pleased to announce that it has signed an exclusive sublicensing agreement with NeoIndicate, LLC ("NeoIndicate") to a PTPμ-targeted radiopharmaceutical agent, which was developed at CWRU in Ohio, USA.

The sublicensing agreement gives Radiopharm the rights to develop the PTPμ-targeted agent as an imaging diagnostic and as a targeted radiopharmaceutical theranostic as part of its clinical development pipeline.

Highly specific, targeted agents for the detection, imaging and treatment of tumors are the future of precision medicine. When combined with low level radiation, the PTPμ-targeted agent functions as a highly specific Positron Emission Tomography (PET) imaging agent. When combined with high energy radiation, the PTPμ-targeted agent works as a radiopharmaceutical theranostic to destroy tumors.

The PTPμ-targeted agent labels invading tumor cells far away from the main tumor mass, achieving specific recognition of the full extent of an invasive tumor. It also recognizes this fragment in multiple tumor types including brain tumors and gynecological cancers.

The technology has shown encouraging pre-clinical data in human glioblastoma (GBM) tumor models[1–6], the focus of Radiopharm's initial studies and the most common and devastating form of brain cancer with a median survival of one year from diagnosis. The current standard of care is surgery followed by nonspecific radiation and chemotherapy. Due to the limited treatment options and poor prognosis, there is an immediate need for targeted therapies with high sensitivity and specificity.

Manufacturing of PTPμ is scheduled to commence in December 2022.

Dr. Susann Brady-Kalnay PhD, Professor in the Department of Molecular Biology and Microbiology at the CWRU School of Medicine, created the PTPμ-targeted agent. Her work spans 30 years of research into the cell adhesion molecules that regulate cancer cell progression and metastasis. Development of agents to improve tumor detection, imaging and treatment led Dr. Brady-Kalnay to found NeoIndicate, a woman-owned and operated biotech company in Wellington, Ohio, United States.

Radiopharm's CEO & Managing Director Riccardo Canevari said:

"We are eager to bring the highly sensitive and tumor specific PTPμ-targeted agent to our clinical development pipeline and plan to enter Phase 1 studies in approximately 12 months. The sublicensing agreement with NeoIndicate, who licensed the technology from CWRU, will build upon our portfolio of targeted radiopharmaceutical therapies. A number of tumor types can be detected with this novel PTPμ-targeted agent. Due to the limited treatment options and immediate need for therapies, we are focused on detecting and treating aggressive brain tumors with the PTPμ-targeted agents.

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"From a cash perspective the commercial terms are very attractive and can be absorbed into our existing cash flow forecasts."

A Research Agreement will provide Radiopharm with access to the inventor & NeoIndicate.

The technology is protected by a broad, long life patent portfolio to 2037.

Key terms of the Sublicence Agreement
Under the terms of the sublicence agreement, Radiopharm has secured the right to use the PTPμ-targeted agent conjugated to radiotherapy for the detection and treatment of human disease. The sublicence agreement commences with an effective date of June 9, 2022 and extends to the expiration or abandonment of the applicable patent rights.

The agreement sets out various development milestones commencing from IND approval.

The cost of the sublicence agreement and various milestone payments are not material to the Company in its initial period and are allowed for in the Company's existing research budget. No additional or new funding is required for commencement of the sublicence agreement. The sublicence agreement may be terminated by agreement, or according to common commercial termination provisions.

The agreement includes industry standard, single digit percentage, royalty for future sales of products developed under the agreement.

The agreement sublicenses Radiopharm to develop products using PTPμ; however, CWRU retains ownership of the PTPμ-targeted agent.

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

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References:

1. Burden-Gulley SM, Gates TJ, Burgoyne AM, Cutter JL, Lodowski DT, Robinson S, Sloan AE, Miller RH, Basilion JP, Brady-Kalnay SM. A novel molecular diagnostic of glioblastomas: detection of an extracellular fragment of protein tyrosine phosphatase mu. Neoplasia. 2010;12(4):305-16. PubMed PMID: 20360941; PMCID: PMC2847738.
2. Burden-Gulley SM, Qutaish MQ, Sullivant KE, Tan M, Craig SE, Basilion JP, Lu ZR, Wilson DL, Brady-Kalnay SM. Single cell molecular recognition of migrating and invading tumor cells using a targeted fluorescent probe to receptor PTPmu. Int J Cancer. 2013;132(7):1624-32. doi: 10.1002/ijc.27838. PubMed PMID: 22987116; PMCID: PMC3558593.
3. Covarrubias G, Johansen ML, Vincent J, Erokwu BO, Craig SEL, Rahmy A, Cha A, Lorkowski M, MacAskill C, Scott B, Gargesha M, Roy D, Flask CA, Karathanasis E, Brady-Kalnay SM. PTPmu-targeted nanoparticles label invasive pediatric and adult glioblastoma. Nanomedicine. 2020;28:102216. Epub 2020/05/16. doi: 10.1016/j.nano.2020.102216. PubMed PMID: 32413511; PMCID: PMC7573884.
4. Herrmann K, Johansen ML, Craig SE, Vincent J, Howell M, Gao Y, Lu L, Erokwu B, Agnes RS, Lu ZR, Pokorski JK, Basilion J, Gulani V, Griswold M, Flask C, Brady-Kalnay SM. Molecular Imaging of Tumors Using a Quantitative T1 Mapping Technique via Magnetic Resonance Imaging. Diagnostics (Basel). 2015;5(3):318-32. doi: 10.3390/diagnostics5030318. PubMed PMID: 26435847; PMCID: PMC4589153.
5. Johansen ML, Gao Y, Hutnick MA, Craig SEL, Pokorski JK, Flask CA, Brady-Kalnay SM. Quantitative Molecular Imaging with a Single Gd-Based Contrast Agent Reveals Specific Tumor Binding and Retention in Vivo. Anal Chem. 2017;89(11):5932-9. doi: 10.1021/acs.analchem.7b00384. PubMed PMID: 28481080.
6. Johansen ML, Perera R, Abenojar E, Wang X, Vincent J, Exner AA, Brady-Kalnay SM. Ultrasound-Based Molecular Imaging of Tumors with PTPmu Biomarker-Targeted Nanobubble Contrast Agents. Int J Mol Sci. 2021;22(4). Epub 2021/03/07. doi: 10.3390/ijms22041983. PubMed PMID: 33671448; PMCID: PMC7922223.

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