

## COMPLETION OF PHASE 1 IMAGING STUDY IN BREAST CANCER

- **40 patients at Shanghai General Hospital**
- **Uniformly excellent, easy to interpret images**
- **Outstanding target-to-background imaging**
- **One minor transient adverse event unrelated to drug product**
- **5 additional compassionate-use patients in Germany**
- **US IND for Phase 1 therapeutic study planned for 2022**

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 it has completed a Phase 1 study investigating the safety, dosimetry and efficacy of RAD201 in HER2 positive breast cancer subjects, in concert with its collaborators at Shanghai General Hospital in China and NanoMab in London, UK and Hong Kong, China.

The single domain antibody RAD201 is a novel single domain antibody, engineered to bind the imaging isotope Tc-99m which targets a protein called human epidermal growth factor receptor 2 (HER2) often associated with breast cancer. HER2 overexpression in breast cancer is often associated with aggressive disease and consequently, poor prognosis.

The study, conducted at Shanghai General Hospital under the direction of Dr Jinhua Zhao, imaged 40 histopathologically-proven breast cancer subjects. The procedure involved injecting the subject with RAD201, allowing time for the single domain antibody to localize at the HER2 positive cancer and clear from non-target organs, then imaging the subject two hours post-injection using a Single Photon Emission Computed Tomography (SPECT) camera. This procedure yielded uniformly excellent, easy to interpret images. The images demonstrated outstanding target-to-background, making quantification straightforward and RAD201 SPECT imaging a potentially fast and non-invasive way of gaining insight to HER2 overexpression in breast cancer primary and metastatic lesions. No concerning safety signal was observed, with only a minor grade 1 adverse event reported as unrelated to RAD201.

Dr Zhao, Director of Nuclear Medicine at Shanghai General Hospital and principal investigator on the study, said: *“The images obtained were outstanding with this novel radiotracer, 99m Tc-anti HER2 single domain antibody SPECT/CT, and can provide clinicians with much more holistic and useful information on HER2 expression in both primary and metastatic neoplasms in breast cancers than the conventional IHC method of assessing HER2 expression. These preliminary results are very encouraging for planning further studies to explore the potential of this single domain antibody in theranostics applications.”*

Felix Mottaghy, MD, Head of Nuclear Medicine Department, University Hospital Aachen, Germany said: *“We have employed 99m Tc-RAD201 in a compassionate use setting for patients with HER2 positive cancers. RAD201 SPECT/CT imaging non-invasively visualizes in vivo heterogeneity of HER2 expression in tumours and displayed a clear delineation of active tumour manifestations when compared to standard of care FDG PET/CT, confirming the theranostics potential of this tracer. In patients on anti-HER2 treatment, RAD201 imaging showed response to treatment more precisely than FDG PET/CT. Given its beneficial biodistribution, RAD201 labelled with therapeutic isotopes (e.g., rhenium-186 or -188 or lutetium-177) has the potential to become a theranostic agent.”*

Based on these encouraging results, RAD plans to accelerate development of RAD201 and to initiate a Phase 1 therapy study for RAD202 as a Company-sponsored Investigational New Drug (IND) recognized by the US Food and Drug Administration (FDA) in H1 CY22. RAD202 will be composed of the same single domain antibody construct as RAD201, but will incorporate the therapeutic, beta particle-emitting isotope, Re-188 that has the potential to kill cancer cells. This approach of demonstrating efficacy with imaging followed by targeted internal radiotherapy is consistent with RAD's vision for improving cancer therapy and the lives of patients living with oncological diseases.

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

**For more information:**

Riccardo Canevari  
CEO & Managing Director  
P: +1 862 309 0293  
E: rc@radiopharmtheranostics.com

Paul Hopper  
Executive Chairman  
P: +61 406 671 515  
E: paulhopper@lifescienceportfolio.com

Media

Matt Wright  
NWR Communications  
P: +61 451 896 420  
E: matt@nwrcommunications.com.au

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