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ASIA EDITION

'Cancer is an increasingly important health issue in the APAC region'

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Australia's Telix Pharmaceuticals is developing an advanced portfolio of radiopharmaceuticals products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer. Recently Telix announced the establishment its Japanese subsidiary and the appointment of the first two members of the Japanese leadership team. Speaking to BioSpectrum Asia Magazine, Dr Shintaro Nishimura, President and Chief Operating Officer of Telix Japan, elaborated on APAC's oncology market as well as opportunities and challenges in the Japanese market for radiopharmaceutical products.

Globally, the radiopharmaceutical medicine market is expected to reach USD 13.8 billion by 2024, according to a new report by Grand View Research. The market is driven by increasing number of cancer cases and rising awareness about nuclear medicine. Radiopharmaceuticals are pharmaceutical formulations comprising radioactive isotopes that are used in diagnosis and therapeutics. They contain a radioactive substance that is used in the treatment of cancer and cardiac and neurological

disorders. The conventional chemotherapy methods are being replaced by more convenient therapeutic radiopharmaceuticals for oncology and cancer treatment, which opens up new avenues in the radiopharmaceuticals market. The convenience of the treatment with minimally invasive techniques attracts more patients towards radiopharmaceuticals mode of treatment as compared to chemotherapy.

Nuclear medicine also helps detect the presence of disease in its earliest stages and is one of the most favorable drivers of the market, as public awareness about chronic diseases is increasing. Increasing diagnostic nuclear medicine procedures is supporting the growth of the market and experts indicate that use of radiopharmaceuticals in diagnosis is growing at over 10% per year throughout the world.

The past decade has seen a mammoth rise in cancer cases and other lifestyle disorders in APAC and thus, this regions is expected to register fastest growth in nuclear medicine space in comparison to other global countries. Research reports elaborate that nuclear medicine practice in Japan is in high demand with a significant increase in cancer cases in recent years. Furthermore, China and India are boosting the growth of the Asia Pacific nuclear medicine market with increasing demand for treatment and diagnosis of Alzheimer's and Parkinson's disease.

With many unique advantages, radiopharmaceuticals offer clear potential for players in emerging Asian countries as there is a need to broaden healthcare coverage and address unmet medical needs. Realizing the market potential, recently several Asian companies have been increasing their focus on radiopharmaceuticals.

Entering the Japanese market, Telix Pharmaceuticals , an Australian biopharmaceutical company focused on the development of radio pharmaceutical diagnostic and therapeutic interventions recently announced the establishment Telix Pharmaceuticals (Japan) ("Telix Japan") and the appointment of the first two members of the Japanese leadership team.

Telix Japan is wholly-owned operating subsidiary of Telix Pharmaceuticals Limited. The purpose of the subsidiary is to support the Company's Japanese clinical and radiopharmaceutical manufacturing activities and to establish a commercial footprint in the Japan, an important market for Telix's products. Telix is developing an advanced portfolio of oncology products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer.

Recently Telix Pharmaceuticals also inked a manufacturing deal with JFE Engineering Corporation in order to develop and make Telix's products available to Japanese cancer patients.

To lead the Telix Japan activities, Dr. Shintaro Nishimura and Dr. Takeshi Oka have been appointed as President and Chief Operating Officer, and Chief Medical Officer (Japan), respectively.

Speaking to BioSpectrum Asia Magazine, Dr Shintaro Nishimura, President and Chief Operating Officer of Telix Japan, elaborated on APAC's oncology market as well as opportunities and challenges in the Japanese market for radiopharmaceutical products.

Why was Japan chosen as a destination for expansion?

Telix chose Japan as a destination for expansion because it is potentially a significant market for Telix's products.

Historically, Japan has been slow to adopt advanced nuclear medicine due to restrictions on importing nuclear material, however, recent healthcare policy developments in the country has recognized the cost-effectiveness of molecularly-targeted radiation (MTR) technology. As such, there is significant momentum to develop domestic capacity to address the oncology needs of Japan's rapidly ageing patient population.

In light of these macro factors, there is significant commercial opportunity for Telix in Japan, and considerable interest in our oncology pipeline from leading nuclear medicine clinics. As such, the company established a Japanese subsidiary in January 2018, and we hope to use this high level of clinical engagement to obtain the additional data required to support product approval in Japan in the future.

What according to you are the major opportunities and challenges for Telix products in the Japanese market?

Japan is the prospectively the second largest market for Telix's products after the United States due to its growing cancer patient population. However, one obstacle faced by radiopharmaceutical companies is the difficulty of importing radioactive isotopes into the country. As such, there is significant clinical interest in the prospect of domestic production of new medical isotopes and, consequently, novel imaging and therapeutic radiopharmaceutical products, especially in oncology.

To address this issue, we were pleased to announce that Telix signed a manufacturing partnership with JFE Engineering

Corporation (JFE), an engineering and manufacturing company with extensive expertise in radiopharmaceutical manufacturing, in December 2017. This partnership will see the production of ^{89}Zr (Zirconium) in mid-2018 - the first commercial production of this isotope in Japan. The Zirconium isotope is critical to Telix's diagnostic imaging portfolio - particularly for TLX-250, our lead program for imaging for renal cancer.

Please throw some light on Telix's further expansion plans

The company's growth strategy involves commercial collaboration and partnering with leading radiation oncology and pharmaceutical companies that have an active interest in Telix and the radiation oncology space generally. Clinical and academic collaborations are also important; hence our recent announcement with Memorial Sloan Kettering Cancer Centre, one of the world's leading cancer hospitals. We are also selectively expanding our portfolio through selective acquisitions or additional partnerships, while also investigating indication expansion opportunities for assets within our existing portfolio.

Please give us an overview of Telix's product pipeline

Telix is an Australian biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or molecularly-targeted radiation (MTR). The Company is developing an advanced portfolio of oncology products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer. The company is listed on the Australian Securities Exchange as "TLX".

The company's portfolio of clinical programs include:

- TLX-250: for the diagnosis and treatment of renal (kidney) cancer, which is the Company's lead program and currently in Phase III and Phase II
- TLX-591: for the treatment of prostate cancer, currently in Phase II
- TLX-101: for the treatment of brain (glioblastoma) cancer, currently in Phase I

How is the APAC market for oncology products?

Cancer is an increasingly important health issue in the APAC region given the ageing population and changes to lifestyles associated with growing economic development and epidemiologic transition, and this is especially the case in Japan. Japan needs cost-effective therapeutic tools and radiopharmaceuticals have a very favorable cost-benefit equation. Generally speaking the global pharmaceutical industry has recognized the growth opportunity for both diagnostic and therapeutic medicine in Asia's healthcare market. Asia remains price-sensitive but the market is also under-served. In particular, for Telix's lead program TLX-250, the region is estimated to have the fastest growth rate for the kidney cancer drugs market – over 6% - due to the increasing patient base and growing disease awareness. Prostate cancer is also on the rise and part of our clinical activities in Japan is better understanding the differences in prostate cancer biology between "western" and Japanese men.

In general, Asian countries have lower rates of kidney cancer compared to North American and European countries, but Japan shows higher incidences of the disease – and most other cancers – than other Asian countries.