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Telix Pharmaceuticals Limited Acquires TheraPharm GmbH

Melbourne (Australia) and Baar (Switzerland) – 30th November 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') announces it has entered into an agreement with Scintec Diagnostics GmbH ('Scintec') to acquire TheraPharm GmbH ('TheraPharm'), a Swiss-German biotechnology company developing innovative diagnostic and therapeutic solutions in the field of hematology.

The acquisition of TheraPharm provides Telix with access to a portfolio of patents, technologies, production systems, clinical data and know-how in relation to the use of Molecularly Targeted Radiation (MTR) in hematology and immunology. TheraPharm is developing antibody MTR technology against CD66, a cell surface target highly expressed by neutrophils (a type of granulocyte, a category of white blood cell) and tumor-infiltrating lymphocytes. As such, the technology has potentially very broad applications in the diagnosis and treatment of hematologic diseases (e.g. blood cancers), infection management and a variety of lymphoproliferative diseases. Of particular interest is the demonstrated use of the technology to safely and effectively condition patients prior to bone marrow stem cell transplant.

Summary of Benefits to Telix from the Acquisition of TheraPharm:

1. A **diagnostic imaging product** (^{99m}Tc-besilesomab, marketed as Scintimun®) targeting white blood cells, for the purpose of locating areas of inflammation or infection in patients with suspected bone infection (osteomyelitis). Scintimun® is an approved product in Europe, currently sold and marketed by Curium Pharma in certain countries.

2. Scintimun® has significant potential for **expanded clinical indications** for serious diseases that represent an unmet medical need.

3. A **therapeutic product** (^{90}Y-besilesomab, referred to as ^{90}Y-anti-CD66-MTR) for the purpose of bone marrow conditioning (BMC) in patients prior to undergoing hematopoietic stem cell transplant (HSCT) for the treatment of blood cancers (hematologic malignancies) and various related conditions. ^{90}Y-anti-CD66-MTR is supported by highly promising clinical safety and efficacy data from phase I and II clinical trials, and has been granted orphan drug designation (ODD) status in Europe for the broad indication of BMC for HSCT.

4. ^{90}Y-anti-CD66-MTR has significant potential for fast track development for the treatment of systemic amyloid light-chain amyloidosis (**SALA**), a rare disease with a poor prognosis and an estimated prevalence of 30,000 and 45,000 patients in US and EU, respectively. Telix estimates the addressable market value for the SALA indication at ~USD $600M for US/EU5.

5. Beyond SALA, ^{90}Y-anti-CD66-MTR has therapeutic potential across a very broad range of stem cell transplant settings including for **multiple myeloma** and **leukemia,** for which there is already compelling preliminary evidence of clinical utility.

6. **Manufacture** of the therapeutic product, which contains the radioisotope yttrium-90 (^{90}Y) is uniquely suited to Telix's Seneffe (Belgium) manufacturing facility. ^{90}Y has already been added to the Seneffe production license in anticipation of this transaction.

Summary of Consideration for the Purchase of TheraPharm:

Following completion of the transaction, Telix will acquire all of the issued capital of TheraPharm via a Share Sale Agreement comprising the following key terms:

- **Upfront payment**: EUR €10.2M (~AUD $16.5M) upfront payment comprising: 1) EUR €10.0M (~AUD $16.2M) in Telix ordinary shares based on the 10-day volume-weighted average price ('VWAP') at the date of completion; and 2) EUR €0.2M (~AUD $0.3M) completion payment.

- **First earn-out component**: EUR €5.0M (~AUD $8.1M) cash payment upon successful completion of a phase III pivotal registration (approval) trial with ^{90}Y-anti-CD66-MTR that meets the primary endpoint, for the first therapeutic indication only.

- **Second earn-out component**: EUR €5.0M (~AUD $8.1M) cash payment upon approval of ^{90}Y-anti-CD66-MTR in either United States or Europe, for the first therapeutic indication only.

- **Third earn-out component**: 5% royalty calculated on net sales for the first three years of sales of therapeutic products based on ^{90}Y-anti-CD66-MTR from the date of first approval (US or EU).

- **Escrow:** As part of the Share Sale Agreement, Scintec will have its shareholding subject to escrow for 24 months from the completion date.

Completion of the transaction is expected to occur within 5–7 days from the date of this disclosure, pending the novation of certain clinical and production agreements to Telix.

Telix CEO, Dr. Christian Behrenbruch stated, "Telix is committed to extending and improving the lives of patients with serious diseases. As such, the acquisition of TheraPharm and its MTR assets are uniquely aligned to Telix's mission and technical strengths in antibody engineering and radiochemistry. TheraPharm's technology has a significant role to play in BMC and stem cell transplantation across a broad range of blood cancers and rare diseases. The current approach to BMC employs highly toxic drugs that have a poor morbidity and mortality profile, and for which many patients are ineligible. MTR offers an excellent safety profile that may greatly expand the number of patients able to undergo life prolonging stem cell transplantation while greatly reducing the hospitalisation burden and cost associated with such procedures."

TheraPharm co-founder and Managing Director, Dr. Klaus Bosslet added, "Over the past 5 years, TheraPharm, in collaboration with Dr. Kim Orchard from the University of Southampton (UK), has made excellent progress developing ^{90}Y-besilesomab for the treatment of hematologic cancers and several related conditions including multiple myeloma, leukemia and amyloidosis. This unique asset is a logical addition to Telix's portfolio, offering a potentially rapid development path to a commercial product for the treatment of patients with SALA, while at the same time having potentially broad applications for stem cell transplantation in patients with more common cancers of the blood, including multiple myeloma and leukemia. We look forward to joining the Telix team in order to expedite the development of products for this under-served field."

About Hematopoietic Stem Cell Transplant (HSCT)

Bone marrow conditioning (BMC) followed by hematopoietic stem cell transplantation (HSCT) is presently performed to treat patients with hematologic malignancies (blood cancers), with the objective of extending patient survival or achieving cure. HSCT is also performed for a broad range of non-cancer conditions. HSCT is preferentially performed in countries of high income (Europe

>30,000, Americas >20,000, worldwide >65,000 p.a., respectively) and has grown at a rate of ~5% annually since the late 1980s.[1]

Hematopoietic Stem Cell Transplant (HSCT) indications that may benefit from ^{90}Y-anti-CD66-MTR bone marrow conditioning (BMC)	
Hematologic Cancer Indications	Non-Cancer Indications
• Acute myeloid leukemia (AML) • Acute lymphoblastic leukemia (ALL) • Chronic myeloid leukemia (CML) • Chronic lymphocytic leukemia (CLL) • Multiple myeloma • Non-Hodgkin lymphoma • Hodgkin disease • Myeloproliferative disorders • Myelodysplastic syndromes • Neuroblastoma • Germ cell tumors	• SALA • Aplastic anemia • Pure red-cell aplasia • Paroxysmal nocturnal hemoglobinuria • Fanconi anemia • Thalassemia major • Sickle cell anemia • Severe combined immunodeficiency • Wiskott-Aldrich syndrome • Hemophagocytic lymphohistiocytosis • Inborn errors of metabolism • Epidermolysis bullosa • Severe congenital neutropenia • Shwachman-Diamond syndrome • Diamond-Blackfan anemia • Leukocyte adhesion deficiency • Autoimmune disorders – lupus, systemic sclerosis • Potentially – rheumatoid arthritis, multiple sclerosis, Crohn's disease, ulcerative colitis

Due to its demonstrated efficacy, further adoption of HSCT is expected in a variety of diseases. This is despite the significant limitations of existing BMC regimens: [2]

- Relatively high morbidity and mortality.
- Potential of prolonged hospitalisation times, particularly for intensive dosing regimens.
- Risk to older patients and patients with co-morbidities often limits use.
- Higher risk profile in pediatric patients.

^{90}Y-anti-CD66-MTR offers significant advantages as an ideal BMC agent for HSCT including:

- Greatly reduced toxicity and a significantly better tolerability profile compared with chemotherapeutic approaches.
- Significantly reduced hospital stays, suitable for outpatient administration.
- A highly favourable health economic profile, primarily due to reduced hospitalisation times and lower intensity of care requirements.
- Applicability to older patients and patients with other health conditions (e.g. impaired renal function).
- Potential for pediatric use already demonstrated.

[1] Orchard K, Bosslet K. Antibody Targeted Radio Therapy (ATRT) for Conditioning before Hematopoietic Stem Cell Transplantation (HSCT). Presented at the 35th International Conference on Advances in the Application of Monoclonal Antibodies in Clinical Oncology, June 2018.

[2] Bayraktar UD, et al. Fifty years of melphalan use in hematopoietic stem cell transplantation. *Biol Blood Marrow Transplant*. 2013;19(3):344-356

^{90}Y-anti-CD66-MTR has demonstrated promising initial clinical safety and efficacy data in SALA, the first non-oncology indication Telix intends to pursue.

About Systemic Amyloid Light-Chain Amyloidosis (SALA)

SALA is a rare, but serious protein deposition disease, caused by a protein known as 'amyloid' that is produced by abnormal plasma cells residing in the bone marrow. As amyloid accumulates in the organs of the body, organ function will eventually deteriorate, ultimately causing organ failure. SALA has an estimated prevalence of 30,000 and 45,000 in United States and Europe, respectively and while a rare disease, SALA portends a very poor prognosis, with a median survival from diagnosis of ~11 months if untreated.

The current standard of care comprises of induction therapy (typically cyclophosphamide, bortezomib, dexamethasone) plus high dose melphalan BMC, followed by HSCT. This approach is typically only accessible to a small proportion of patients (<20%) who are able to tolerate induction therapy and melphalan BMC.

About Telix Pharmaceuticals Limited

Telix is a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan and the United States. Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical needs in prostate, kidney and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

About TheraPharm GmbH

TheraPharm is a biotechnology company specialised in the research, development and manufacturing of monoclonal antibodies for targeted radiation of hematopoietic malignant and non-malignant diseases, lymphoproliferative diseases, conditioning for allogeneic stem cells as well as in diagnostics of inflammatory diseases and bone marrow metastases.

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