

USA FDA Grants Orphan Drug Status for PAT-SM6

- FDA grants orphan designation for PAT-SM6 in multiple myeloma
- Provides 7 years market exclusivity in the USA post approval

Melbourne, Australia; 6 November, 2013: Patrys Limited (**ASX: PAB**), a clinical stage biotechnology company, has received confirmation of Orphan Medicinal Product Designation for its lead anti-cancer product PAT-SM6, from the USA Food and Drugs Administration (FDA).

PAT-SM6 has previously been granted orphan drug designation for multiple myeloma in Europe.

Orphan product designation is intended to provide incentives to encourage companies to pursue cures and treatments for rare diseases with high unmet medical needs.

Under orphan drug status, PAT-SM6 qualifies for scientific and protocol assistance, potential grant funding during development as well as a period of 7 years of marketing exclusivity in the USA upon FDA approval.

In the USA, there are 78,000 people currently living with multiple myeloma, with 22,000 new cases and around 11,000 deaths each year. Approval of the orphan designation in the USA adds to the already existing orphan status granted in Europe and significantly expands the potential market for PAT-SM6. It also presents a unique opportunity for Patrys to fast track the development of the PAT-SM6 product in both the USA and Europe.

No cure currently exists for multiple myeloma patients and limitations of available therapies are particularly evident in patients that have relapsed or become resistant to treatments. Even though the appearance of some new agents in recent years have shown promise in treatment of multiple myeloma, a clear need for the development of additional novel therapeutics still exists.

Patrys' lead antibody drug PAT-SM6 is showing convincing evidence of potential therapeutic benefit in its ongoing Phase I/IIa clinical trial in patients with relapsed and refractory multiple myeloma and as such has a potential to improve and add to current treatments for myeloma.

Dr. Marie Roskrow, Patrys' CEO said: "The FDA's orphan drug designation for PAT-SM6 represents yet another confirmation of the quality of our product and supports and extends our efforts for a quicker development process in the USA as well as Europe."

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About Patrys Limited:

Based in Melbourne, Australia, Patrys (ASX: PAB) is focused on the development of natural human antibodies as therapies for cancer and other major diseases. Patrys has a deep pipeline of anti-cancer natural human antibodies that enable both internal development and partnering opportunities. More information can be found at www.patrys.com.

About PAT-SM6:

The natural human antibody PAT-SM6 has been shown to have potent anti-cancer properties in a large number of laboratory and animal studies. More specifically, Patrys has now screened PAT-SM6 against more than 200 tumours from individual patients with various cancers, and the product binds to over 90% of the tumours screened regardless of cancer type or patient age, gender or disease stage. With respect to multiple myeloma PAT-SM6 has shown particularly strong promise. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target, and the mechanism of action. Patrys has successfully completed a Phase I clinical trial to evaluate PAT-SM6 as a therapy for melanoma.

About Multiple Myeloma:

Multiple myeloma is a type of bone marrow cancer arising from plasma cells, and new therapies are desperately needed to treat patients who become resistant to established chemotherapeutics. There is an estimated 200,000 cases worldwide and the incidence is increasing. The five-year survival of patients is approximately 30% (at 10 years ~20%). Despite new marketed therapies, multiple myeloma remains largely incurable and fatal. The multiple myeloma market is dominated by three major products: Revlimid, Velcade and Thalidomide with combined net sales greater than US\$6 Billion in 2012.