

PAT-SM6 Receives Orphan Drug Designation for Multiple Myeloma in Europe

- **Orphan designation confirmed for PAT-SM6 clinical product**
- **Provides 10 years market exclusivity in Europe post approval**
- **PAT-SM6 is active in multiple myeloma patients with end stage disease who are resistant to other marketed therapies**

Melbourne, Australia; 12 September, 2013: Patrys Limited (**ASX: PAB**), a clinical stage biotechnology company is pleased to announce that lead anti-cancer product PAT-SM6 has been granted orphan drug designation by the European Medicines Agency (EMA) for multiple myeloma.

Orphan drug status is awarded to drugs that offer potential therapeutic value in the treatment of rare diseases and conditions. Orphan drug designation will entitle PAT-SM6 to:

- ten years of market exclusivity for multiple myeloma;
- scientific advice and protocol assistance by the EMA to optimise drug development;
- regulatory assistance and facilitated access to the Centralised Procedure for marketing approval;
- numerous financial incentives and fee reductions for regulatory activities; and
- access to grant funding schemes

In Europe, there are 60,000 people currently living with multiple myeloma, with over 20,000 new cases and around 15,000 deaths each year. Importantly, the global market is much larger with multiple myeloma the second most common haematological malignancy affecting approximately 200,000 people worldwide with approximately 100,000 new cases annually. The disease is deadly, as the lives of approximately 70,000 multiple myeloma patients worldwide are lost every year.

No single standard therapy currently exists for multiple myeloma patients that have relapsed or become resistant to treatment and these patients have an expected survival of just 6-9 months. Despite the appearance of some new agents with significant activity in relapsed disease, multiple myeloma remains an incurable disease, with a clear need for the development of additional novel therapeutics.

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 the potential to improve and add to current treatments for multiple myeloma. Orphan drug status presents a unique opportunity for Patrys to fast track PAT-SM6 development in Europe, which can subsequently be leveraged in larger global markets.

"Patrys is committed to the development of new therapies to help address the unmet medical needs of multiple myeloma patients worldwide" said Dr. Marie Roskrow, Patrys' CEO. "The EMA's orphan drug designation for PAT-SM6 represents an important milestone in PAT-SM6 development and will support our efforts to move PAT-SM6 as quickly as possible through the clinical and regulatory development process."

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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 qualify for 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' PAT-SM6 is currently showing convincing evidence of potential therapeutic benefit in its ongoing Phase I/IIa clinical trial in patients with relapsed and refractory multiple myeloma. Patrys has also 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.