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ASIA EDITION

EMA gives Patrys cancer drug orphan status

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Singapore: Australia-based Patrys, a clinical stage biotechnology company, has been granted orphan drug designation by the European Medicines Agency (EMA) for its lead anti-cancer product PAT-SM. 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 six-to-nine 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.

â€œPatrys is committed to the development of new therapies to help address the unmet medical needs of multiple myeloma patients worldwideâ€• said Dr Marie Roskrow, Patrys' CEO. â€œThe 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."