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FDA follows EU, declares Patrys drug as 'orphan'

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Singapore: Australia-based Patrys, a clinical stage biotechnology company, has received confirmation of Orphan Medicinal Product Designation for its lead anti-cancer product PAT-SM6, from the US 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 the orphan drug status, PAT-SM6 qualifies for scientific and protocol assistance, potential grant funding during development as well as a period of seven years of marketing exclusivity in the US upon FDA approval.

In the US, 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 US 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 US and Europe.