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ASIA EDITION

GC Biopharma's Hunter Syndrome treatment 'Hunterase' receives drug approval in India and Taiwan

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Accelerating expansion into the Asian rare disease market

GC Biopharma, a leading global pharmaceutical company based in South Korea, has announced that its Hunter syndrome treatment, 'Hunterase IV', has received marketing authorisation from India's Central Drugs Standard Control Organisation (CDSCO) and Taiwan's Food and Drug Administration (TFDA).

Additionally, 'Hunterase ICV' (brand name in Taiwan: Irifaze ICV), an intracerebroventricular infusion, has also been approved by the Taiwan TFDA.

With these approvals, Hunterase IV is now authorised in 14 countries worldwide, while Hunterase ICV is approved in 4 countries.

India, which approved the intravenous (IV) formulation, presents high growth potential and significant unmet medical needs, as the proportion of patients currently receiving existing treatments remains low. Taiwan, having approved both the IV and ICV formulations, is recognised for its high market accessibility, supported by well-established systems for early Hunter syndrome screening and patient support.

Having successfully established a presence in key Asian markets—including Japan, China, and Malaysia, alongside the latest approvals in India and Taiwan—GC Biopharma plans to further expand its footprint in the global rare disease market.

Hunter syndrome is a rare congenital disorder caused by a deficiency in lysosomal enzymes that break down glycosaminoglycans (GAGs). This deficiency leads to skeletal abnormalities, cardiac dysfunction, and cognitive decline. It predominantly affects males, occurring in approximately 1 in 100,000 to 150,000 live male births.

Hunterase ICV delivers the therapeutic enzyme directly into the cerebral ventricles, effectively bypassing the blood-brain barrier (BBB) into the central nervous system (CNS). This approach aims to manage symptoms associated with CNS damage, including cognitive decline. Approximately 70% of all Hunter syndrome patients suffer from severe forms of the

disease accompanied by CNS impairment.