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UAE becomes first country worldwide to approve new use of UltomirisÂ® for immune-mediated kidney disease

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Emirates Drug Establishment reinforces its regulatory leadership in approving innovative therapies and expanding treatment options for patients



The Emirates Drug Establishment (EDE) has granted conditional approval for a new indication of AstraZeneca's Ultomiris® (ravulizumab) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of disease progression, making the UAE the first country in the world to approve this indication. Ultomiris® has been registered in the UAE since 2022 for the treatment of several rare diseases.

The approval is in line with the UAE's strategic priorities and the "We the UAE 2031" vision, which aims to strengthen the country's leadership and global competitiveness in vital sectors, particularly healthcare and pharmaceuticals, while advancing innovation, research and development.

It also supports EDE's strategic objectives of building an advanced, proactive pharmaceutical regulatory system based on efficiency, regulatory excellence and the highest international standards of quality, safety and efficacy, helping accelerate patient access to the latest treatments.

Primary IgA nephropathy is an immune-mediated kidney disease caused by the deposition of an immune protein in kidney tissue, which can lead to inflammation and a gradual decline in kidney function. Elevated protein levels in the urine are an important indicator associated with disease progression, highlighting the need for treatment options that help reduce these levels and limit the risk of progression.