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AstraZeneca India launches Eculizumab, first anti-complement therapy approved in India

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For the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) and atypical Hemolytic Uremic Syndrome (aHUS)

AstraZeneca India, a leading global biopharmaceutical company, has announced the official launch of Eculizumab concentrate solution for infusion (300 mg,10 mg/ml) in India. This follows the Central Drugs Standard Control Organisation (CDSCO) approval received in January 2025 for the import, sale, and distribution of the product.

With this development, Eculizumab is now the first anti-complement therapy authorised in India for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) and atypical Hemolytic Uremic Syndrome (aHUS) in both adults and children.

Both aHUS and PNH are ultra-rare, life-threatening disorders caused by chronic, uncontrolled activation of the complement system, leading to severe complications in blood and kidney health.

aHUS is an ultra-rare, progressive disorder triggered by, uncontrolled activation of the complement system, leading to thrombotic microangiopathy (TMA)- the formation of blood clots in small vessels. According to a study by BMC Nephrology, aHUS occurs at rates as low as 0.23–1.9 cases per million annually in India, with root causes ranging from pregnancy and infections to certain cancers. Its clinical course may result in kidney failure, haemolytic anaemia, high blood pressure, and, in severe cases, heart disease or stroke.

PNH is equally serious, with a global median survival of just 10–20 years without treatment. Thrombosis is the leading cause of death, with up to 72% of untreated patients dying within 25 years of diagnosis.

Until now, limited awareness, diagnosis, and access to targeted therapies have contributed to prolonged hospitalisations and increased complications for those affected. The availability of Eculizumab marks a breakthrough in the standard of care.

The launch of Eculizumab in India aligns with AstraZeneca’s ambition to transform outcomes in rare and complex diseases through pioneering science and early intervention.