# Final Clinical Research Phase for Novel Haemolytic Uraemic Syndrome Treatment Underway in Europe

*This international multicentre study will assess the efficacy and safety of INM004 in hospitalised paediatric patients with a clinical diagnosis of HUS.*

BUENOS AIRES, ARGENTINA, August 14, 2026 /EINPresswire.com/ -- A Phase 3 clinical study of an investigational drug for haemolytic uraemic syndrome (HUS) is currently underway in Europe, including Belgium, France, Germany, Italy, Romania and the United Kingdom. HUS is a severe disease primarily caused by consuming food or liquids contaminated with Shiga toxin-producing Escherichia coli (STEC) bacteria. This condition can affect children of any age, particularly those under five, although it can also affect adults.

> This clinical trial evaluates an innovative therapeutic concept that may help mitigating the course of HUS in children"
> *Dr. Franz Schaefer (Germany)*

The investigational drug named INM004 was developed by Inmunova, an Argentine biotechnology company and member of the global firm Insud Pharma. It is a potential treatment designed to halt the progression of HUS and prevent its severe forms. This biologic drug contains specific polyclonal antibodies against the Shiga toxin, which causes HUS. These antibodies have the advantage of being broad-spectrum: they recognise and neutralise different variants of the toxin.

This international multicentre study is being conducted across 23 healthcare centres in Europe and 20 centres in Argentina. It will assess the efficacy and safety of the therapy in hospitalised paediatric patients with a clinical diagnosis of HUS. Currently, there is no approved vaccine or specific drug available worldwide to treat the condition.

HUS is one of the leading causes of acute kidney injury in the paediatric population. It can result in lifelong complications such as chronic renal problems, hypertension, and neurological impairments, and can be fatal in approximately 3% of cases. Given its severity, acting fast upon symptoms –including bloody or non-bloody diarrhoea accompanied by severe abdominal pain, paleness, fatigue, and reduced urination– makes an immediate visit to the nearest health centre crucial for early detection.

The study was authorized by Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT), the European Medicines Agency (EMA), and the UK's Medicines and Healthcare products Regulatory Agency (MHRA). Additionally, the clinical development program of INM004 was endorsed by the U.S. Food and Drug Administration (FDA) and the EMA, with both regulatory bodies granting Orphan Drug designation to this investigational drug. Furthermore, INM004 received Rare Pediatric Disease status from the FDA.

"HUS is a life-threatening disease and the most important cause of acute renal failure in previously healthy children. Between 40% and 50% of patients require dialysis and long-term renal sequelae are common. Current management consists solely of supportive care. The treatment under evaluation represents a specific therapy that could modify the course of HUS and improve its prognosis", said Dr. Gianluigi Ardissino, paediatric nephrologist and referent of the Center for the Treatment and Study of Hemolytic Uremic Syndrome at the Policlinico di Milano (Italy).

Dr. Ramona Stroescu, paediatric nephrology specialist at Spitalul Clinic de Urgență pentru Copii "Louis Țurcanu" (Timisoara, Romania) noted that "STEC-HUS primarily drives acute kidney injury, but it is a systemic disease; in severe cases, we see extrarenal involvement such as neurological, cardiac, or pancreatic complications. These patients can become critically ill very quickly, meaning early detection and prompt medical attention are paramount". She added, "This clinical trial could help shift STEC-HUS management from supportive care to a targeted, evidence-based approach, potentially reducing both acute severity and long-term consequences".

For his part Dr. Franz Schaefer, professor of Paediatrics and head of the Paediatric Nephrology Division at Universitätsklinikum Heidelberg AöR (Germany), remarked: "STEC-HUS is rare, but still the most common cause of acute kidney failure in children beyond the neonatal age. In our tertiary care centre we see a lot of children suffering from this disease; many have a severe course and the long-term outcomes are not always good. In the acute phase we cannot offer any treatment other than dialysis. This clinical trial evaluates an innovative therapeutic concept that may help mitigating the course of HUS in children".

Before entering the final stage of clinical research, INM004 successfully completed the first two phases of clinical studies. In Phase 1, its safety was assessed in healthy adult volunteers and showed an adequate safety profile for its pharmacological class. In Phase 2, which included paediatric patients diagnosed with HUS, the treatment showed an adequate safety profile and provided signs of being potentially useful in treating the disease. The findings of both studies were published in British Journal of Clinical Pharmacology and Pediatric Nephrology, respectively.

More information linked here.

Martina Barone
INMUNOVA

martina.barone@inmunova.com
Visit us on social media:
LinkedIn
Instagram
YouTube

---