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Two Phase III Trials Evaluating Crovalimab in Patients with Atypical Haemolytic Uraemic Syndrome (aHUS): COMMUTE-a and COMMUTE-p

Ming-hui Zhao[1], Neil Sheerin [2], Larry A. Greenbaum [3], Ito Shuichi[4], Chantal Loirat [5], Shoichi Maruyama [6], Khaled Benkali [7], Mona Shah , Sasha Sreckovic, Fadi Fakhouri
[1]Department of Nephrology, Peking University First Hospital, Beijing, China
[2]Department of Translational and Clinical Research Institute, Newcastle University, Newcastle upon Tyne, United Kingdom
[3]Department of Pediatric Nephrology, Emory University and Childrens Healthcare of Atlanta, United States
[4]Department of Paediatrics, Graduate School of Medicine, Yokohama City University, Kanagawa, Japan
[5]Department of Pediatric Nephrology, University Hospital Robert Dubre, Paris, France
[6]Department of Nephrology, Nagoya University Graduate School of Medicine, Nagoya, Japan
[7]Department of Clinical Pharmacology, Certara, Inc., Paris, France
[8]Department of Medical Safety, Genentech, Inc., South San Francisco, California, United States
[9]Department of Medicine, Service of Nephrology and Hypertension, Vaudois University Hospital Center (CHUV), Lausanne, Switzerland

Objectives : Atypical haemolytic uraemic syndrome (aHUS) is a rare life-threatening complement-mediated disease, characterised by thrombotic microangiopathies (TMAs). While treatment with C5 inhibition is effective, currently approved therapies require regular intravenous infusions every 2 weeks (Q2W, eculizumab) or every 8 weeks (ravulizumab). Crovalimab, a novel anti-C5 monoclonal antibody that can also bind to C5 in patients with the C5 R885H polymorphism, allows for small-volume, subcutaneous self-injections every 4 weeks (Q4W). Crovalimab is being tested for treatment of aHUS in two global, Phase III single-arm trials: COMMUTE-a and COMMUTE-p.
Methods : COMMUTE-a (NCT04861259) is enrolling 3 cohorts of patients with aHUS aged ≥12 years (Figure): Naive: complement inhibitor-naive patients (n≈40); Switch: patients switching from eculizumab or ravulizumab (n≈40); and C5 SNP: patients with a known single-nucleotide polymorphism (SNP; n≤5). COMMUTE-p (NCT04958265) is enrolling three cohorts of patients with aHUS aged ≥28 days to <18 years (Figure): Naive: complement inhibitor-naive patients (n≈20); Switch: patients switching from eculizumab or ravulizumab (n≥20); and Pretreated: patients who received and discontinued prior eculizumab or ravulizumab treatment (n≤10). In both COMMUTE-a and COMMUTE-p, patients will receive weight-based crovalimab as a weekly loading series (Weeks 1-4), followed by self-administered, subcutaneous maintenance doses (Weeks 5 and after; Q4W or Q2W if <20 kg). The primary objective for both studies is to evaluate crovalimab efficacy in naive patients, based on the proportion of patients with complete TMA response any time from baseline to Week 25.
Results : COMMUTE-a and COMMUTE-p are currently enrolling in 19 and 14 countries, respectively, including China, India, Japan, and New Zealand.
Conclusions : COMMUTE-a and COMMUTE-p will assess crovalimab in patients with aHUS.

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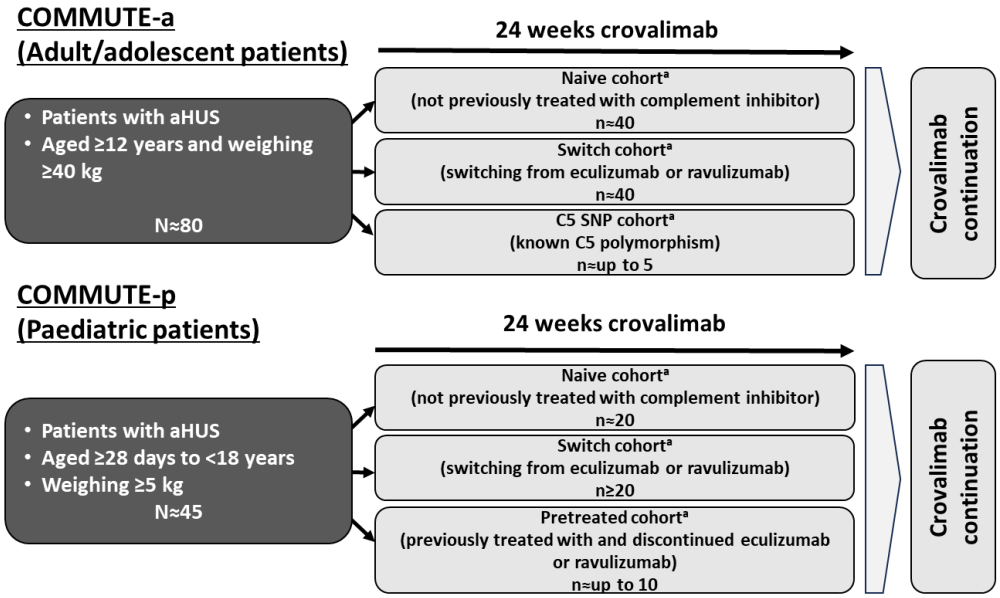

[a] Loading intravenous dose on Day 1, followed by subcutaneous dosing for subsequent loading and maintenance doses. Weight-based maintenance dosing Q2W or Q4W (depending on the weight of patients). Q2W, once every 2 weeks; Q4W, once every 4 weeks; SNP, single-nucleotide polymorphism.