

European Medicines Agency
EudraCT Registration team
Domenica Scarlatti
HS Amsterdam
Zuid 1083 HS

18 August 2021

Dear EudraCT registration team,

Re: Reason and justification for early termination

EudraCT number: 2019-002226-79

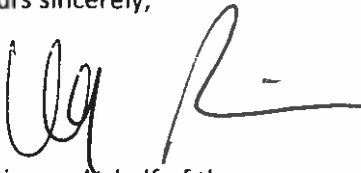
Title: A 30-day, randomized, evaluator-blind, controlled, multi-centre, parallel Group, phase III study to evaluate the Effect of a Low Maintenance Dose TicAgrelor Regimen versus Standard Dose Clopidogrel on Coronary Flow Reserve in Diabetes Mellitus Patients with impaired microvascular function without Prior Myocardial Infarction or Stroke Undergoing Elective Percutaneous Coronary Intervention

Sponsor code: AUGÉAS

Sponsor: Region Skåne

It was difficult to find suitable patients and this was confirmed by screening failures in the initial weeks of the study. The treatment recommendations had also changed after the announcement of the ISCHEMIA trial, making enrollment of patients to the study even more challenging. There were concerns the recruitment would be significantly delayed and run over budget. From an ethical perspective it was judged better to stop the trial before the first patient had been included.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Ulf Malmqvist', written over a horizontal line.

Acting on behalf of the sponsor,

Ulf Malmqvist, MD, PhD,
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Skåne University Hospital
221 85 Lund
Sweden