

Press Release

Adrenomed completes full enrollment with 300 patients in AdrenOSS-2 trial with Adrecizumab in septic shock

- **Proof-of-concept Phase II trial AdrenOSS-2 is assessing first-in-class antibody Adrecizumab, designed to restore and maintain vascular integrity**
- **AdrenOSS-2 trial design and Adrecizumab mode of action will be presented at the European Society of Intensive Care Medicine (ESICM) annual congress, LIVES**
- **Top-line study results are expected in Q1 2020**

Hennigsdorf/Berlin (Germany), September 26, 2019 – Adrenomed AG, the vascular integrity company, announced today the successful completion of patient enrollment in the proof-of-concept Phase II trial, AdrenOSS-2, evaluating Adrecizumab in patients with early septic shock. Adrecizumab is a first-in-class antibody targeting the vasoprotective peptide Adrenomedullin to restore and maintain vascular integrity in life-threatening conditions associated with vascular leakage, congestion and shock.

Three hundred patients with early septic shock and elevated blood levels of Adrenomedullin (bio-ADM[®]), have been randomized in the multicenter, double-blind, placebo-controlled AdrenOSS-2 trial ([NCT03085758](https://clinicaltrials.gov/ct2/show/study/NCT03085758)). The study's primary endpoints are safety and tolerability of Adrecizumab over a 90-day period; key secondary endpoints are the Sepsis Support Index (SSI), defined as days with organ support or death within 14 days and mortality at day 28. Top-line results from the trial are expected in the first quarter of 2020.

“Adrenomed is pleased to announce the completion of patient enrollment in our proof-of concept Phase II trial, reaching another important step in the development of our drug candidate. Sepsis remains the major life-threatening condition in ICU,” commented Jens Schneider-Mergener, CEO of Adrenomed AG.

CSO Andreas Bergmann added: “With Adrecizumab, we are pursuing a new strategy to fight sepsis and septic shock. By restoring and preserving vascular integrity, we aim to provide physicians with a new therapy to improve outcomes for their patients with this devastating disease.”

“The research into the pathogenesis of sepsis has traditionally focused on the immune response. During the last decade, a fundamental rethinking has taken place and the breakdown of vascular integrity now is considered to play a crucial role in the development of sepsis,” commented Prof. Dr. Peter Pickkers, Radboud University, Department of Intensive Care, Nijmegen, The Netherlands. “Adrecizumab targets the vasoprotective peptide Adrenomedullin, a key regulator of vascular integrity, in order to restore and preserve the endothelial barrier function.”



Prof. Dr. Pickkers will present the AdrenOSS-2 trial design and Adrecizumab's mode of action in the talk "Adrenomedullin in sepsis, effect of the non-inhibitory antibody Adrecizumab," during the session, "Innovation in sepsis treatment," at the 32nd European Society of Intensive Care Medicine (ESICM) LIVES annual congress in Berlin, on October 1st, 16:20 CEST.

About Adrenomed

Adrenomed AG is a German privately financed, clinical-stage biopharmaceutical company. Adrenomed's mission is to rescue vascular integrity in order to save the lives of critically ill patients with limited treatment options. Founded in 2009 by a management team with decades of in-depth experience in sepsis and deep knowledge in diagnostics and drug development, the company's lead product candidate Adrecizumab is a first-in-class monoclonal antibody. Adrecizumab targets the vasoprotective peptide Adrenomedullin, an essential regulator of vascular integrity. Adrecizumab is currently under clinical evaluation in a biomarker-guided, double-blinded, placebo-controlled, randomized, multicenter proof-of-concept Phase II trial with 300 patients suffering from septic shock. Excellent safety and tolerability were demonstrated in two Phase I trials. For further information, please visit www.adrenomed.com or see our LinkedIn profile [Adrenomed AG](#).

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