



## Press Release

# Adrenomed AG receives approval to conduct proof of concept study with Adrecizumab in patients with early septic shock

- Germany first country to grant full approval for Phase II study ADR-02 (AdrenOSS-2) with Adrecizumab in patients with early septic shock.
- ADR-02 study to enroll 300 patients in Germany, Belgium, France and the Netherlands for proof of safety and efficacy
- Patient enrollment in Germany expected to start by September, study approvals expected soon in Belgium, France and the Netherlands

**Hennigsdorf (Germany) August 11, 2017** – German corporation Adrenomed AG today announced that it received the favorable opinion of the Central Ethics Committee of the University of Aachen for its Phase-II study ADR-02 (AdrenOSS-2). Together with the approval of the German regulatory authority Paul Ehrlich Institute (PEI), received in July 2017, the ADR-02 study can now be started in Germany.

With this first in a series of studies across Europe, Adrenomed aims to demonstrate that its human monoclonal antibody Adrecizumab is safe and well tolerated and can improve outcomes in patients with early septic shock who show increased levels of the targeted vascular biomarker bio-adrenomedullin. The German full approval is the first step in the roll-out of the randomized, double-blind, multi-center study ADR-02, which will recruit 300 patients with early septic shock in Germany, Belgium, France and the Netherlands.

In preclinical studies Adrecizumab reduced mortality from sepsis and septic shock (Struck et al, 2013). In addition, Adrecizumab positively impacted the vasoactive adrenomedullin system leading to stabilization of blood pressure (Blet et al. 2015) and renal function (Wagner et al 2013). Two Phase-I studies demonstrated excellent tolerability and safety of Adrecizumab without any severe adverse effects (NCT02991508, NCT03083171).

„We are delighted that the Paul Ehrlich Institute has granted approval for the ADR-02 study as it is the next crucial step to demonstrate that Adrecizumab has the potential to reduce the high mortality rates from sepsis,“ said Andreas Bergmann, PhD., Chief Scientific Officer (CSO) of Adrenomed. „Sepsis affects millions of people globally. To date, there is no causative treatment for the systemic inflammation that leads to multi-organ failure.“

#### About Adrenomed

Adrenomed AG is a privately financed biopharmaceutical company, based in Hennigsdorf near Berlin, Germany, with a clear mission to improve survival by improving vascular integrity in critically ill patients. Its lead candidate, Adrecizumab, a monoclonal antibody therapy targeting the vasoactive adrenomedullin system, is in clinical testing for septic shock. Impaired vascular integrity is a pathology that serves a variety of medical conditions. A further indication besides sepsis is acute decompensated heart failure.

#### About Adrenomedullin

Adrenomedullin is a strong vasodilatory hormone released by endothelial cells. It is a key regulator of blood pressure and vascular tone and plays a pivotal role in the development of septic shock.

#### About Adrecizumab

Adrecizumab is a proprietary humanized monoclonal Adrenomedullin-specific antibody, as first-in-class therapy for the treatment and prevention of impaired vascular integrity, which is a hallmark of septic shock. Adrecizumab showed excellent safety & tolerability as well as high efficacy in a variety of preclinical animal models, mimicking human standard of care treatment on ICU. In several resuscitated vascular integrity models (mouse, rat, pig), Adrecizumab reduced vascular leakage, stabilized the circulation, by restoring blood pressure, normalized fluid balance and reduced vasopressor demand, improved renal function and reduced mortality from septic shock by 50%. The excellent tolerability and safety of Adrecizumab was confirmed in clinical Phase-I studies in healthy subjects with and without LPS challenge. Adrecizumab will now be tested in a first Phase-II proof-of-concept study in patients with early septic shock.

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