Adrenomed AG: Adrecizumab is safe, well tolerated and shows additional therapeutic potential in acute heart failure

- **Phase-I study demonstrates excellent tolerability and safety of Adrecizumab in healthy subjects**
- **Unique mode of action confirmed in humans**
- **Phase-II study in septic shock is on the way**
- **Adrenomed plans additional Phase-II study in acute heart failure**

Hennigsdorf, Germany, March 08, 2017 – Adrenomed AG announces the successful completion of a first-in-human study (Phase-I) that demonstrates excellent safety and tolerability of Adrecizumab in healthy volunteers.

The monoclonal Adrenomedullin-specific antibody Adrecizumab was developed to selectively support the beneficial effects of Adrenomedullin, an endogenous hormone that maintains endothelial integrity and prevents vascular leakage. The efficacy of Adrecizumab will be assessed in a first clinical proof-of-concept study (Phase-II) in patients with early septic shock. Septic shock is an acute circulatory breakdown that frequently occurs in patients with inflammation-induced endothelial dysfunction and leads to death in up to 80% of the cases.

According to Dr. Andreas Bergmann, Founder and Chief Scientific Officer of Adrenomed AG, the successful Phase-I represents an important milestone. "In addition to Adrecizumab´s excellent safety and tolerability profile, the fact that the mode of action, which was derived from animal data, could be confirmed in humans makes us very confident for the proof-of-concept study in patients with early septic shock that is already underway", says Dr. Bergmann.

In humans, Adrecizumab provokes the same characteristic increase in plasma Adrenomedullin level, which is known to improve blood vessel integrity. At the same time Adrecizumab prevents Adrenomedullin from exerting its vasodilatory, blood pressure-reducing actions. "A therapeutic elevation of Adrenomedullin has been attempted by others. However, they tripped over the shock-triggering side-effect. Only Adrecizumab masters this balancing act and fulfils all desired pharmacological properties," Dr. Bergmann says.

Preventing the leakage of fluid into the surrounding tissue is an unmet medical need in a variety of medical conditions, such as congestive heart failure. Dr. Andreas Bergmann is convinced, "Adrecizumab and its unique mode of action will be of great use here as well". Adrenomed is hence planning an additional clinical Phase-II study in patients with acute decompensated heart failure (ADHF).

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 was developed by Adrenomed AG, a biopharmaceutical company based in Hennigsdorf near Berlin, Germany. The preclinical development has been supported by a research grant of the German Federal Ministry of Education and Research (BMBF) with more than 1.6 million euros. 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. The excellent tolerability and safety of Adrecizumab could be confirmed in a clinical Phase-I study in healthy subject (see below). Adrecizumab will now be tested in a first Phase-II proof-of-concept study in patients with early septic shock.

About the Phase-I Study

The randomized double-blind, placebo-controlled Phase-I study on the safety, tolerability and pharmacokinetics/-dynamics of escalating single intravenous doses of Adrecizumab (HAM8101) in healthy male subjects was conducted at the Radboudumc University Hospital Nijmegen (NL), under the supervision of Prof. Dr. Peter Pickkers (ClinicalTrials.gov identifier: NCT02991508). Adrecizumab was applied in three doses (0.5, 2.0 and 8.0 mg/kg) by single short-term intravenous infusion. The infusion was, without exception, very well tolerated. No adverse effects occurred during the observation period of 90 days.

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