Press Release

Adrenomed's Adrecizumab successfully passes interim analysis in early septic shock study AdrenOSS-II

- **AdrenOSS-II trial continues as planned after positive interim efficacy analysis triggered by the treatment of 50% of randomized patients**
- **Proof-of-concept trial design testing Adrecizumab in early septic shock presented at International Symposium on Intensive Care and Emergency Medicine (ISICEM)**
- **Adrecizumab is a first-in-class antibody targeting Adrenomedullin, to restore and maintain vascular integrity in early septic shock**
- **At BIO-Europe® Spring, Adrenomed will host a company presentation on March 27 at 09:30 CET**

Hennigsdorf (Germany), March 21, 2019 – Adrenomed AG, the vascular integrity company, announced today that the phase II AdrenOSS-II trial, evaluating Adrecizumab in patients with early septic shock, will continue as intended after successful completion of a planned interim analysis for 50 % (n= 150) of randomized patients. The decision was made after the evaluation of the Sepsis Support Index (SSI) – a secondary efficacy endpoint – indicated a positive outcome for the whole study.

"As we expected, the study has successfully passed this important interim assessment point and will continue as planned," said Prof. Dr. Peter Pickkers, Radboud University, Department of Intensive Care, Nijmegen, The Netherlands. "By focusing on restoring and maintaining endothelial barrier function, Adrecizumab treatment pursues a unique and logical strategy to counteract vascular leakage, congestion and shock.

Today, Prof. Dr. Pickkers presented the trial design of AdrenOSS-II and Adrecizumab's mode of action, during the session 'New therapies for sepsis' at the 39th International Symposium on Intensive Care and Emergency Medicine (ISICEM), Brussels, 19-22 March 2019.[1]

The biomarker-guided, randomized, double-blind, placebo-controlled AdrenOSS-II trial (NCT03085758) is currently running in 28 centers throughout Germany, Belgium, France and the Netherlands in order to assess safety, tolerability and efficacy of Adrecizumab in 300 patients with early septic shock and elevated blood levels of the vasoprotective peptide Adrenomedullin (bio-ADM®).[2,3,4] Primary endpoints of the trial are safety and tolerability of Adrecizumab over a 90-day period. A key secondary endpoint is the Sepsis Support Index (SSI) defined as days with organ support or death within 14 days.

"Sepsis is affecting millions of people around the world every year with a remaining high, mortality rate at about 30%.[5] Once the patient develops septic shock, due to loss of vascular integrity, the mortality rate rises significantly. Currently, patients diagnosed with this life-threatening disease have limited treatment options," said Dr. Jens Zimmermann, Chief Medical Officer of Adrenomed. "The positive outcome of the interim analysis is very encouraging for us, and we are looking forward to the further continuation of the study."

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 clinical-stage, 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 study with 300 patients suffering septic shock. Excellent safety and tolerability were demonstrated in two Phase I trials.

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Adrenomed will be pleased to meet you at BIO-Europe® Spring 2019!

We will be attending the conference from the opening reception on Sunday, March 24, until Wednesday, March 27 and looking forward to seeing you in Vienna.

Adrenomed will host a **company presentation on Wednesday, March 27, at 09:30 CET** in room Schubert 5 (level 1), as part of the cardiovascular category.

You are welcome to contact Dr. Frauke Hein, Chief Business Officer of Adrenomed, through the partnering system.

References:

1 ISICEM, Brussels, March 21, 2019, "New therapies for sepsis / The adrenomedullin antibody adrecizumab", 8:30 – 8:45 CET, salle M (Bozar)
2 BMJ Open, 2019;9:e024475
3 clinicaltrials.gov/ct2/show/NCT03085758?term=NCT03085758&rank=1
4 bio-ADM® is a registered trademark of sphingotec GmbH
5 Intens Care Med, 2017;43:304-377; AJRCCM 2016;193(3):259-272