

Policy for Expanded Access / Compassionate Use of Enibarcimab

AdrenoMed AG is a biopharmaceutical company specialized in the development of novel medicines targeting the vascular endothelium for critically ill patients with limited treatment options.

The company's lead candidate is enibarcimab, a non-blocking antibody binding to the vasoprotective hormone adrenomedullin, resulting in the restoring and protection of the vascular endothelium. Clinical development via the conduct of clinical trials is currently ongoing. If successful, these trials may serve as basis for submissions for drug approval to regulatory authorities, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

AdrenoMed believes that at this stage of development, participation in controlled clinical trials is the most adequate way of providing access to enibarcimab for eligible patients. Our clinical trials are conducted according to current state of the art and in compliance with applicable regulations.

Details about our clinical trials, including eligibility requirements for participating in ongoing trials are published in public databases such as clinicaltrials.gov and clinicaltrialsregister.eu.

We recognize that there may be patients with septic shock or a related condition for whom participation in a clinical trial may not be an option. Where allowed, such patients may seek access to investigational drugs prior to regulatory approval of a drug via compassionate use or expanded access. Providing access outside of controlled clinical trials at this time could jeopardize the conduct of these trials and thereby even prevent or delay access to enibarcimab for patients in need. Also, in consideration of the currently available data on safety and efficacy of enibarcimab, AdrenoMed's current policy is that it is not appropriate and premature to provide access to enibarcimab outside of our controlled clinical trials at this point in time.

This policy is reviewed according to the progress of our development and may be amended in the future. For additional information about this policy, please contact info@adrenomed.com. We aim to provide responses within one week.

AdrenoMed AG Neuendorfstraße 15A 16761 Hennigsdorf, Germany