

Prematurely ended-statement

EudraCT number	2013-005362-19
Full title of the study	Therapy of Antibody-mediated Autoimmune Diseases by Bortezomib Therapie antikörper-vermittelter Autoimmunerkrankungen durch Bortezomib
Sponsor ID	TAVAB
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Product	Bortezomib (Velcade®)
Date of the early termination of the trial	30 - AUG - 2019
Statement on discontinuation of the study	<p>The trial ended prematurely due to lack of recruitment.</p> <p>Only 11 of 18 planned patients were included in the trial and only 6 regularly ended the treatment.</p> <p>In the last phase of the study, no further patients could be included for 1.5 years and it was expected that the planned number of patients could not be reached. Thus, in accordance with the protocol, the study was prematurely terminated.</p> <p>All included patients had finished the study, either by premature termination or by completion of treatment and observation period. The premature termination of the study did not have any negative impact on any of the participants.</p>
Results	In our study, we detected no significant effect of bortezomib treatment on the primary outcome parameter, i.e. the reduction of autoantibody titers compared before and after application of two cycles of bortezomib.

	<p>In the detailed analysis of predefined secondary endpoints there were some indications for a temporary reduction of antibody titers and an improvement of clinical parameters detectable.</p> <p>However, these results might clearly be influenced by the low number of included patients and a high drop-out rate. Furthermore, only 1 systemic lupus erythematoses (SLE) patient completed the study. Therefore, the results are mostly relevant for the 5 myasthenia gravis patients that finished the study after completion of 2 treatment cycles.</p>
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Signature **Prof. Dr. Andreas Meisel**
Job role **Sponsor representative**