STATEMENT FOR PREMATURE ENDING OF THE FOLLOWING CLINICAL TRIAL

Clinical trial to investigate the efficacy, safety and tolerability of the use of ANGOCIN® *Anti-Infekt N* versus placebo for MRSA eradication.

Trial Information

Medicinal product	ANGOCIN® *Anti-Infekt N*
Clinical indication	MRSA Eradication at primary refractory colonised patients
Sponsor	Repha GmbH Biologische Arzneimittel Alt-Godshorn 87 30855 Langenhagen, Germany research@repha.de
Development phase of the study	Phase II
Inclusion of the first patient	01.04.2015
Premature Finalization of study	01.06.2021
Study title	Clinical trial to investigate the efficacy, safety and tolerability of the use of ANGOCIN® *Anti-Infekt N* versus placebo for MRSA eradication.
Study design	Prospective, randomised, two-arm, placebo-controlled, double-blind, multicentre, parallel group design.
Aims of the study	Investigation of the efficacy, safety and tolerability of ANGOCIN® *Anti-Infekt N* when used for MRSA eradication.
Reason for premature finalization of the study	This clinical trial was terminated as decided by the Sponsor because the originally targeted number of patients of N=100 - 120 could not be recruited in the intended study setting. In fact,

all patients screened did not qualify for inclusion in the clinical trial. The achieved rates of positive MRSA findings in reality were far below the data published by literature and data from public institutions. The study concept made a very extensive screening activity necessary. Despite corrective actions regarding the planned conduct of the study, no patient was randomized during the clinical trial. Thus, none of the patients screened received study medication. The date of early termination was 01.06.2021.