Cadazolid/ACT-179811

Clostridium difficile-associated diarrhea
Protocol AC-061A301

Version 3

Confidential

EudraCT: 2013-002528-17 Doc No D-15.418

## INVESTIGATOR SIGNATURE PAGE

Drug name / number

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Cadazolid / ACT-179811

Indication

Clostridium difficile-associated diarrhea

## Protocol number, study title

AC-061A301, a multi-center, randomized, double-blind study to compare the efficacy and safety of cadazolid versus vancomycin in subjects with Clostridium difficile-associated diarrhea (CDAD).

I agree to the terms and conditions relating to this study as defined in this protocol, the Case Report Form (CRF), and any other protocol-related documents. I fully understand that any changes instituted by the investigator(s) without previous agreement with the Sponsor would constitute a violation of the protocol, including any ancillary studies or procedures performed on study subjects (other than those procedures necessary for the well-being of the subjects).

I agree to conduct this study in accordance with the Declaration of Helsinki principles, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, and applicable regulations and laws. In particular, I will obtain approval by an Institutional Review Board or Independent Ethics Committee (IRB/IEC) prior to study start and signed informed consent from all subjects included in this study. If an amendment to the protocol is necessary, I will obtain approval by an IRB/IEC and ensure approval by regulatory authorities (if applicable) have been obtained before the implementation of changes described in the amendment. In addition, I will allow direct access to source documents and study facilities to Sponsor representative(s), particularly monitor(s) and auditor(s), and agree to inspection by regulatory authorities or IRB/IEC representatives. I will ensure that the study drug(s) supplied by the Sponsor are being used only as described in this protocol. Furthermore, I confirm herewith that the Sponsor is allowed to enter and utilize my professional contact details and function in an electronic database for internal purposes and for submission to Health Authorities worldwide.

Country

Site number Town

Date

Signature

Site Principal Investigator

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