

CLINICAL STUDY REPORT

Appendix 16.1 Study Information

16.1.5 Signature Page

A Randomized, Placebo-Controlled, Phase IIb Dose-Finding Study of CYT003-QbG10, a TLR9-Agonist, in Patients with Moderate to Severe Allergic Asthma not Sufficiently Controlled on Current Standard Therapy (GINA Steps 3+4)

Trial Number:	CYT003-QbG10 12		
EudraCT number:	2012-003070-39		
Study Dates:	FPFV: 14 Oct 2012	LPLV (Week 12): 24 Jan 2014	
	Screening: 14 Oct 2012		
	1 st injection: 28 May 2013		
Investigational Product:	CYT003 (CYT003-QbG10)		
Indication Studied:	Persistent Allergic Asthma		
Development Phase:	Phase IIb		
Study Design:	Double-blind, randomized, placebo-controlled, parallel, multi-center study		
Sponsor:	Cytos Biotechnology AG, Wagistrasse 25 CH-8952 Schlieren, Switzerland		
Legal representative in EU:	Clinical Technology Center (International) Limited, Granta Park, Great Abington, Cambridge Cambridgeshire CB21 6GQ, United Kingdom		
Global Principal Investigator:	PD Dr. Thomas Casale American Academy of Allergy Asthma and Immunology University of South Florida 12901 Bruce B Downs Blvd, MDC19, Tampa, FL 33612, USA		
CRO:	PPD Development 929 North Front Street, Wilmington, NC 28401, USA		

By signing below, this is confirmation that, to the best of their knowledge, the content of the respective sections of the clinical study report are an accurate representation of the conduct and results of the clinical study, and that the study was conducted in compliance with current Good Clinical Practices and regulations.

For Clinical Conduct of the Clinical Study

Thomas B Casale, MD
Co-ordinating Investigator
Professor of Medicine
University of South Florida; USA

18 Aug 2014
Date


Signature

For Review and Approval of Report

Cheryl Lassen, MD
VP, Clinical Development
Cytos Biotechnology AG

11 Aug 2014
Date


Signature