

*Translation from Italian to English of the approval given by the Ethics Committee for clinical drug experimentation of Azienda Ospedaliero-Universitaria Careggi, Medical Oncology, Florence, Italy, to study ML21380 entitled:*

*"OPEN LABEL, EFFICACY AND SAFETY STUDY OF BEVACIZUMAB (AVASTIN®) IN COMBINATION WITH XELOX (OXALIPLATIN PLUS XELODA) FOR THE FIRST LINE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC CANCER OF THE COLON OR RECTUM "OBELIX".*

Sponsor: Roche S.p.A.

Drug: Bevacizumab

Responsible physician: Prof. Francesco Di Costanzo  
S.O.D. Medical Oncology

Study protocol number ML21380 version 1.0 of 19.09.2007

EUDRACT Code: 2007-004969-18

Phase IV

[...] after having taken into consideration the scientific and ethical aspects of study protocol ML21380 version 1.0 of 19.09.2007;

after having taken into consideration the adequacy of expenses, reimbursement and payment for the staff involved;

ascertained the adequacy of the investigator Prof. Francesco di Costanzo and of the hospital where the study will be undertaken

with an unanimous vote

### **GIVES UNIVOCAL FAVORABLE CONSENSUS**

To the clinical trial proposed upon responsibility of the investigator and sponsor, and approves study protocol N. ML21380 version 1.0 of 19.09.2007, patient informed consent version 1.0 of 19.09.2007, the informed consent of a partner in case of pregnancy version 1.0 of 19.09.2007 and the document of informed consent for the treatment of data with the aim of clinical experimentation.

Yours faithfully,

Colin Gerard Egan

