Sponsor:	Istituto di Ricerche Farmacologiche Mario Negri IRCCS - Via G. La Masa 19, 20156 Milano
Study Title:	"Outcome-related factors in patients with metastatic renal cell carcinoma treated with everolimus after failure of a first-line treatment with VEGF inhibitor"
Short Title:	-
Acronym:	ORCHIDEE
EudraCT:	2014-002508-26
Phase:	IV
Start Date (mm/dd/yyy):	03/24/2015
Completion date (mm/dd/yyy):	11/16/2016
Reason for interruption:	Poor enrollment
Keywords:	metastatic renal cell carcinoma; everolimus; VEGF inhibitor

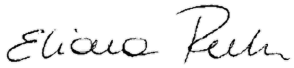
Short Report

ORCHIDEE was a multicentre, prospective, single arm, phase IV study in patients with mRCC after failure of a first line treatment with a VEGF inhibitor.
The primary objective of the study was to identify factors predictive of favourable outcome, in terms of survival without an unfavourable event, in patients treated with everolimus as second line treatment for mRCC after failure of a first-line treatment with a VEGF inhibitor.

Primary endpoint was survival free from an unfavourable event, defined in each patient as the time from the date of written informed consent provision to the date of occurrence of the first among the following events: death from any cause, disease progression (according to RECIST 1.1), interruption of everolimus due to toxicity and/or deterioration of clinical conditions, and HRQoL deterioration (7-point decrease from baseline evaluation on the EQ-5D visual analogue scale).
Eligible patients were treated with daily doses of everolimus (10 mg daily tablets) until one of the following conditions apply - whichever comes first:

- tumour progression, according to RECIST 1.1;
- unacceptable toxicity according to investigator's judgment;
- death;
- discontinuation from the study for any other reason.

According to Concato et al, 200 patients were required in order to ensure the achievement of 150 events within the study conduct period.
The trial has been prematurely closed on 16 November 2016, when 31 patients out of 200 were enrolled. This decision was taken due to unsatisfactory recruitment by all participating experimental centers, despite all the numerous attempts on our part to reverse this trend.
The formal communication of premature closure of the study was sent to the National Competent Authority (Italian Medicines Agency, AIFA) and to all Ethics Committees of the participating centres through a letter dated 20 December 2016.



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