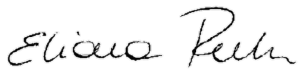
Sponsor:	Istituto di Ricerche Farmacologiche Mario Negri IRCCS - Via G. La Masa 19, 20156 Milano
Study Title:	"International, multicenter, phase II, randomized, parallel-arm trial investigating the role of two different metronomic chemotherapy regimens in locally advanced or metastatic triple negative breast cancer patients (TNBC) as maintenance therapy after first line treatment"
Short Title:	-
Acronym:	Victor-3
EudraCT:	2016-001864-12
Phase:	II
Start Date (mm/dd/yyy):	10/30/2017
Completion date (mm/dd/yyy):	09/13/2018
Reason for interruption:	Poor enrollment
Keywords:	Breast, neoplasm, triple negative

Short Report

Victor-3 study was an international, multicenter, randomized, open-label, parallel arm trial conducted in patients with locally advanced or metastatic TNBC, defined according to ASCO guidelines (hormone receptor [HR] expression <1%; HER2 negative status). Approximately 30. The study will be conducted involving clinical centers in three European member states – Italy, Spain and Portugal.
180 patients to be randomized, in order to have 138 patients evaluable for the primary analysis
The Study primary aim was: to evaluate the activity of the two study regimens (oral metronomic schedule of Vinorelbine and combination of oral metronomic schedule of Vinorelbine with fixed doses of Capecitabine) in terms of proportion of patients alive and without disease progression after 12 weeks of maintenance therapy.
The secondary aims were to evaluate the two treatment regimens in terms of clinical benefit, overall survival and progression free survival and the tolerability and safety profile of each treatment regimen.
After verification of inclusion and exclusion criteria, eligible patients were randomized with a 1: 1 ratio, with country, centre, prior first line of chemotherapy and BRCA mutation status as stratification factors, to receive:
Arm A: Vinorelbine 50 mg, thrice a week
Arm B: Vinorelbine 40 mg, thrice a week + Capecitabine 500 mg thrice a day
Both treatments were administered continuously until disease progression, unacceptable toxicity, patient or physician decision. However, for the purpose of study procedures and evaluations one treatment cycle was defined as 3 weeks treatment in both arms.
The study addressed one primary question: the proportion of patients alive and without progression after 12 weeks of maintenance therapy (PFS12w). The Study had a total period of 36 months, 24 months of recruitment and 12 months of minimum follow-up.
The trial has been prematurely closed on 13th September 2018. This decision was taken due to unsatisfactory recruitment by the twenty-two participating experimental centers, despite all the numerous attempts on our part to reverse this trend.
At that date only 4 patients were enrolled overall, about 2% of the expected sample (180 patients). 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 24th September 2018. Moreover a formal closure letter it was sent to the Spain and Portugal authorities on 15th October 2018.



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