

NEWTON study

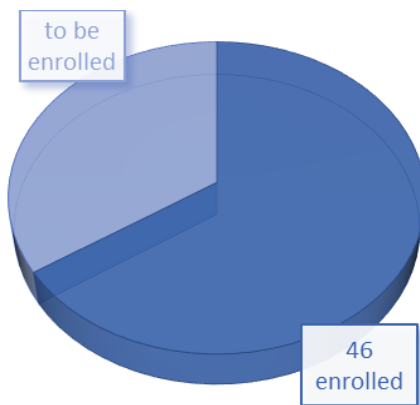
A multicenter, open-label phase II trial of a new customized dosing (Rational Adjustment of Dose to reduce Adverse Reactions “RADAR” dosing) of niraparib as maintenance therapy in platinum sensitive ovarian, fallopian tube or primary peritoneal recurrent cancer patients

Study update	
Summary of happy and unhappy events	☹️ Only 2 patients have been randomized since the last update
	☹️ Overall 81 patients (out of 105) have been registered/randomized from the start of the study (<u>October 2019</u>)
	☹️ One site has never enrolled patients although it was opened more than one year ago (in Germany)
	☹️ There are 3 sites in Italy and one in Germany that have enrolled few patients (maximum 3) although they were opened more than 3 years ago
	☹️ The accrual of the random cohort (≥ 58 Kg and <77Kg or ≥77 Kg and platelet <150,000/μL) is still lagging behind and it urgently needs to be speed up! (24 patients to be enrolled).

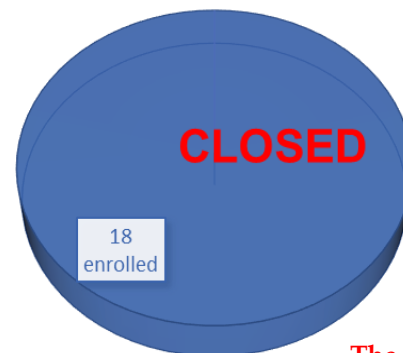
Accrual update by study cohort

The following graphs summarize the status of the enrolment by study cohort

**Random Cohort /
target 70 pts**

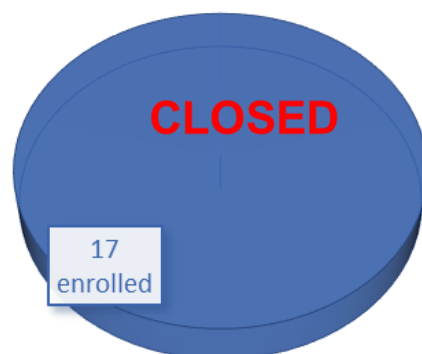


**Not-Random Cohort
<58 kg - 200 mg / target 18 pts**



**The number of patients,
as per sample size, was
reached!**

**Not-Random Cohort
≥77kg and platelet ≥150,000/ μ L
300 mg / target 17 pts**



**The number of patients,
as per sample size, was
reached!**

N.B. We remind you that, whenever possible, no approximation should be applied to values of weight and platelet count (e.g. a patient with body weight of 76.8 Kg will be included in the random cohort)

Please consider this information to identify patients to be enrolled.
We invite you to report any issues related to the enrolment.

A focus on the enrolment by site

Following the enrolment by site. The sites are ordered by their recruiting speed.

Place in the ranking	Site and PI	Activation date	Enrolled patients (including screening failures)	Registered/ Randomized patients	Date of last registration/ randomization	Average time between registrations/ randomizations (days)
1 st	Milano IEO (Italy) - PI Colombo	30-10-2019	39	34	06-03-2023	43
2 nd	Padova (Italy) - PI Tasca	10-09-2020	15	14	17-07-2023	82
3 rd	Brescia (Italy) - PI Tognon	28-02-2020	14	12	24-05-2022	112
4 th	Monza (Italy) - PI Lissoni	30-07-2020	9	8	27-10-2023	132
5 th	Milano INT (Italy) - PI Raspagliesi	28-06-2022	1	1	09-10-2023	247
6 th	Torino (Italy) - PI Ferrero	15-09-2020	3	3	21-02-2022	381
7 th	Roma (Italy) - PI Perniola	14-06-2022	1	1	17-04-2023	507
8 th	Torino (Italy) - PI Katsaros	01-12-2020	2	2	14 -05-2021	534
9 th	Dresden (Germany) - PI Wimberger	10-11-2020	2	2	27-06-2022	544
10 th	Reggio Emilia (Italy) - PI Bologna	27-01-2021	2	2	01-03-2023	688
11 th	Essen (Germany) - PI Heitz	23-02-2021	1	0	-	-
12 th	Berlin (Germany) - PI Chekerov	07-04-2022	0	0	-	-

Please try to improve your contribution!

For any issue please write an email to newton@marionegri.it