Ongoing Trials – status update

ENGOT-cx1 Randomized Phase II of paclitaxel-carboplatin +/- Nintedanib

- Advanced stage IVB, or recurrent cx ca
- **Up to one prior line of chemotherapy for metastatic cervical cancer now allowed***
- **Prior treatment with angiogenesis inhibitors now allowed***

n = 70/120

Randomization 1:1

Stratification

1. Primary advanced Stage IVB versus recurrent disease.
2. Previous line of chemotherapy for metastatic disease

Carboplatin AUC5 + paclitaxel 175 mg/m2 (tri)weekly + Nintedanib 200mg

followed by Nintedanib maintenance

Carboplatin AUC5 + paclitaxel 175 mg/m2 (tri)weekly + Placebo

followed by Placebo maintenance

* Protocol v5.0 or above

Trial setting: Cervix/ primary stage IVB, recurrent
Sponsor(s): BGOG
Planned No. of patients: 120
Current accrual: 70
FPI: Mar 2014 ; LPI: expected Aug 2018
Primary endpoint: PFS Secondary endpoint: OS, toxicity, safety, QOL and RR

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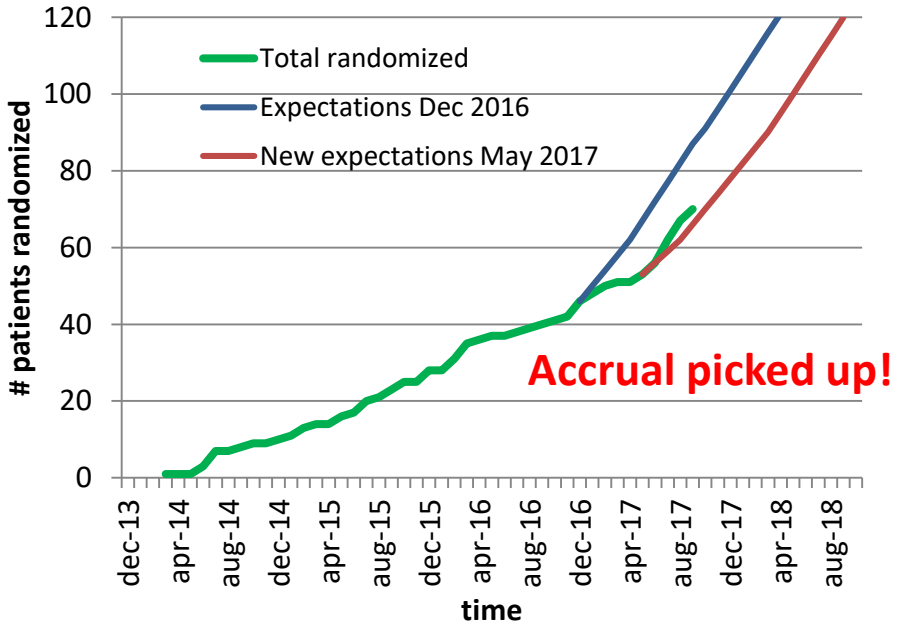
GROUP	SITES ACTIVATED	SUBJECT ENROLLMENT
GEICO	5/5	19
BGOG	10/10	35
NOGGO	6/6	9
MITO/MANGO	4/9	7
Total	23/30	70/120

Protocol v5.0: approved in Belgium, Germany, Spain

- Allow prior treatment with angiogenesis inhibitors
- Allow one prior line of chemotherapy for metastatic cervical cancer
- Allow inclusion for patients with recurrence within 6 months after last therapy



IDMC	First interim analysis	interim analysis – patients on weekly TC
How many patients?	First 40 evaluable patients	First 3, 6, 9 and 18 evaluable patients
When?	After 2 months of treatment	After 6 weeks of treatment
What kind of analysis?	Safety	Safety
19/09/2017	51 patients included (including 40 > 2 months of treatment)	2 patients included (>6 weeks of treatment)
	One clarification requested during meeting IDMC recommendation expected by end October	