Disclosure:

All authors have declared no conflicts of interest.

Legal entity responsible for the study:

France, 3Gynaecologic Oncology, Gustave Roussy Cancer Center, INSERM U981, and Groupe d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens (GINECO), Villejuif, France, 4Department of Pathology, Institut Gustave Roussy, Villejuif, France, 5Medical Oncology, Gustave Roussy Institut de Cancérologie, Villejuif, France, 6Radiation Oncology, Healthcare Global Enterprises Ltd., Bangalore, India, 7Radiation Oncology, Healthcare Global Enterprises Ltd., Bangalore, India, 8Medical Oncology, HCG Bangalore Institute of Oncology Speciality Centre, Bangalore, India, 9Radiation Oncology, Bharath Hospital and Institute of Oncology, Mycore, India, 10Medical Oncology, HCG Malnad Hospital Institute of Oncology, Shimoga, India, 11Medical Oncology, Centre d'Oncologie de Gentilly, Nancy, France, 12Medical Oncology, Clinique Mutualiste de l'Estuaire, Saint-Nazaire, France, 13Oncology Department, CERTIM, Hopital Cochin, Paris, France, 14Oncology, Centre Antoine Lacassagne, Nice, France, 15Medical Oncology, Healthcare Global Enterprises Ltd., Bangalore, India, 16Oncology, Centre Franc¸ois Baclesse&CETAPS Univ, Rouen, Caen, France, 17Research Unit for Cancers Prevention and treatment, Axis BioTICLA "Biology and Innovative Therapeutics for Ovarian Cancers", UNICANCER, Centre Franc¸ois Baclesse, Caen, France, 18Department of Pathology, Gustave Roussy Cancer Center, Villejuif, France, 19Department of Pathology, Gustave Roussy Cancer Center, Villejuif, France, 20Department of Pathology, Gustave Roussy Cancer Center, Villejuif, France, 21Department of Pathology, Gustave Roussy Cancer Center, Villejuif, France, 22Medical Oncology & Clinical Research & INSERM U1086"ANTICIPE" (Interdisciplinary Gynaecological cancers Volume 28 | Supplement 5 | September 2017

### Background:

EGFR inhibitors have proven to improve the efficacy of anticancer treatments in lung, colon, pancreas, or HNC. Results from studies show EGFR expression in cervical Ca to improve survival outcomes in the same. This study was designed to assess...
safety and efficacy of Nimotuzumab with concurrent cisplatin and RT in patients with Ca Cervix.

Methods: In this open-label randomized controlled multicentric study 100 patients with histologically confirmed Ca Cervix were recruited over a 4 year period with an equal allocation of 1:1 for intervention (Standard arm - concurrent CTRT (Cisplatin 40mg/m² weekly IV + RT) plus 200mg weekly BIOMAB IV (n = 50) on same day of cisplatin infusion) vs. standard arm only (n = 50). At 2 years data were available for 59 patients in the intervention arm and 35 patients in standard arm. The size of the lesion was documented using CT/PETCT at baseline. The response was analyzed using RECIST criteria at the following treatment every 3 months for subsequent 2 years. Toxicity was assessed using CTCAE v4 toxicity criteria.

Results: There were 74 evaluable patients at end of 2 years. The mean age was 49.6 ± 10.2 years. The complete response following treatment was seen in 37.8% (BIOMAB arm) of patients at two years following treatment compared to 38.2% in standard arm. However, progressive disease was seen more in standard arm (52.9%) compared to BIOMAB arm (35.1%). Best overall response was seen in 64.9% patients in the intervention arm compared to 47.1% patients in the standard arm at two years following treatment which is significant. At 2 years 60% progressed on standard arm compared to 37.5% in the intervention arm. The mean estimate of progression-free survival being 36 months vs. 56.5 months (Biomab arm) (Log rank Mantel-Cox χ² = 3.9, p = 0.05). Except for one patient with Biomab sensitivity, there was no additional toxicity compared to the standard arm.

Conclusions: Nimotuzumab appears to be safe and effective targeted therapy in cervical cancer patients with long-term benefits.

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