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## Globalization of biosimilars

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Globalization of biosimilar will come soon in the near future. China will be one of the largest biosimilar markets in the World. This presentation will articulate challenges, and opportunities and great investment potentials in China biopharma industry.

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## The role of topoisomerase [IIA] as a predictive factor for response to neoadjuvant anthracyclines based chemotherapy in locally advanced breast cancer

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**Background:** Surrogate markers may be used to assess the response to neoadjuvant chemotherapy. The purpose of the study was to evaluate topoisomerase II $\alpha$  as predictive factor for response to neoadjuvant anthracyclines based chemotherapy in locally advanced breast cancer patients. Tumor grade scored according to the Elston-Ellis classification, hormonal receptor (HR) status, tumor cell proliferation evaluated by Ki-67 staining, HER-2 and topoisomerase II alpha (TopoII $\alpha$ ) expression evaluated by immunohistochemistry (IHC).

**Method:** Between January 2012 and June 2012, 50 locally advanced breast cancer patients had received 3 cycles neoadjuvant chemotherapy were studied in clinical oncology department at Tanta university. Regimens including either CEF (cyclophosphamide 500 mg/m<sup>2</sup>, epirubicin 100 mg/m<sup>2</sup>, 5-fluorouracil 500 mg/m<sup>2</sup>) or FAC (cyclophosphamide 500 mg/m<sup>2</sup>, doxorubicin 50 mg/m<sup>2</sup>, 5 fluorouracil 500 mg/m<sup>2</sup>). Protein expression of HER2 and Topo II $\alpha$  were determined by immunohistochemistry. The primary endpoint was pathological and clinical tumor response that assessed clinically and by mamography, then by pathological assessment.

**Results:** Of 50 primary locally advanced breast cancer patients had been assessed after 3 cycles of NACT, the clinical complete response was in 6% (3/50), clinical partial response was in 86% (43/50) and overall clinical response was 92% (46/50), 4 (8%) patients had clinical stable disease and no one developed disease progression. 1-Responders had the following biomarkers criteria: Clinical (CR): 3 patients had co-expression of topo II and HER2, hormonal receptor negative and high KI-67. Clinical (PR): 43 patients majority of them had topo IIA over expression. 2-Non responders had the following criteria: 4 (8%) patients all had negative (TOPOII/HER2), low KI-67 and 2 had hormonal receptor positive and another 2 had hormonal receptor negative.

**Conclusion:** Our study suggests that HER2 and Topo II $\alpha$  overexpression could be predictors of the response to neoadjuvant chemotherapy in both the CEF and FAC arms.

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