Background: Niraparib is an oral PARP-1/2 inhibitor with efficacy in both germline BRCA mutated (gBRCA) ovarian cancer (OvCa) and high grade serous OvCa (HGSC) patients (pts) who are non-gBRCA. Phase I data established a RP2D of 300 mg. At the recommended dose, 75% platinum sensitive patients achieved RECIST response in phase 1.

Trial design: ENGOT-OV16/NOVA study (n = 360) is a double-blind, 2:1 randomized, placebo controlled phase III study of oral niraparib versus placebo in pts with platinum (plat) sensitive recurrent OvCa. Primary objective is to evaluate efficacy of niraparib as maintenance therapy assessed by the prolongation of progression free survival (PFS). PFS will be independently evaluated in a cohort of gBRCA pts and in HGSC pts who are non-gBRCA. Secondary objectives: overall survival in each cohort; bridge the centralized BRCA mutation test method to the candidate companion diagnostic test; patient-reported outcomes; PFS2; chemotherapy free interval; safety/tolerability; QTc in a subset of niraparib-treated pts. Study eligibility includes: histologically confirmed OvCa, HGSC histology or known gBRCA, plat sensitive recurrence, at least 2 prior courses of plat-containing therapy with no/minimal radiological residual disease, and normal CA125 or decrease by 90% after last plat, PS 0-1, and normal organ function. The study is powered to assess PFS and OS in both cohorts (gBRCA & non-gBRCA). The trial is being conducted in 126 sites in collaboration with European Network of Gynaecological Oncological Trials Groups (NSGO Denmark-Norway-Sweden, AGO Austria, AGO Germany, BGOG Belgium, ISGO Israel, GEICO Spain, GINECO France, MaNGO Italy, MITO Italy, NCRI UK), US, Canada, Hungary & Poland. The pt. enrolment is according to the timelines. ClinicalTrials.gov Identifier: NCT01847274

Disclosure: S. Agarwal: Medical Officer, Tesaro Bio Inc. (sponsor of the trial); R.E. Martell: Chief Medical Officer, Tesaro Bio Inc. (Sponsor of the trial). All other authors have declared no conflicts of interest.