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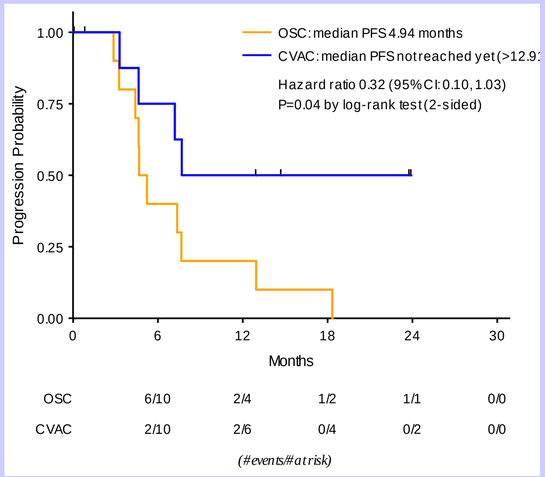
Trial evaluating overall survival in epithelial ovarian cancer (EOC) patients in second remission with an autologous dendritic cell therapy targeting mucin 1

S.E. Gargosky and the CAN-004 Study Team
Prima BioMed USA and CAN-004 study team of Belgium, Belarus, Bulgaria, Germany, Poland, Lithuania, Latvia, Ukraine

Rationale: CVac (autologous dendritic cell therapy) is well tolerated. Treatment with CVac results in a mucin 1 specific T cell response. In the second remission patients the median PFS for CVac was greater than 12.91 months versus a median PFS for SOC of 4.94 months (HR 0.32, p=0.04) and in overall survival SOC groups had a median of 26.25 months consistent with literature but CVac median is not yet reached at 36 months. Thus, based on these compelling PFS and OS signals, Prima is now moving forward with a 210-patient study of EOC patients in second remission as compared to SOC.

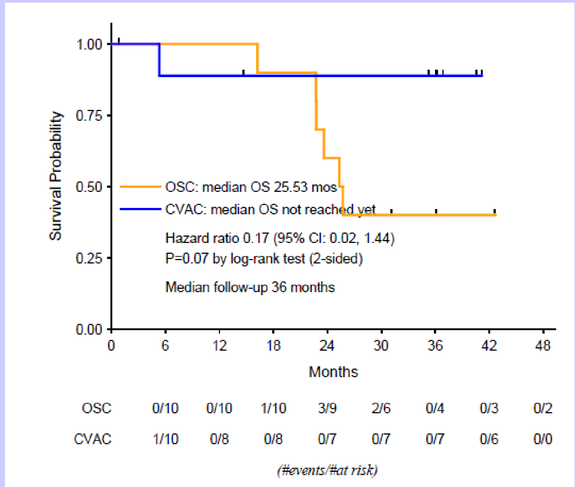
Background (CAN-003): 63 patients were enrolled into the trial; 7 NR CVac, and 29 CVac and 27 SOC randomized. 41 patients were CR1 and 22 CR2. Overall CR1 and CR2 demographics were similar regarding tissue histology, optimal debulking and staging. 10 SAEs were reported in total. None were unexpected and only one (small bowel obstruction) was classified as unlikely-related to CVac.

Progression Free Survival
Second remission



PFS was not improved in CR1 with CVac over SOC (HR=1.18, p=0.69) where as in CR2, CVac demonstrated a significant improvement in PFS; median PFS for SOC was 4.94 months; the median PFS for CVac was >12.91 months (p=0.04).
Multivariate analysis did not reveal country, age, stage, surgery or CA-125 to affect the outcomes.

Overall Survival
Second remission



Overall survival with a median follow up of 36 months showed SOC was at 25.53 months (consistent with the literature) where as CVac median OS had not been reached yet.
HR 0.17, p=0.07

Design: CAN-004 is a multinational, multicenter, randomized trial of CVac (autologous dendritic cells [DCs] pulsed with recombinant human fusion protein [mucin 1-glutathione S-transferase] coupled to oxidized polymannose) compared with standard of care as maintenance treatment in patients with EOC with no evidence of disease (NED) following second remission defined as after response to second-line platinum-based therapy.

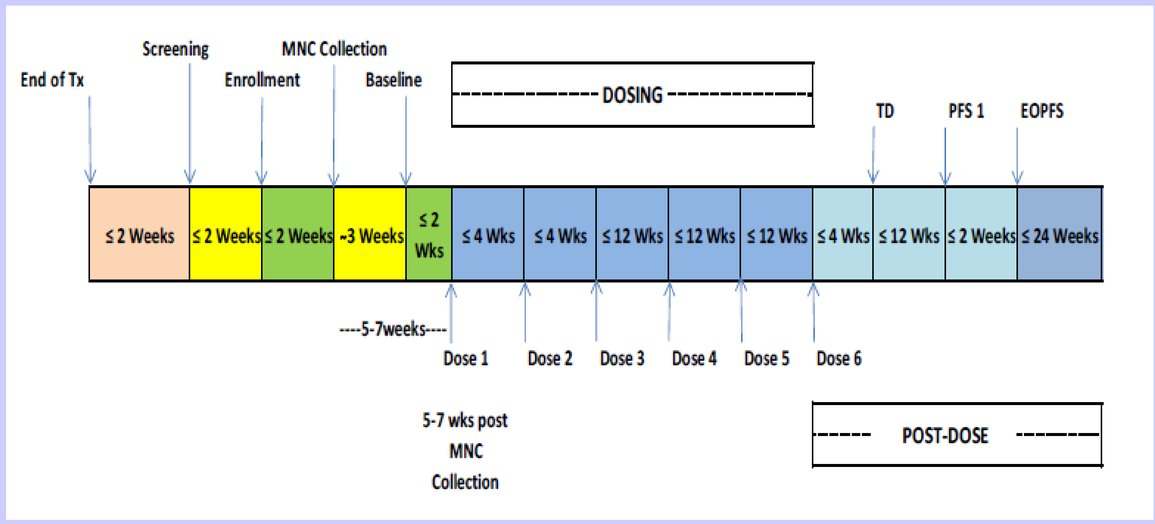
Eligibility: To be eligible for participation patients must have had first-line platinum-based chemotherapy with a first remission lasting for at least 6 months prior to relapse. Patients must have a second remission defined as:
1) no definitive evidence of disease detected by computed tomography (CT) or magnetic resonance imaging (MRI) of the abdomen and pelvis;
2) cancer antigen 125 (CA-125) tumor marker within normal limits OR at least a 90% reduction from pretreatment levels at the start of second-line platinum based therapy; and
3) negative physical exam (i.e., no clinical signs) following standard platinum-based second-line chemotherapy (at least 3 cycles).
Patients must have a tumor that overexpresses mucin 1, as well as meet all other study eligibility criteria

Primary Endpoint:
The primary endpoint for this study is **overall survival** (OS). OS is defined as the number of days elapsed between the randomization date and the date of death (regardless of cause). A secondary analysis of OS will use the baseline visit as the reference starting date.

Secondary Endpoints:

- **Time to next treatment** (TTNT) is defined as the number of days from the randomization date to the date when a next treatment for EOC is started.
- **Progression free survival** (PFS) is defined as the number of days from the randomization date to the earliest of documented disease progression or death without prior progression.
  Each patient will be assessed for progressive disease (PD) every 12 weeks beginning at the baseline visit, until PD is determined by the investigator, or until death, or until the end of the study, whichever occurs first. A secondary analysis of TTNT and PFS will use the baseline visit as the reference starting date.
- To assess the **safety and tolerability** of Cvac compared with observational standard of care
- To assess health-related quality of life (**QoL**) related to CVac treatment compared with observational standard of care

Study Design:



European Countries enrolling:

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