GLORIOSA

RANDOMIZED PHASE 3 TRIAL OF MIRVETUXIMAB + BEVACIZUMAB MAINTENANCE IN Folate Receptor α-HIGH PSOC PATIENTS

-**Özet**: *Rekürren platin duyarlı over kanserinde 2. Hat KT adayı hastalarda CR, PR ya da SD elde edildikten sonra, idame Mirvetuximab+BEVA ya da yalnızca BEVA'nın etkinliğinin araştırılması*
-Hedef Hasta Sayısı: 200
-Kompetetif global hasta alımı
-ENGOT Model C Study
-Leading Group: MITO

Dahil Etme Kriterleri

- HG-seröz over, tuba ya da primer periton kanseri
- ECOG status 0-1
- Tümör dokusunda teyid edilmiş yüksek Frα etkinliği
- Birincil hat platin KT sonrası, en az 6 ay sonra nüks etmiş (platin duyarlı) hastalık (SEKONDER SİTOREDUKSİYON SONRASI DA HASTALAR DAHİL EDİLEBİLİR)
- BRCA pozitif olgular 1. Hatta PARPi idame tedavisi almış olmalıdır.
- İkinci hat tedavi sonrası CR, PR, SD olmalı

Dışlama Kriterleri

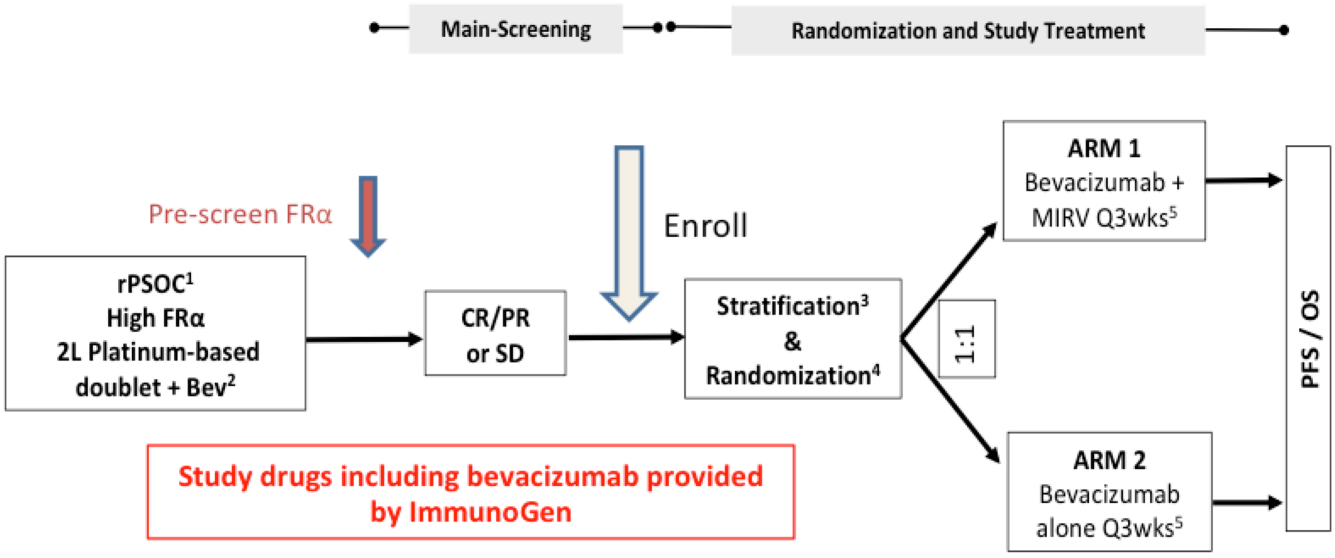
- Seröz dışı histolojiler
- Birden fazla hat KT almış olmak
- Platin sonrası progresif hastalık
- Randomizasyon öncesi ara Beva tedavisi almış olması
- >Grade 1 periferal nöropati
- Kornea nakli, kronik kornea hastalığıaktif diyabetik retinopati, maküler dejenerasyon, kontrolsüz glokom gibi sebeplerle devam eden göz tedavisi alıyor olmak

Amaç

- Primer amaç: PFS
- Sekonder amaç: OS
- Ek amaçlar: -Mirvetuximab soravtansine (MIRV)-Beva kombinasyonu güvenliği ve tolerabilitesi
  -Time to second progression (PFS2)
  -ORR (Objective Response Rate)
  -DOR (duration of response)
  -DFS
  -CA125 RR
  -QoL

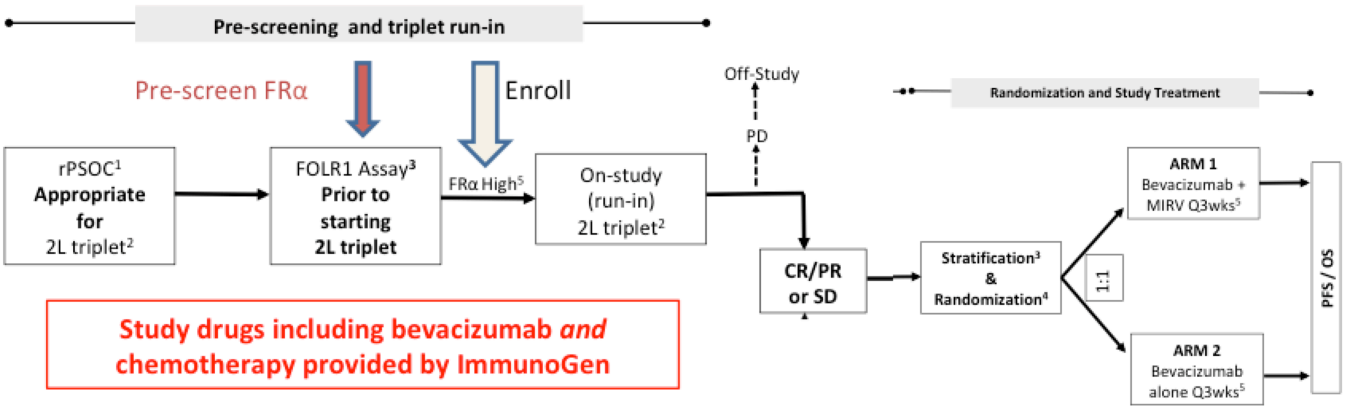
HASTA ALIMI İÇİN 2 OPSİYON VAR

1. **OPSİYON: 2. hat KT tamamlandıktan sonra**
   - KT : Karboplatin, Beva, (PAC-PLD ya da Gem)



[1] High-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers
[2] Platinum + chemo + bevacizumab for planned 6 cycles (minimum of 4 and maximum or 8 cycles) including at least 3 cycles of bevacizumab
[3] Stratification factors: prior PARP inhibitor: Yes vs No; CR or PR or SD; prior bevacizumab: Yes vs. No.
[4] Enrollment into Trial for Randomization will require documented radiographic confirmed CR, PR or SD
[5] Maintenance treatment must begin 12 weeks or less from last dose of triplet therapy and w/in 30 days of randomization. Treatment continued until progressive disease, unacceptable toxicity, withdrawal of consent, death, or Sponsor terminates the study
Abbreviations - CR: complete response; PR: partial response; SD: stable disease; MIRV: mirvetuximab soravtansine; PFS: progression free survival; OS: overall survival

2. **OPSİYON: 2. Hat KT öncesi hasta alımı**
   - KT :Karboplatin, Beva, (PAC-PLD ya da Gem)



[1] High-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers
[2] Triplet = Platinum + chemo + bevacizumab for planned 6 cycles (minimum of 4 and maximum of 8 cycles) including at least 3 cycles of bevacizumab
[3] Patients pre-screened by FOLR1 Assay **prior to initiation of 2L triplet**. FRα high patients receive 2L triplet on-study (run-in). Upon completion of triplet, patients determined to have PD will not proceed to randomization and will come off study.
[4] Patients pre-screened by FOLR1 Assay **during or upon completion of their ongoing triplet.** FRα high patients determined to have PDs after completion of triplet are screen failures.
[5] Patients who are FRα negative by FOLR1 Assay will be considered screen failures.
Abbreviations - 2L Second Line; CR complete response; FOLR1 Folate Receptor 1; FR α Folate Receptor alpha; PD progressive disease; PR partial response; SD stable disease.