To determine whether abagovomab maintenance therapy prolongs recurrence-free (RFS) and overall survival (OS) in patients with ovarian cancer in first clinical remission. Patients with International Federation of Gynecology and Obstetrics stage III to IV ovarian cancer in complete clinical remission after primary surgery and platinum- and taxane-based chemotherapy were randomly assigned at a ratio of 2:1 in a phase III, double-blind, placebo-controlled, multicenter study. Abagovomab 2 mg or placebo was administered as 1-mL suspension once every 2 weeks for 6 weeks (induction phase) and then once every 4 weeks (maintenance phase) until recurrence or up to 21 months after random assignment of the last patient. The primary end point was RFS; secondary end points were OS and immunologic response. Characteristics of the 888 patients included: mean...
age, 56.3 years; Eastern Cooperative Oncology Group performance status, 99% of patients; serous papillary subtype, 81.5%; stage III, 85.9%; and cancer antigen 125 1 cm) was 1.099 (95% CI, 0.919 to 1.315; P = .301). HR of OS using tumor size categorization ( 1 cm) was 1.150 (95% CI, 0.872 to 1.518; P = .322). The most frequently reported type of adverse event was an injection site reaction in 445 patients (50.2%), followed by injection site erythema and fatigue in 227 (25.6%) and 212 patients (23.9%), respectively. By the final visit, median anti-anti-idiotypic antibody level was 493,000.0 ng/mL, indicating a robust response. Abagovomab administered as repeated monthly injections is safe and induces a measurable immune response. Administration as maintenance therapy for patients with ovarian cancer in first remission does not prolong RFS or OS.