

일반 연제(I) - 5

PHASE II TRIAL OF 2-N (2-DIETHYLAMINOETHYL) 9-HYDROXY ELLIPTICINIUM CHLORIDE (SR95156B, DATELLIPTIUM) IN ADVANCED MEASURABLE GASTRIC CARCINOMA. Jae Kyung Roh, Jin Hyuk Choi, In Sook Lee, Jean-Marc Mondesir, Byung Soo Kim. Div. of Med. Onc., Yonsei Cancer Res. Center, Yonsei University, Seoul, Korea. Sanofi Recherche, Paris, France.

Elliptinium acetate (EA); a fully synthesized derivatives of Ellipticine; showed significant antitumor activities in patients with refractory breast cancer, malignant lymphoma, and renal cell carcinoma, but substantially low activity in gastric carcinoma (Proc ASCO 9:124, 1990). Datelliptium (DE), new sub-series of EA, showed excellent efficacy on the murine and human tumor models with higher therapeutic indices than that of EA. Phase I studies showed minimal bone marrow depression, and mild to moderate reversible hepatic toxicities with MTD of 500mg/m²/d

We initiated the phase II trial of DE in patients with previously untreated advanced measurable gastric adenocarcinoma from Jan. 1991 to evaluate the drug responses and toxicities. Seventeen pts were enrolled with 15 evaluable pts (2: refused follow up). Median age was 59 (37-66), M:F was 8:7, and median ECOG performance was 1 (0-2). 6 patients had moderately differentiated, 2 poorly, and 7 undifferentiated adenocarcinoma. 11 pts had distant metastases (7:liver, 3: supraclavicular nodes, 1:paraortic nodes), and 4 had unresectable locally advanced diseases.

DE 250mg/m²/d in 250 CC 5% dextrose water was administered IV for 3 consecutive days every 3 weeks until progression, or untoward toxicities which prohibit from further treatment. Median courses of treatment were 2 (1-5). Treatment related toxicities were mild nausea and vomiting (4 pts), mild phlebitis (4 pts), mild fever (2 pts), and reversible grade II(1 pts), III (2 pts) elevations of hepatic enzymes. No patients showed any evidence of hemolytic anemia, but grade III anemia (2 pts) were noted probably due to chronic blood loss.

Of the evaluable 15 pts, 1 pt showed partial regression of tumor. The response rate of 6.7% was substantially low in patients with gastric adenocarcinoma after the Datelliptium treatment.