EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +32 2 774 16 11
Fax : +32 2 772 35 45
E-mail : eortc@eortc.be
Web : http://www.eortc.be

Short Study Report for Health Authorities

Name of Sponsor/Company: EORTC **Name of the finished product** **Name of Active Ingredient**	Individual study Table Referring to Part of the Dossier Volume: Page	*(For National Authority Use Only)*
Title of the Study	A randomised, multicentre, phase III study of Erlotinib versus observation in patients with no evidence of disease progression after first line, platinum-based chemotherapy for high-risk Stage I and Stage II-IV ovarian epithelial, primary peritoneal, or fallopian tube cancer	
Investigators & Study Centers	• Dr. Antonio Jimeno phone: + 34 91 3908349 fax: + 34 91 4603310 e-mail: ajlonco12octubre@yahoo.es institution: HOSPITAL UNIVERSITARIO 12 DE OCTUBRE (EORTC 365) Enrolled patients: 13 • Professor Ignace Vergote phone: + 32 16 344 636 // 635 fax: + 32 16 347687 e-mail: ignace.vergote@uz.kuleuven.ac.be institution: U.Z. GASTHUISBERG (EORTC 147) Enrolled patients: 52	
Publication (reference)	The overall study data have not been published yet, however, study results have been presented at ASCO 2012 meeting (Vergote et al, J Clin Oncol 30, 2012 (suppl; abstr LBA5000))	
Objective(s)	To determine whether the administration of Erlotinib (maintenance treatment) in patients with ovarian cancer that have either (1) no evidence of disease or (2) a response or (3) a stabilization of the disease after first line, platinum-based chemotherapy benefits this subset of patients, compared with the standard approach of observation alone.	
Methodology	This is a randomised, multicentre, open-label, phase III study of Erlotinib versus observation in patients with no evidence of disease progression after first line, platinum-based chemotherapy for high-risk Stage I and Stage II-IV ovarian epithelial, primary peritoneal, or fallopian tube cancer. The benefit will be evaluated primarily in terms of progression-free survival, and secondarily in terms of overall survival, safety, and quality of life.	

Name of Sponsor/Company: EORTC	Individual study Table Referring to Part of the Dossier	*(For National Authority Use Only)*
Name of the finished product	Volume:	
Name of Active Ingredient	Page	
Number of patients Number planed (Statistical design) Number analyzed	830 patients planned. 835 patients enrolled. 835 patients analyzed.	
Diagnosis and main criteria for inclusion	1. Histologically confirmed high-risk FIGO stage I (grade 3, or aneuploidy grade 1 or 2, or clear cell), or stage II-IV ovarian epithelial, primary peritoneal, and fallopian tube cancer. 2. No adenocarcinoma of unknown origin. 3. No more than 6 weeks since the end (the end being defined as day 21 of the last cycle) of first line therapy for ovarian cancer. First line therapy should include 6-9 cycles (as per institutional policy) of a platinum derivative alone or in combination with other agents. Accepted doses for the platinum agent are: a) Carboplatin at a minimal dose of AUC 5/3weeks when using EDTA clearance or calculated GFR (however, when using calculated GFR a minimal dose of AUC 6/3weeks is recommended), or b) Cisplatin initially scheduled at ≥ 60 mg/m2/3weeks). 4. Complete response (CR) (clinical and/or pathological, i.e., no evidence of disease [NED] status), partial response (PR), or disease stabilization (SD) after first line therapy, as assessed according to the RECIST criteria and/or to the GCIG criteria in case of CA125-based evaluation at the end of first line therapy. 5. Age over 18 years. 6. ECOG 0-1. 7. Adequate bone marrow, hepatic and renal functions (within 14 days before first day of study treatment): ♦ Absolute white blood cell count ≥ 2.0 x 109/l. ♦ Absolute platelet count ≥ 100 x 109/l. ♦ Serum total bilirubin ≤ 1.5 x UNL. ♦ ASAT and ALAT ≤ 2.5 x UNL in patients with no known liver metastases; ≤ 5 x UNL in patients with known liver metastases. ♦ Alkaline phosphatase ≤ 5 x UNL, except in patients with known bone metastases. ♦ PT, PTT ≤ 1-1.5 UNL (gr. 1 CTCAE v3.0) ♦ Serum Creatinine ≤ 2.0 x UNL. 8. No prior or concurrent treatment with any other investigational agent. 9. No prior therapy targeting the epidermal growth factor receptor. 10. No prior allergic reaction to any compound chemically related to the study drug. 11. No previous (within the last 5 years) or concurrent malignancies, with the exception of adequately treated cone-biopsied in situ carcinoma of the cervix uteri or basal or squamous cell carcinoma of the skin. 12. No known history of brain metastases and/or leptomeningeal disease. 13. No gastrointestinal tract disease resulting in an inability to take oral medication or requiring parenteral nutrition or affecting absorption. No active peptic ulcer disease. 14. No uncontrolled bowel inflammatory disease (e.g., Crohn´s disease or ulcerative colitis). 15. No myocardial infarction within the past 6 months. 16. No second- or third-degree heart blocks unless pacemaker implanted. 17. No significant dermatological disease. 18. No inflammatory changes of the surface of the eye. 19. No other significant medical condition, neurological or psychiatric disorder. 20. No pregnant or lactating women (or potentially fertile women not using adequate contraception). 21. No prior radiotherapy. However, any radiotherapy more than 5 years ago and outside the abdomen/pelvis is permitted. 22. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; these conditions should be discussed with the patient before participation in the trial. 23. Before patient randomization, written informed consent must be given according to ICH/GCP, and national/local regulations. Patients can only be randomized in this trial once. NB: Double randomization in the neoadjuvant versus primary debulking surgery (EORTC 55971/NCIC OV13/Chorus) is allowed.	

Name of Sponsor/Company: EORTC **Name of the finished product** **Name of Active Ingredient**	Individual study Table Referring to Part of the Dossier Volume: Page	*(For National Authority Use Only)*
Treatment Test product, dose and mode of administration (batch number if applicable) Duration of treatment	Erlotinib 150 mg orally, administered on a daily basis, up to 2 years.	
Reference therapy, dose and mode of administration (batch number if applicable)	Observation (no interventions) up to 2 years.	
Criteria for evaluation Efficacy Safety	 Primary: Progression-free Survival (PFS) Secondary: ♦ Overall Survival (OS) ♦ QoL ♦ rash ♦ Safety profile: CTCAE v3.0	
Statistical methods	The analyses will be performed according to EORTC standard operating procedures. Where possible, all tests will be presented by means of a point estimate (hazard ratio, proportion, …), a 95% CI and a p-value. Time-to-event data (including the primary endpoint: progression free survival but also secondary endpoints such as overall survival and time to occurrence of rash/acne) will be summarized by the Kaplan-Meier technique and differences between the two arms will be assessed using a two-sided log-rank test. To adjust for confounding variables, the Cox proportional hazards model may be used on the primary endpoint.	
Summary of Results Efficacy Results Safety Results Conclusions	 Maintenance erlotinib after first line chemotherapy in patients with ovarian, peritoneal or fallopian tube cancer did not increase PFS nor OS. 25% of the patients stopped the treatment due to side effects (mainly rash). Currently there was no subgroup identified that might benefit from erlotinib maintenance therapy after first-line chemotherapy for ovarian	
Date of Report	15/06/2012	