ATEZOLACC

RANDOMIZATION (1/5)



Patient's last name _	First name
Center name	Center number _

Complete all items on 5 forms

- Fax to Katty MALEKZADEH (33) 1 42 11 52 58
- Or send by e-mail to katty.malekzadeh@gustaveroussy.fr
- If problem call (33) 1 42 11 41 96 or (33) 1 42 11 49 00

In

1.	Signed informed consent (after informing the patient).	☐ Yes ☐ No
2.	Age between 18 and 70 years.	☐ Yes ☐ No
3.	Histologically confirmed cancer of the uterine cervix: squamous cell carcinoma (SCC), adenocarcinoma, or adenosquamous carcinoma.	☐ Yes ☐ No
4.	At least one evaluable lesion according to RECIST v1.1 criteria for the assessment of the principal judgment criteria.	☐ Yes ☐ No
5.	International Federation of Gynecology and Obstetrics (FIGO) classification (confirmed by both clinical staging and imaging): (i) stage IB2-IIA tumour with positive pelvic nodal status, as assessed by magnetic resonance imaging (MRI) and/or fluorine-18 fluorodeoxyglucose positron emission tomography (18-FDG PET)/computerised tomography (CT); (ii) stage IIB-IVA tumour, regardless of pelvic lymph node involvement; (iii) stage IVB tumours only if the metastases are limited to the para-aortic lymph nodes. No evidence of metastatic disease outside the para-aortic area by primary staging (including clinical examination, pelvic MRI, 18-FDG PET, +/- laparoscopic para-aortic lymph node staging.	□ Yes □ No
6.	Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1.	☐ Yes ☐ No
7.	Adequate haematologic and end-organ function, defined by the following laboratory results obtained within 15 calendar days prior to the first study treatment:	
	a) Absolute neutrophil count (ANC) \geq 1,500/mm ³ (\geq 1.5 x 10 ⁹ /L) without granulocyte colony-stimulating factor (G-CSF) support.	
	b) Polymorphonuclear neutrophils (PMN) >2,000/mm ³ (>2.0 x 10 ⁹ /L).	
	c) Lymphocyte count $\geq 500/\text{mm}^3$ ($\geq 0.5 \times 10^9/\text{L}$)	
	d) Platelet count $\geq 100,000/\text{mm}^3$ ($\geq 100 \times 10^9/\text{L}$) without transfusion.	☐ Yes ☐ No
	e) Haemoglobin \geq 9.0 g/dL (90 g/L; patients may be transfused to meet this criterion).	
	f) International Normalized Ratio (INR) and activated partial thromboplastin time (aPTT) $\leq 1.5 \times$ upper limit of normal (ULN) for patients not receiving therapeutic	
	anticoagulation. Patients receiving therapeutic anticoagulation should be on a stable dose.	

(calculated using the Cockcroft-Gault formula).		
h) Aspartate transaminase (AST), alanine transaminase (ALT), and alkaline phosphatase $<$ 2.5 x ULN.		
i) Serum bilirubin <1.5 x ULN.		
8 · Proteinuria < 200 mg/dL (2 g/L).	☐ Yes ☐ No	
9. Ability to comply with the study protocol.		
10. Geographical, social and psychological ability to undergo the follow-up required by the study.		
11.Women who are not postmenopausal (≥ 12 months of non-therapy-induced amenorrhoea) and not surgically sterile:		
a. Must agree to either use an acceptable contraceptive method* or to remain abstinent** (refrain from heterosexual intercourse) during the treatment period and for at least 5 months after the last dose of atezolizumab.		
*Acceptable contraceptive methods include single or combined contraceptive methods that result in a failure rate of < 1% per year, such as: tubal ligation, male sterilization, hormonal implants, established, proper use of combined oral or injected hormonal contraceptives, and certain intrauterine devices. Alternatively, two methods (e.g., two barrier methods such as a condom and a cervical cap) may be combined to achieve a failure rate of < 1% per year. Barrier methods must always be supplemented with the use of a spermicide.	□ Yes □ No	
** Abstinence is acceptable only if it is in line with the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception.		
b. Must have a negative serum pregnancy test result within 7 days prior to initiation of study drug.		
12 . Patients must be affiliated to a social security system or beneficiary of the same, as per local regulatory requirements.	□ Yes □ No	