PATIENT IDENTIFICATION	GETUG- AFU 35 CRF Version 1.0 of 07/12/2018
unicancer |__|__| |__|__| Centre N° Patient N°	**SELECTION VISIT**

N°	INCLUSION CRITERIA	Validation	
		Yes	No
1	Muscle-invasive bladder cancer (MIBC) pT2-T3 histologically confirmed: • Urothelial and squamous cell histological types are allowed. • De novo MIBC or after a history of non-muscle-invasive bladder cancer.	☐1	☐0
2	Complete transurethral resection of bladder tumour (TURBT), either: ✓ within 6 weeks of registration if no chemotherapy was administered, or ✓ before starting chemotherapy.	☐1	☐0
3	Patients for which chemo-radiotherapy is planned	☐1	☐0
4	No major pelvic involvement: pelvic nodes ≤15 mm on CT scan.	☐1	☐0
5	No distant metastasis.	☐1	☐0
6	Patient unfit for radical cystectomy because of age, comorbidities, or patient's refusal.	☐1	☐0
7	Patients ≥18 years old	☐1	☐0
8	ECOG performance status ≤2.	☐1	☐0
9	Life expectancy ≥12 months.	☐1	☐0
10	Haematological and biological parameters allowing pelvic radiotherapy and anti-PDL1 administration: • White blood cell count ≥4000/mm^3 • Platelet count ≥100000 cells/mm^3 • Haemoglobin level ≥9 g/dL or corrected after transfusion • A glomerular filtration rate ≥25 mL/min. • Adequate renal function: clearance >50 mL/min (MDRD) • Adequate hepatic function: AST (SGOT) and ALT (SGPT) ≤2.5 x ULN, or ≤3.5 x ULN in the case of concurrent disease with known etiology and for which a corrective treatment is possible.	☐1	☐0
11	Patients of childbearing potential who agree to use a medically acceptable method of contraception during the study and for 120 days after the last study treatment. Women must have a negative urine or serum pregnancy test before receiving the study treatment and within 14 days prior to selection.	☐1	☐0
12	Patients having provided written informed consent prior to any study-related procedures.	☐1	☐0
13	Patients affiliated to the social security scheme	☐1	☐0
14	Patients willing and able to comply with the scheduled visits, treatment plan, laboratory tests, and other study procedures indicated in the protocol.	☐1	☐0
15	Patient consents to the use of their collected tumour specimen, as well as, blood samples as detailed in the protocol for future scientific research which includes but not limited to DNA, RNA, and protein-based biomarker detection.	☐1	☐0

N°	EXCLUSION CRITERIA	Validation	
		Yes	No
1	Patient with bladder carcinoma in situ (CIS)	☐1	☐0
2	Prior pelvic irradiation.	☐1	☐0
3	MIBC histology other than urothelial or squamous cell carcinomas (e.g., adenocarcinomas, micropapillary, sarcomas, or small cell histological types).	☐1	☐0
4	History of neoplastic disease, during the 3 years before registration, except completely resected cutaneous basal-cell carcinomas, carcinoma in-situ or localised prostate cancer without biochemical recurrence following definitive treatment.	☐1	☐0
5	Prior treatment with CD137 agonists or immune checkpoint inhibitors, including anti-cytotoxic T lymphocyte-associated antigen 4 (anti-CTLA-4), anti-programmed death-1 receptor (anti-PD-1), and anti-programmed death-ligand 1 (anti-PD-L1) therapeutic antibodies.	☐1	☐0
6	Contraindications for pelvic radiotherapy (e.g., inflammatory bowel disease).	☐1	☐0
7	History of immunodeficiency, including HIV infection, or systemic steroid therapy for any other disease.	☐1	☐0
8	A history of active autoimmune disease, except autoimmune-related hypothyroidism and type I diabetes mellitus.	☐1	☐0
9	History of severe allergic anaphylactic reactions to chimeric, human or humanised antibodies, or fusion proteins.	☐1	☐0
10	Known hypersensitivity to Chinese hamster ovary (CHO) cell products or any component of the atezolizumab formulation.	☐1	☐0
11	Prior allogeneic stem cell or solid organ transplant.	☐1	☐0
12	Patients with the following severe acute co-morbidity are not eligible: • Unstable angina or congestive heart failure that required hospitalisation in the 6 months before registration. • Transmural myocardial infarction in the 6 months prior to registration. • Acute bacterial or fungal infection requiring intravenous antibiotics at registration. • Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalisation or precluding study therapy at the time of registration. • Severe hepatic disease: Child-Pugh Class B or C.	☐1	☐0
13	Patients with any other disease or illness which requires hospitalisation or is incompatible with the study treatment are not eligible.	☐1	☐0
14	Patients unable to comply with study obligations for geographic, social, or physical reasons, or who are unable to understand the purpose and procedures of the study.	☐1	☐0
15	Patients enrolled in another therapeutic study within 30 days of registration.	☐1	☐0
16	Pregnant or breast feeding women.	☐1	☐0
17	Person deprived of their liberty or under protective custody or guardianship.	☐1	☐0