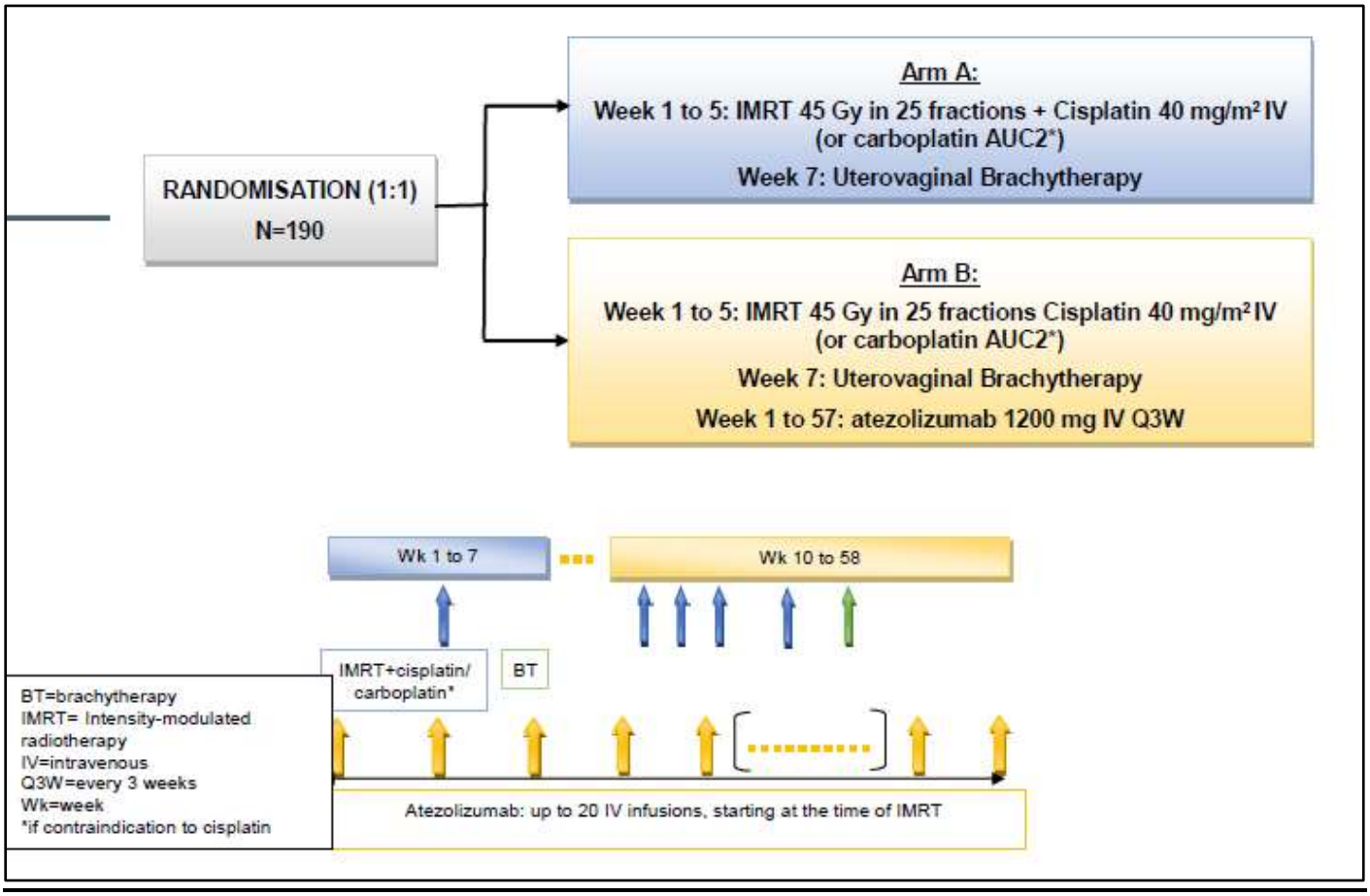
CGFL Centre Georges François Leclerc – Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE ATEZOLAAC**	Identité patient (coller étiquette patient)
Version 1.0 du 01/11/2021	Investigateur en charge du patient : …….. PI : **Dr Karine PEIGNAUX** Mail : kpeignaux@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Patricia LECERF** Poste : 8084

ATEZOLAAC

Randomized Phase II Trial Assessing the Inhibitor of Programmed Cell Death Ligand 1 (PD-L1) Immune Checkpoint Atezolizumab in Locally Advanced Cervical Cancer



VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion :

Signed informed consent (after informing the patient).	□ oui □ non

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Age ≥18 years old. Patients above 70 years old will be screened according to the G-8 screening tool. If required (G-8 score ≤14), a consultation with an onco-geriatrician will be held in order to confirm the patient eligibility.	□ oui □ non
Histologically confirmed cancer of the uterine cervix: squamous cell carcinoma (SCC), adenocarcinoma, or adenosquamous carcinoma.	□ oui □ non
At least one evaluable lesion according to RECIST v1.1 criteria for the assessment of the principal judgment criteria. At baseline, lesion(s) must be ≥10 mm in the longest diameter (except lymp nodes which must have a short axis ≥15 mm).	□ oui □ non
International Federation of Gynecology and Obstetrics (FIGO 2009) classification (confirmed by clinical staging and/or imaging): (i) stage IB1-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).	□ oui □ non
Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1.	□ oui □ non
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) ≥1,500/mm3 (≥1.5 x 109/L) without granulocyte colony-stimulating factor (G-CSF) support. b. Total white blood cells (WBC) >2,000/mm3 (>2.0 x 109/L) (including Polymorphonuclear neutrophils > 1,500/mm3 or 1.5 x 109/L) c. Lymphocyte count ≥500/mm3 (≥ 0.5 x 109/L) d. Platelet count ≥ 100,000/mm3 (≥ 100 x 109/L) without transfusion. e. Haemoglobin ≥ 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) ≤ 1.5 × upper limit of normal (ULN) for patients not receiving therapeutic anticoagulation. Patients receiving therapeutic anticoagulation should be on a stable dose. g. Creatinine <1.5 ULN or calculated creatinine clearance (CrCL) ≥ 45 mL/min (calculated using the Cockcroft-Gault formula).	□ oui □ non

h. Aspartate transaminase (AST), alanine transaminase (ALT), and alkaline phosphatase <2.5 x ULN. i. Serum bilirubin <1.5 x ULN.	
Proteinuria < 200 mg/dL (2 g/L). Patients with ureteral stent or with bladder invasion are eligible if the proteinuria is above the former threshold.	□ oui □ non
Ability to comply with the study protocol	□ oui □ non
Geographical, social and psychological ability to undergo the follow-up required by the study.	□ oui □ non
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 in arm B and at least 6 months after the last cisplatin/carboplatin dose in arm A. * 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. ** 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.	□ oui □ non
Patients must be affiliated to a social security system or beneficiary of the same, as per local regulatory requirements	□ oui □ non

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Critères de non inclusion :

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Histological types of cervical cancer other than those listed in the inclusion criteria (based on FIGO 2009 classification), including: a. Stage IB1, IB2 and IIA cervical cancer with no regional lymph node metastases (N0). b. Stage IVB cervical cancer with presence of distant metastases other than para-aortic lymph node metastases.	□ oui □ non
Prior surgery for cervical cancer unless cone resection and paraaortic lymphadenectomy.	□ oui □ non
Prior pelvic radiotherapy, other radiotherapy, chemotherapy or immunotherapy.	□ oui □ non
Any malignancy other than the disease under study in the past 5 years excepting skin cancers such as BCC or SCC.	□ oui □ non
Pregnant or lactating women, or intending to become pregnant during the study.	□ oui □ non
For patient ≥ 70 years old with a G-8 score ≤ 14, unconfirmation of patient eligibility done by the onco-geriatrian at screening	□ oui □ non
History of clinically relevant cardiovascular disease, congestive heart failure (New York Heart Association [NYHA] Class II or greater; see Appendix 3), or a known left ventricular ejection fraction (LVEF) <50%, symptomatic coronary artery disease, poorly controlled cardiac arrhythmia, or myocardial infarction.	□ oui □ non
Active inflammatory bowel disease, lack of physical integrity of the upper gastrointestinal tract, malabsorption syndrome.	□ oui □ non
Serious infection requiring oral or IV antibiotics within 4 weeks prior to randomisation, including but not limited to hospitalization for complications of infection, bacteraemia, or severe pneumonia	□ oui □ non

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Treatment with another investigational therapy within 30 days prior to initiation of the study drug.	□ oui □ non
Major surgical procedure within 4 weeks prior to randomisation or anticipation of the need for a major surgical procedure during the study other than for diagnosis. The following are not considered a major surgical procedure and are therefore permitted: (i) placement of central venous access catheter(s) (e.g., port or similar); (ii) surgical lymph node staging with no perioperative complications; (iii) placement of ureteral catheters.	□ oui □ non
History of severe allergic anaphylactic reactions to chimeric, human or humanized antibodies, or fusion proteins.	□ oui □ non
Known hypersensitivity to Chinese hamster ovary (CHO) cell products or any component of the atezolizumab formulation	□ oui □ non
Any contraindication to the use of cisplatin and/or carboplatin.	□ oui □ non
History of autoimmune disease, including but not limited to myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, vascular thrombosis associated with antiphospholipid syndrome, Wegener's granulomatosis, Sjögren's syndrome, Guillain-Barré syndrome, multiple sclerosis, meningoencephalitis, or glomerulonephritis (see Appendix 6 for a more comprehensive list of autoimmune diseases) with the following exceptions: patients with a history of autoimmune-related hypothyroidism on a stable dose of thyroid replacement hormone, patients with controlled Type 1 diabetes mellitus on a stable insulin regimen, and patients with mild autoimmune skin disorders (such as eczema or atopic dermatitis involving <10% of the skin) may be eligible for this study.	□ oui □ non
History of idiopathic pulmonary fibrosis (IPF, including pneumonitis), drug-induced pneumonitis, organizing pneumonia (i.e., bronchiolitis obliterans, cryptogenic organizing pneumonia), or active pneumonitis.	□ oui □ non
Peripheral neuropathy ≥grade 2.	□ oui □ non

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Positive test for human immunodeficiency virus (HIV).	□ oui □ non
Active hepatitis B (positive hepatitis B surface antigen [HBsAg] test at screening) or hepatitis C (positive hepatitis C virus antibody [HCVAb] test at screening). Note: Patients with past hepatitis B virus (HBV) infection or resolved HBV infection (defined as having a negative HBsAg test and a positive hepatitis B core antibody [HBcAb] test) are eligible.	□ oui □ non
Known active tuberculosis.	□ oui □ non
Receipt of a live, attenuated vaccine within 4 weeks prior to randomisation or anticipation that such a live, attenuated vaccine will be required during the study. Note: Patients must agree not to receive live, attenuated influenza vaccine (e.g., FluMist®) within 28 days prior to randomisation, during treatment or within 5 months following the last dose of atezolizumab	□ oui □ non
Prior treatment with CD137 agonists, anti-PD-1, or anti-PD-L1 therapeutic antibody or immune checkpoint targeting agents.	□ oui □ non
Treatment with systemic corticosteroids or other systemic immunosuppressive medications within 2 weeks prior to randomisation. The use of inhaled corticosteroids and mineralocorticoids (e.g., fludrocortisone) is allowed.	□ oui □ non
Treatment with systemic immunostimulatory agents (such as interferons or IL-2) within 4 weeks or five half-lives of the drug (whichever is shorter) prior to randomisation.	□ oui □ non
Illicit drug or alcohol abuse within 12 months prior to screening, in the investigator's judgment Any other serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study.	□ oui □ non
Patients under judicial protection (curatorship, tutorship) and/or deprived of freedom.	□ oui □ non

Date : _____

Signature de l'investigateur : _____