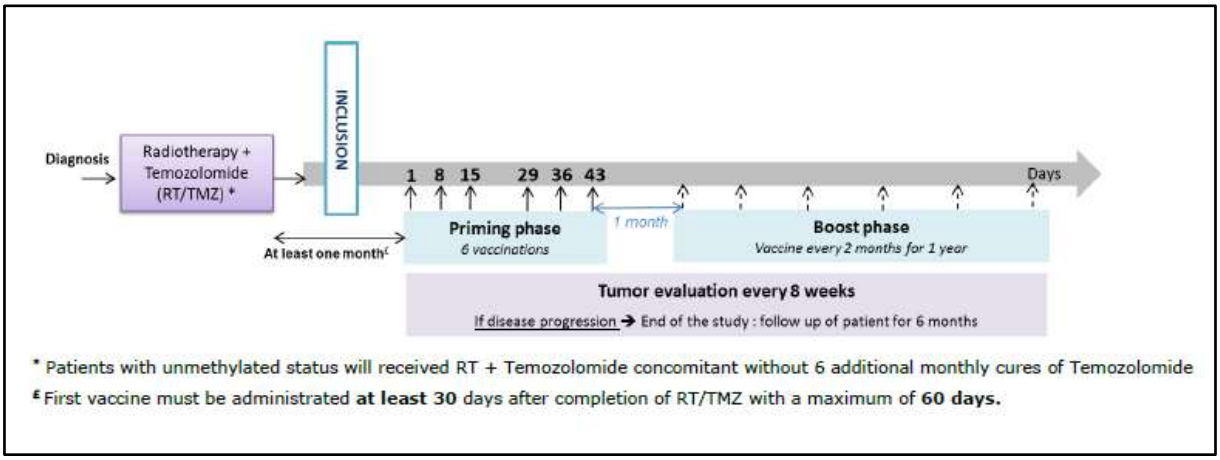
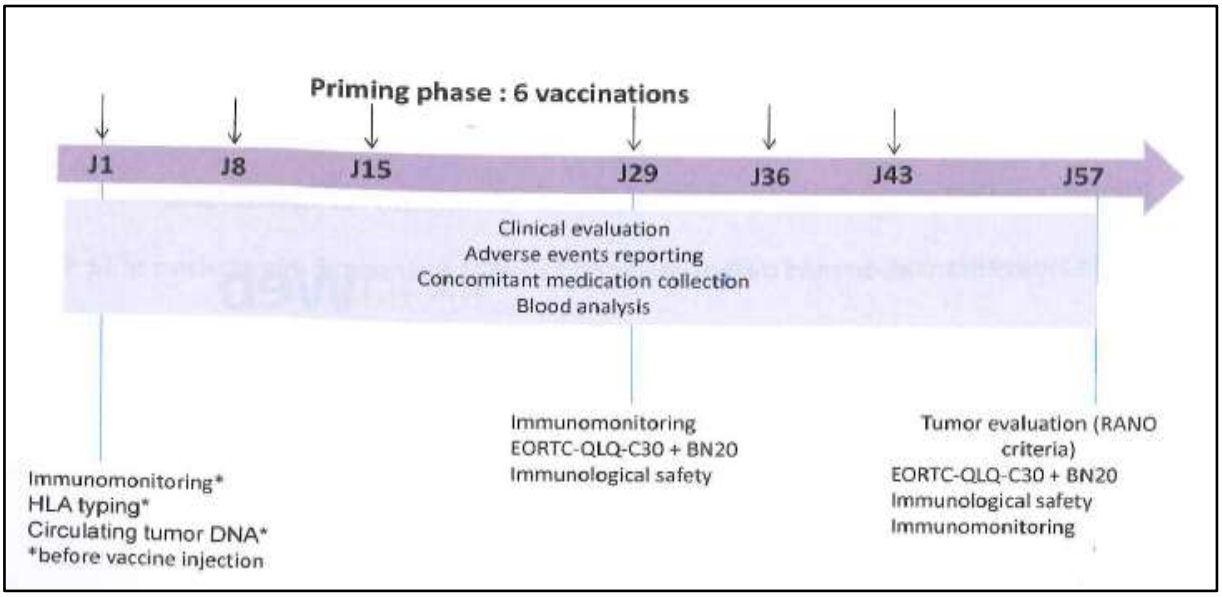
	CRITERES DE SELECTION **ETUDE UCPVax-Glio**	Identité patient (coller étiquette patient)
Version 1.0 du 25/11/2021	Investigateur en charge du patient : …….. PI : **Pr GHIRINGHELLI** Mail : fghiringhelli@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Nathalie LEVEQUE** Poste : 3485

« UCPVax-GLIO »

Vaccination thérapeutique anti-cancer utilisant les peptides UCP dérivés de la télomérase : une cohorte exploratrice dans le glioblastome





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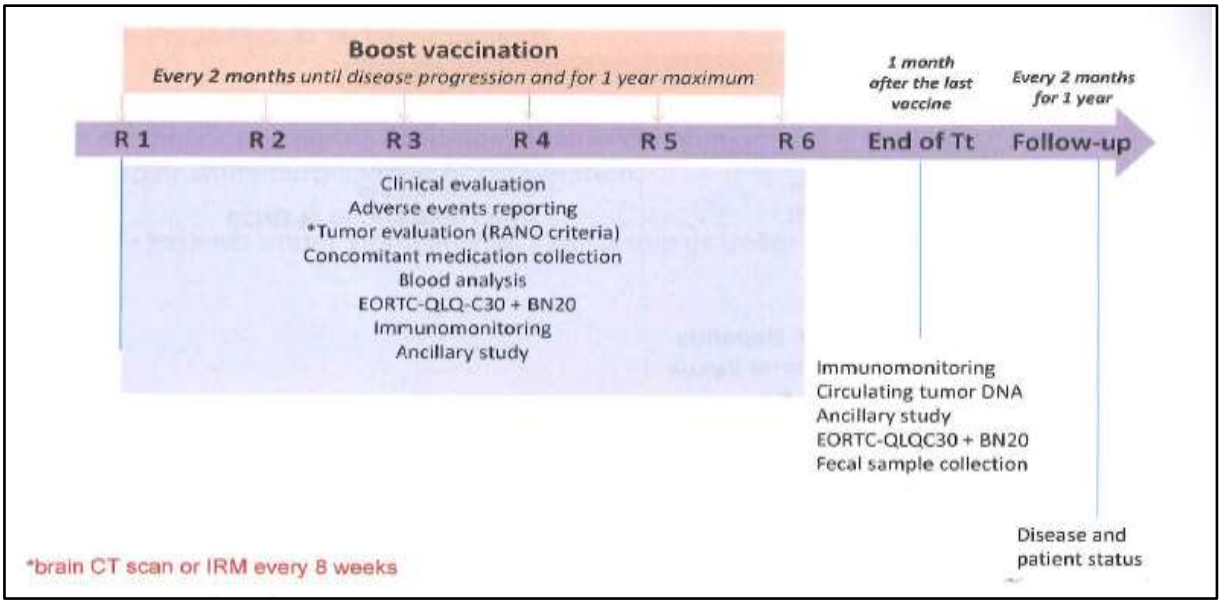

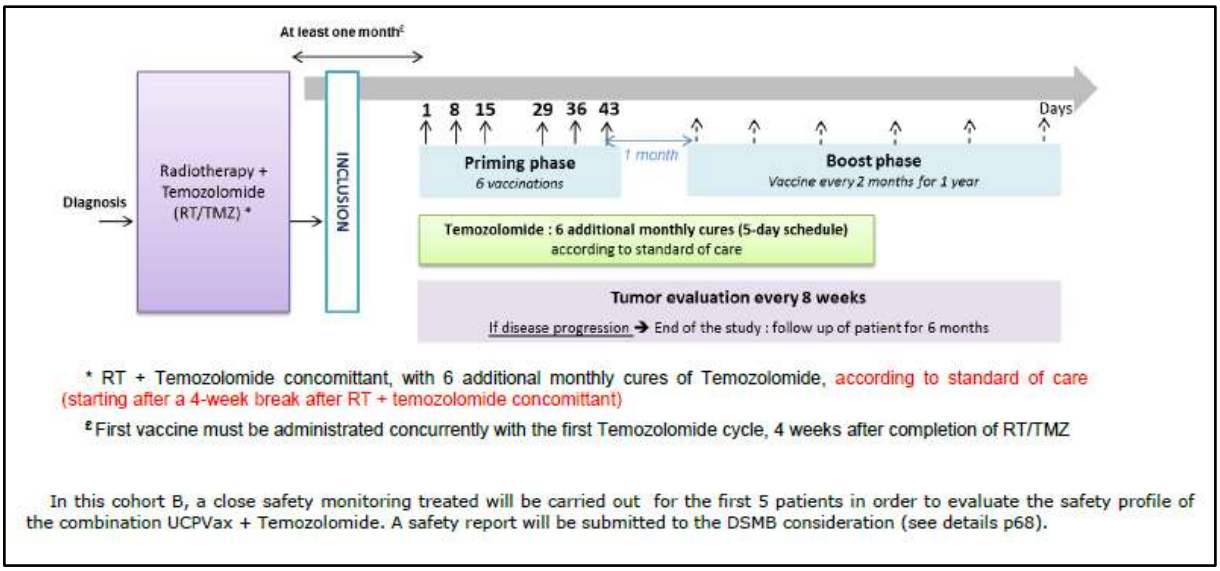

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VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion :

1. Male or female patients, age ≥ 18 ans and ≤ 75 years old	□ oui □ non
2. Written informed consent	□ oui □ non
3. Histologically confirmed glioblastoma :	□ oui □ non

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4.	Patient with unmethylated MGMT status **(cohort A)** or Patient with methylated MGMT status **(cohort B)**	□ oui □ non
5.	Patients previously pre-treated with standard radiochemotherapy	□ oui □ non
6.	Karnofsky Performance status ≥ 70 %	□ oui □ non
7.	Life-expectancy > 3 months	□ oui □ non
8.	Adequate hematological, hepatic, and renal function : - Hemoglobin ≥ 10.0 g/dL - White blood cells (WBC) ≥ 3.0 x 10^9/L including neutrophils ≥ 1.5 x 10^9/L and total lymphocytes **count ≥ 0.8 x 10^9/L** - Platelets count ≥ 100 x 10^9/L - Serum alkaline phosphatase ≤ 3 x ULN Serum transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST] ≤ 2.5 x ULN - Total bilirubin ≤ 1.5 x ULN - Glomerular Filtration Rate ≥ 50 mL/min (according to Modification of the Diet in Renal Disease [MDRD] formula or Cockcroft & Gault formula) -Serum albumin ≥ 30 g/L	□ oui □ non
9.	Females must be using highly effective contraceptive measures (see Section V-4), and have a negative pregnancy test prior to the start of dosing if of childbearing potential, or must have evidence of non-childbearing potential by fulfilling one of the following criteria at screening: - Post-menopausal is defined as aged more than 50 years an amenorrhoeic for at least 12 months following cessation of all exogenous hormonal treatments. - Women under the age of 50 years would be considered postmenopausal if they have been amenorrhoeic for 12 months or more following cessation of exogenous hormonal treatments and with luteinizing hormone and follicle stimulating hormone levels in the post-menopausal range for the institution. - Women with documentation of irreversible surgical sterilisation by hysterectomy, bilateral oophorectomy or bilateral salpingectomy but not tubal ligation. Females of childbearing potential should use reliable methods of contraception from the time of the screening until 5 weeks after discontinuing study treatment. Male patients with a female partner of childbearing potential should be willing to use barrier contraception during the study and for 5 months following discontinuation of study drug. Patients should refrain from donating sperm from the start of dosing until 5 months after discontinuing study treatment.	□ oui □ non
10.	Affiliation to French social security or receiving such a regime	□ oui □ non

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Critères de non inclusion :

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1. Presence of known extracranial metastatic or leptomeningeal disease	□ oui □ non
2. Glioblastoma with mutated IDH1 (assessed by Immunohistohemistry)	□ oui □ non
3. Current or recent treatment with another investigational drug	□ oui □ non
4. Carmustine implant during surgery	□ oui □ non
5. History of autoimmune diseases (lupus, rheumatoid arthritis, inflammatory bowel disease…)	□ oui □ non
6. Prohibited medications : a- Chronic treatment with immunosuppressive drugs b- Ongoing requirement for supraphysiologic steroid defined as > 10 mg prednisone daily (or equivalent) c- Treatment with therapeutic oral or IV antibiotics within 4 weeks prior to enrollment. Patients receiving prophylactic antibiotics (e.g., to prevent a urinary tract infection or pulmonary disease) are eligible for the study	□ oui □ non
7. Known positive serology for Human Immunodeficiency Virus (HIV) or Hepatitis C virus (HCV); presence in the serum of the antigens HBs	□ oui □ non
8. Non-hematologic toxicities Grade >1 severity (or, at the investigator's discretion, Grade >2 if not considered a safety risk for the patient)	□ oui □ non
9. Patient with intra-alveolar hemorrhage, pulmonary fibrosis, or uncontrolled asthma, or chronic obstructive disease (COPD), defined as at least 1 hospitalization within 4 months prior to enrollment or as at least 3 exacerbations during the last year prior to enrollment	□ oui □ non
10. Hospitalization for cardiovascular or pulmonary disease within 4 weeks prior to enrolment	□ oui □ non
11. Patient with LEVF <40%	□ oui □ non
12. Participation in a clinical study with an investigational product within 4 weeks prior to the start of the study treatment or patient in the exclusion period of a previous clinical trial	□ oui □ non
13. Pregnancy or lactating patients	□ oui □ non
14. Patients with any severe/uncontrolled inter current illness, significant comorbid or psychiatric conditions that in the opinion of the investigator would impair study participation or cooperation	□ oui □ non
15. Patients under guardianship, curatorship or under the protection of justice.	□ oui □ non

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Date : _____

Signature de l'investigateur : _____