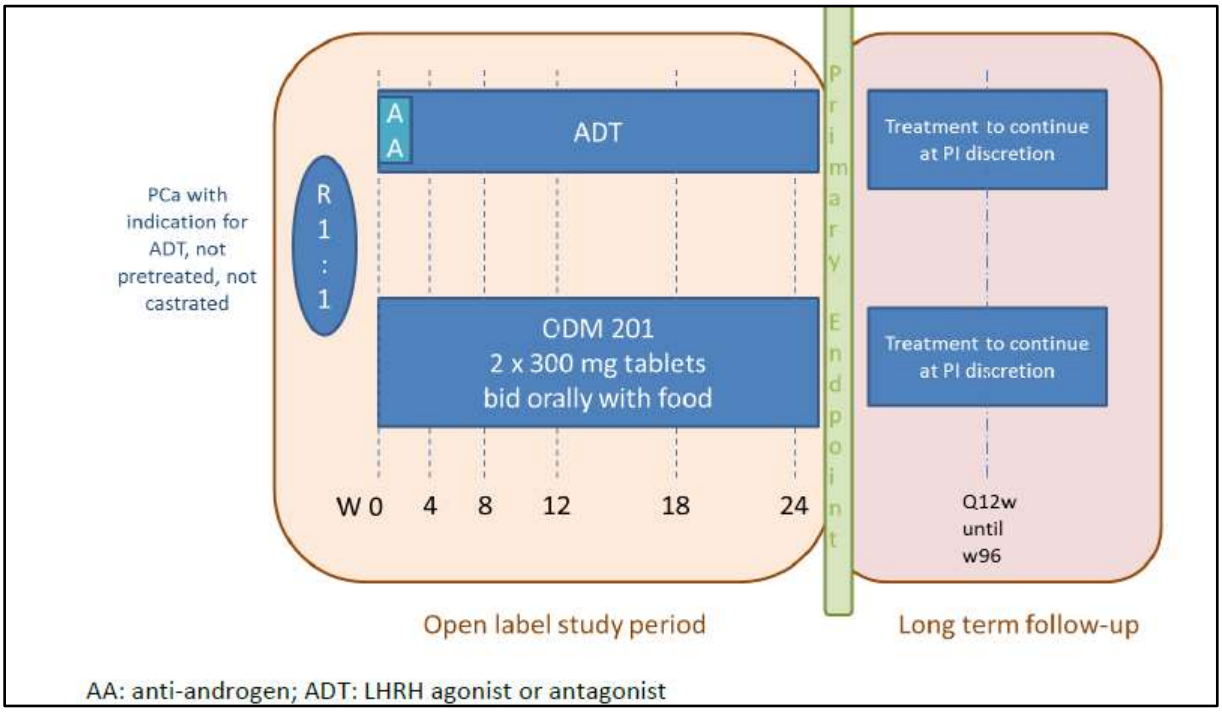
CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE EORTC 1532**	Identité patient (coller étiquette patient)
Version 1.0 du 10/03/2015	Investigateur en charge du patient : …….. PI : **Dr Magali QUIVRIN** Mail : mquivrin@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Philippe BATAILLARD** Poste : 8137

« EORTC 1532 »

A phase 2 Randomized Open-Label Study of Oral ODM-201 vs. androgen deprivation therapy (ADT) with LHRH agonists or antagonist in Men with Hormone Naive Prostate Cancer.



VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion

1.	Aged 18 years or older	□ oui □ non
2.	Histologically confirmed prostate cancer (all stages) for whom continuous ADT is indicated for a minimum period of 24 weeks	□ oui □ non
3.	Patients presenting with a maximum of 4 confirmed metastatic lesions, including bone, extra-pelvic lymph nodes, and > 2 cm pelvic lymph nodes by imaging (contrast enhanced CT Scans or	□ oui □ non

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MRI, Tc-99m BS according to local practice, see 6.1.1). Visceral metastases are excluded	
4. Asymptomatic for metastatic prostate cancer ; urinary symptoms are allowed	□ oui □ non
5. Baseline total testosterone ≥ 8 nmol/L or 230 ng/Dl	□ oui □ non
6. Two subsequent PSA values ≥ 2 ng/ml, done in the past 3 months with a minimum of 2 weeks between the two, with the second being equal to or highter than the first	□ oui □ non
7. WHO performance status (PS) of 0-1	□ oui □ non
8. G8 score ≥ 14 for patients aged ≥ 70 years old	□ oui □ non
9. A life expectancy of at least 12 months	□ oui □ non
10. Able to swallow the study drug whole as a tablet	□ oui □ non
11. Adequate bone marrow function (absolute neutrophil count (ANC) ≥ 1.5 10^9 /L ; hemoglobin ≥ 10.0 g/dl ; platelets ≥ 100 10^9/L)	□ oui □ non
12. Adequate renal function : creatinine ≤ 1.5 x ULN	□ oui □ non
13. Albumin > 25 g/L	□ oui □ non
14. Adequate hepatic function : * Bilirubin : total bilirubin ≤ 1.5 x ULN * AST and/or ALT ≤ 2.5 x ULN	□ oui □ non
15. Normal 12-lead ECG as per local standard	□ oui □ non
16. Patients of reproductive potential should use adequate birth control measures, during the study treatment period and for at least 3 months after the last tudy treatment. A highly effectuve method of birth control is defined as those which result in low failure rate when used conssistently and correctly	□ oui □ no
17. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow up schedule ; those conditions should be discussed with the patient before registration in the trial	□ oui □ no
18. Before patient registration / randomisation, written informed consent must be given according to ICH / GCP, and national / local regulations	□ oui □ no

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Critères de non inclusion :

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1. Previously or currently receiving hormonal therapy with intent to treat prostate cancer disease (surgical castration or other hormonal manipulation, e.g. LHRH agonists, LHRH antagonists, antiandrogens, oestrogens, 5α reducatse inhibitor). For patients that have received (neo)adjuvant ADT before radiotherapy, it should have been stopped for more than 1 year	□ oui □ non
2. Prior use of inestigational agents that block androgen synthesis or block androgen receptor	□ oui □ non
3. Use of herbal products taht may have hormonal anti-prostate cancer activity and / or are known to decrease PSA levels	□ oui □ non
4. Has received systemic glucocorticoids within 24 weeks prior to enrollment or is expected to require systemic glucocorticoids during the study period, unless determined to be medically necessary by the investigator for other indications than prostate cancer	□ oui □ non
5. Radiation therapy for treatment of the primary tumor within 3 months prior to enrollment	□ oui □ non
6. Use of an investigational agent within 4 weeks prior to enrollment is not allowed	□ oui □ non
7. Gastrointestinal disorder affecting absorption	□ oui □ non
8. Known hypersnsitivity to the study treatment or any of it's ingredients (refer to investigator's brochure).	□ oui □ non
9. Severe or uncontrolled concurrent disease, infection or co-morbididty including active viral hepatitis, known human immunodeficiency virus infection with detectable viral load (HIV) or chronic liver disease	□ oui □ non
10. History of prior malignancy. Adequately treated basal cell or squamous cell carcinoma of skin or superficial bladder cancer that has not spread behind the connective tissue layer (i.e. pTis, pTa, pT1) is allowed, as well as any other cancer from which the patient has been disease-free for period of at least 5 years.	□ oui □ non
11. Clinically significant cardiovascular disease including : * myocardial infarction within siw months prior to randomization * uncontrolled angina within 3 months prior to randomization * Coronary / peripheral artery bypass within 6 months prior randomization	□ oui □ non

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* Stroke within 6 months prior to randomization * Congestive heart failure NYHA class 3 or 4 * History of clinically signifcant ventricular arrhythlias * history of Mobitz II second degree or third degree heart block without a permanent pacemaker in place	
12. Uncontrolled hypertension as indicated by a resting systolic blood pressure > 170 mm Hg OR DIASTOLIC BLOOD PRESSURE > 105 MM hG at the screening visit	□ oui □ non

Date : _____

Signature de l'investigateur : _____