P027

FINAL RESULTS OF GERICO 10 GETUG P03 TRIAL EVALUATING FEASIBILITY OF DOCETAXEL IN VULNERABLE OR FRAIL ELDERLY (75+) PATIENTS WITH METASTATIC CASTRATION RESISTANT PROSTATE CANCER

M. Loic[1,*], I. Latorzeff[2], N. Houede[3], J. Meunier[4], F. Priou[5], G.-M. Gwenaëlle[6], E. Carola[7], C. Orsini[8], T. Filleron[9]
[1]*Medical Oncology, Institut Claudius Regaud - IUCT-Oncopole,* [2]*Radiotherapy, Clinique Pasteur, Toulouse,* [3]*Medical Oncology, CHU, Nîmes,* [4]*Medical Oncology, CHR, Orléans,* [5]*Medical Oncology, CH Vendée, La Roche sur Yon,* [6]*Medical Oncology, Institut Paoli Calmette, Marseille,* [7]*Medical Oncology, CH, Senlis,* [8]*R&D Unicancer, Paris,* [9]*Methodologist, Institut Claudius Regaud - IUCT-Oncopole, Toulouse, France*

Introduction: Prostate cancer (PC) in the elderly is a major issue for medical community because of epidemiologic and demographic data.

Treatment of metastatic castration resistant PC (mCRPC) has evolved with new hormonal therapies but chemotherapy remains a key treatment for this disease.

Benefit of chemotherapy is independent of age in pivotal study by Tannock (cut-off:69) in a highly selected population.

But data, especially geriatric data, are lacking to determine which patient should not receive Docetaxel because off anticipated toxicity.

Objectives: Our study aims to evaluate prospectively the feasibility of a chemotherapy with Docetaxel/Prednisone administered every 3 weeks in patients 75+, evaluated by comprehensive geriatric assessment, belonging to group 2 "vulnerable" or to group 3 "frail" of the classification proposed in 2010 by the International Society of Geriatric Oncology (SIOG) [1].

Methods: Chemotherapy with Docetaxel/Prednisone was administered every 3 weeks (arm A: 60 mg/m² C1 then 70 mg/m² for subsequent cycles if tolerance is good) or weekly (arm B: 35mg/m² J1J8 with Day 1 = Day 21) in patients 75+, evaluated by comprehensive geriatric assessment, belonging to group 2 "vulnerable" or to group 3 "frail" (SIOG 2010).

Feasibility is defined as the possibility for a patient to receive 6 cycles of chemotherapy without fulfilling the criteria for withdrawal from study defined "a priori" by GERICO group:

- stop or delay chemotherapy ≥2 weeks
- necessity to reduce chemotherapy dose ≥25%
- febrile neutropenia or NCI CTC grade III non-haematological toxicity (except alopecia)
- loss of autonomy (Activity of Daily Living (ADL) decrease ≥2 points) leads to geriatric criterion

The trials is a double randomized phase II based on a Simon's optimum two stages design for each strata defined according to the SIOG criteria (α = 5%, 1-β = 90%, p0 = 0.70 and p1 = 0.90).

A pharmacokinetic/pharmacodynamic study is associated to our project, based on a method of population pharmacokinetics, trying to highlight clinical, geriatric and biological parameters as predictors of haematological tolerance. A pharmacogenetic study of PXR (pregnane X receptor or nuclear receptor NR1I2) but also other enzyme systems (such as CYP3A4 and CYP3A5) will be associated with pharmacokinetic investigations.

Results: From dec 2010 until Aug 2012 21 centers have included 66 patients, 45 and 21 in groups 2 and 3 respectively based on investigators evaluation. All allocations were reviewed by a steering committee.

Enrolment in group 3 was prematurely closed in OCT 2012 on the recommendation of a safety committee. In group 2, planned interim analysis was performed after inclusion of 30 pts. (ARM A/B n=15/15). 11pts (73,3%; 95%CI=[44,9;92,2]) in arm A and 10 pts (66,6%;95%CI [38,4;88,2] didn't meet the predefined criteria.

Conclusion: According to the criteria of our study, defined *a priori*, Docetaxel weekly or every 3 weeks is not feasible in patients 75+ with mCRPC classified in groups 2 or 3 of SIOG 2010 recommendations.

In our opinion, m CRPC pts 75+ should not receive chemotherapy without prior geriatric screening (G8) ±geriatric assessment ± geriatric intervention.

These results confirm the central role of geriatric assessment in mCRPC elderly patients.

Full geriatric description of the population and all secondary end points will be presented at the meeting.

Reference:

[1] Droz JP. BJU Int. 2010 Aug;106(4):462-9

Disclosure of interest: M. Loic Grant/Research Support from: GSK, Consultant for: Sanofi Astellas Janssen Roche Pfizer Novartis Ipsen, I. Latorzeff: None declared, N. HOUEDE: None declared, J. Meunier: None declared, F. Priou: None declared, G.-M. Gwenaëlle: None declared, E. Carola: None declared, C. Orsini: None declared, T. Filleron: None declared

Keywords: Castration resistant, Chemotherapy, frail, metastatic, prostate

---

P028

UNRESECTABLE AND METASTATIC PANCREATIC ADENOCARCINOMA IN THE ELDERLY: A 10-YEAR SINGLE-CENTER EXPERIENCE

M. Langlois[1,*], A. Beaudoin[1], F. Lemay[1]
[1]*University of Sherbrooke, Sherbrooke, Canada*

Introduction: Pancreatic adenocarcinoma is the fourth leading cause of cancer deaths in Canada and mainly affects individuals older than 60 years of age. Pancreatic cancer follows a relatively silent clinical course and is more often diagnosed at an advanced stage, thereby ruling out the possibility of cure. When faced with a diagnosis of unresectable pancreatic adenocarcinoma, patients may be offered palliative chemotherapy. Unfortunately, a paucity of data exists regarding the use, efficacy and safety profile of chemotherapeutic agents in the elderly population with pancreatic cancer. With an aging population, clinicians are bound to be faced with oncologic decisions regarding treatment of those under-represented elderly patients with pancreatic adenocarcinoma. It is therefore imperative to