Ensuring equity of access to innovation
Objective 2

When the same alteration is found

Main objective: Identification of subsets of patients that may benefit from treatment

Population

Patients with tumors harboring a genomic alteration on one of the biological targets of the drug
- PI: Gilles Vassal / NCT02134081
- FROM AUGUST 5, 2013 TO MAY 7, 2015
- The institutional support from Pfizer
- The Foundation, the UNICANCER’s partner
- Financial support from INCa
- French Thyroid Cancer Network (TUTHYREF)
- French Cooperative Gynecological Cancer Research Group (ARCAGY-GINECO)

Cohorts – MET amplified

Patients on treatment

To May 7, 2015:

- 14 patients compliant
- 42 stopped for treatment

Survival Data

OS: Median survival: 11.8 months; 75 progressions or deaths
ES: Median 10 months; 73 deaths

Overall toxicity (All ampil MET) (% of pts)

** Including 6 patients with no RECIST evaluation but early death related to disease progression

** Response of target lesions but appearence of new lesions: PD

* RECIST evaluation is not yet evaluable for 4 patients, because of recent start of treatment, 1 MD

Conclusions

Rate of mutation detection via genomic profiling on tumor biopsies is excellent.

On a scale from 1 to 5

1 = Unlikely

2 = Possible

3 = Likely

4 = Highly Likely

5 = Certain

**Doctor’s choice: Preferred strategy

**Patient’s choice: Preferred strategy

Other

Efficacy

Best response

** Complete objective response

** Partial objective response

** Stable disease

** Progression in target lesion

** Progression in non-target lesion/lesions

** Progression in target lesion and new lesion(ies)

** Progression in new lesions

Unknown 1

Doctor choice** 1

Patient choice* 1

Other

Pulmonary embolism 1

Fatigue + ASAT increase 1

ALAT and ASAT increase 2

Toxicity

32

Unknown 1

Doctor choice** 1

Patient choice* 1

Other

Pulmonary embolism 1

Fatigue + ASAT increase 1

ALAT and ASAT increase 2

Inclusions per cohort

Quality of life

EORTC QLQ-C30

Global health status/quality of life

Functionality

Emotional functioning

Cognitive functioning

Fatigue

Nausea/vomiting

Palliative care

Social functioning

Phoria

Pain

Palliative care

Other

Phase 2 clinical trial: secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug – PI: Gilles Vassal / NCT02134081

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