SYNOPSIS

Name of Sponsor/Company: Centre Eugène Marquis	**Individual Study Table Referring to Part of the Dossier**	(For National Authority Use only)
Name of Finished Product: Vesicare®	**Volume:** NA	
Name of Active Ingredient: Solifenacin succinate	**Page:** NA	

Title of Study:
Succinate of solifenacin impact in the treatment of acute irritative urinary toxicity during radiotherapy for prostate cancer

Investigators:
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Study centre(s):
Centre Eugène Marquis, Rennes; Hôpital Saint Louis, Paris; Centre Hospitalier Lyon Sud, Lyon; Centre Hospitalier Bretagne Sud, Lorient; Clinique Pasteur Lanroze, Brest.

Publication (reference):
NA

Studied period (years): date of first enrolment: 2016/07/07 date of prematurely ended: 2017/05/02	**Phase of development:** Therapeutic confirmatory (Phase III)

Objectives:
The main objective is to assess solifenacin succinate efficacy on irritative urinary symptomatology occurring during prostate irradiation in patients suffering from prostate cancer.

The secondary objectives are:

- to assess solifenacin succinate efficacy on non-irritative symptoms and on global urinary symptomatology
- to assess solifenacin succinate efficacy on quality of life
- to describe qualitatively and quantitatively acute urinary toxicity of prostate irradiation
- to assess solifenacin tolerance of patients during and after prostate irradiation.

Methodology:
This is a randomised against placebo, double-blinded parallel-group study.

Number of patients (planned and analysed):
It was planned to include 70 subjects.
7 subjects consented to participate and 4 were finally included.
One patient withdrew his consent; 2 patients completed the study and 1 patient's participation was interrupted due to the prematurely ended of the study.

Diagnosis and main criteria for inclusion:
The medical condition investigated was the symptomatology related to acute urinary toxicity occurring during prostate irradiation.

The main eligible criteria were patient with prostate localized adenocarcinoma complaining with urinary symptoms during irradiation (standard scheme with a global dose between 70 and 80 Gy), obtaining greater than 5 in the overactive bladder score of the USP scale.

Test product, dose and mode of administration, batch number:
Solifenacin succinate, 5 mg per day by oral use (batch number: BX1006154)

Duration of treatment:
3 months

Reference therapy, dose and mode of administration, batch number:
Placebo, 5mg per day, by oral use (batch number: BX1005037)

Criteria for evaluation:
Efficacy:

- Global, dysuria and overactive bladder scores of the USP scale, at initiation, and 6 weeks, 3 months and 6 months after beginning of the test drug intake (main criteria underlined)
- Frequency and CTCAE grade of urinary symptoms at initiation, 6 weeks, 3 months and 6 months after beginning of the test drug intake
- QLQ-C30 and PR25 at initiation, 6 weeks, 3 months and 6 months after beginning of the test drug intake

Safety:

- Frequency and CTCAE grade of adverse events occurring during the study

Statistical methods:

Analysis is planned on the intent to treat population. Only patients with consent withdraw are excluded from the analysis. Demographics and medical history including prostate disease characteristics are described by groups defined according to the randomisation assignment.

Means of scores of the USP scale and of the quality of life scales, and means of CTCAE grades per each symptom are compared between groups, independently at initiation, week 6, month 3 and 6 by Student's tests (or Mann Whitney U tests if necessary). A 5% p value is considered as level of significance. Only the comparison of the overactive bladder score is considered as a confirmatory measure to avoid inflate of the alpha risk.
Absolute and relative frequency is used to describe adverse event occurrence between the two study arms.

SUMMARY – CONCLUSIONS

EFFICACY RESULTS:
NA

SAFETY RESULTS:
NA

CONCLUSION:
Early study termination for failure to recruit patients. Given the small number of patients included, the sponsor decided not to conduct the planned statistical analysis. The regulatory authorities were informed accordingly.

Date of the report: 2020, 27th may.