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(54) NOVEL ANTITUMORAL USE OF CABAZITAXEL

(75) Inventor: Sunil GUPTA, Chester Springs, PA

(US)

(73) Assignee: **AVENTIS PHARMA S.A.**, Antony

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(57) ABSTRACT

The invention relates to a compound of formula:

which may be in base form or in the form of a hydrate or a solvate, in combination with prednisone or prednisolone, for its use as a medicament in the treatment of prostate cancer, particularly metastatic prostate cancer, especially for patients who are not catered for by a taxane-based treatment.



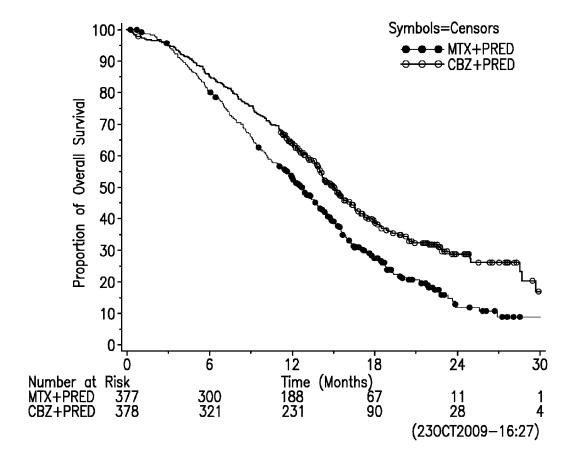


FIG. 1

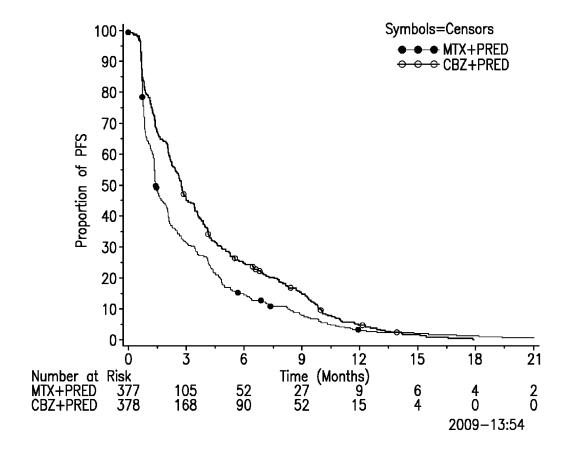
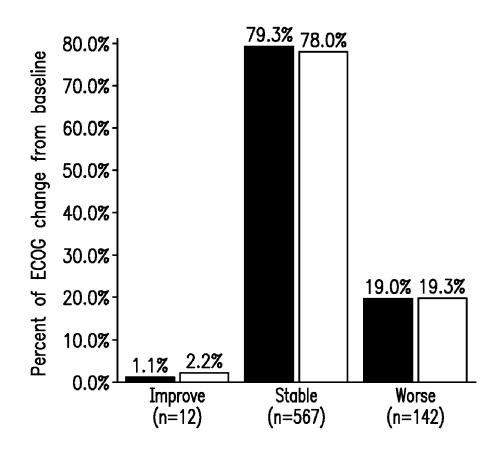


FIG. 2

| Factor | Patient number | Hazard ratio (95% CI) | ← Favors Cabazitaxel Favors Mitoxantrone ■ | _ | | |
|---|--------------------------------------|--------------------------|--|----|--|--|
| All randomized patients | 755 | 0.70 (0.59-0.83) | - | .7 | | |
| ECOG status: 0,1 | 694 | 0.68 (0.57-0.82) | — | | | |
| ECOG status: 2 | 61 | 0.81 (0.48-1.38) | - | | | |
| Measurable disease: No | 350 | 0.72 (0.55-0.93) | — | | | |
| Measurable disease: Yes | 405 | 0.68 (0.54-0.85) | | | | |
| No. of prior chemotherapies: 1 | 528 | 0.67 (0.55-0.83) | | | | |
| No. of prior chemotherapies: ≥2 | 227 | 0.75 (0.55–1.02) | | | | |
| Age: <65 years | 295 | 0.81 (0.61-1.08) | - | | | |
| Age: ≥65 years | 460 | 0.62 (0.50-0.78) | -• | | | |
| Rising PSA at baseline: No | 159 | 0.88 (0.61-1.26) | | | | |
| Rising PSA at baseline: Yes | 583 | 0.65 (0.53-0.80) | | | | |
| Total docetaxel dose: <225 mg/m ² | 59 | 0.96 (0.49-1.86) | | | | |
| Total docetaxel dose: ≥225 to 450 mg/m ² | 206 | 0.60 (0.43-0.84) | | | | |
| Total docetaxel dose: ≥450 to 675 mg/m ² | 217 | 0.83 (0.60-1.16) | | | | |
| Total docetaxel dose: ≥675 to 900 mg/m² | 131 | 0.73 (0.48-1.10) | | | | |
| Total docetaxel dose: ≥900 mg/m ² | 134 | 0.53 (0.47-0.90) | — | | | |
| Progression during docetaxel treatment | 219 | 0.68 (0.57-0.82) | — | | | |
| Progression <3 months after docetaxel | 339 | 0.70 (0.55-0.91) | -• | | | |
| Progression ≥3 months after docetaxel | 192 | 0.75 (0.51-1.11) | | | | |
| | | | 0 0.5 1 1.5 2 | | | |
| | Hazard ratio and 95% confidence inte | | | | | |

FIG. 3



| | | ECOG Categories | |
|------------|---|-----------------|----|
| Treatment | | | |
| CBZ+PRED | 4 | 283 | 70 |
| ☐ MTX+PRED | 8 | 283 | 72 |

FIG. 4

DOCKET

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