

RESULTS OF PHASE I PROMOTOR STUDY FOR ETHYPHARM'S ORAL FORMULATION OF CISPLATINE

PARIS – The ETHYPHARM Group have announced the Phase I Promotor Study results for its oral formulation of Cisplatin. All the studies demonstrated the good tolerance and good bioavailability of Cisplatin by the oral route associated with radiotherapy, in comparison with the intravenous form. The development of this product will permit the marketing of an oral form for the treatment of inoperable ORL tumours in association with radiotherapy.

The first study evaluated tolerance of the treatment and its bioavailability in comparison with the intravenous form. The oral form developed by Ethypharm presents, after administration of a dose of 10mg/m², a bioavailability of around 40% with a slight inter-individual variability equivalent to that observed by the IV route.

The second study administered in association with 5FU permitted to demonstrate that the maximum dose tolerated is attained at a level of 30mg/m² after 5 consecutive days of treatment.

The third study was conducted on patients presenting an inoperable ORL tumour in association with radiotherapy.

This study demonstrated good general tolerance at a maximum tolerated daily dose of à 25mg/m². The total effective dose of Cisplatin IV in association with radiotherapy (7 weeks) in the treatment of ORL cancer is 200 mg/m². The oral formulation of Cisplatin having a bioavailability of approximately 40%, the equivalent cumulated total dose is 500 mg/m², i.e., 15 mg/m²/ daily for 7 weeks of radiotherapy. The last Phase I Study demonstrates that this dose level has been attained.

" Furthermore, it demonstrates that tolerance of the treatment seems to be linked more with the actual dose administered rather than the cumulated dose. This tends to demonstrate the advantage of the administration of oral Cisplatin in several daily doses " declared Marie-Louise Vo Van, Deputy Medical Affaires Director.

The purpose of the next study will be to evaluate the tolerance of oral Cisplatin administered in 2 daily doses in association with radiotherapy on ORL cancer patients.

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