

# Palonosetron (PALO) Versus Ondanestron/Dolasetron (OND/DOL)

## In Preventing Chemotherapy-Induced Nausea and Vomiting (CINV) in Elderly Patients: Combined Results from 2 Phase III Trials

M. S. Aapro, A. Macciocchi; Clinique de Genolier, Genolier, Switzerland; Helsinn Healthcare, Lugano, Switzerland

### Background

The majority of cancer patients (pts) are elderly (age  $\geq 65$  yrs) with age-related increases in mortality, comorbidity, and potential for treatment complications. Therefore, simple, convenient treatment regimens are desirable in this population. PALO is a pharmacologically distinct 5-HT<sub>3</sub> receptor antagonist which offers multiday prevention of CINV with a single 0.25-mg IV dose. To assess efficacy/safety of PALO in elderly pts, a retrospective subset analysis of randomized studies (N = 754) in pts receiving moderately emetogenic CT was conducted.

### Overall Efficacy: 0-120 h Post-CT N = 165

Endpoint	PALO 0.25 mg (n = 79)	OND/DOL (n = 86)
CR (%)	70.9*	51.2
Pts with no EE (%)	77.2	61.6

\*P = 0.01

### Methods

The subset consisted of pts (n = 165)  $\geq 65$  yrs in the pooled data from 2 phase III, multicenter, randomized, double-blind trials

comparing single IV doses of PALO 0.25 mg, OND 32 mg, or DOL 100 mg. Concomitant dexamethasone was administered in 3% of pts. Endpoints included complete response rates (CR: no emetic episodes [EE] & no rescue therapy) and % of pts with no EE through 5 days post-CT.

### Results

A greater proportion of PALO-treated pts had a CR or were emesis-free compared with those treated with OND/DOL during the 5 days post-CT. (See table below) Pts in the PALO group experienced a longer time to treatment failure than pts in the

*continued on page 27*

### Abstract #8051

# Prevention of Delayed Nausea and Vomiting (D-CINV)

## Carryover Effect Analysis of Pooled Data from 2 Phase III Studies of Palonosetron (PALO)

S. M. Grunberg, J. A. Vanden Burgt, S. Berry, E. B. Rubenstein, D. Berry; University of Vermont, Burlington, VT; MGI Pharma, Bloomington, MN; Berry Consultants, College Station, TX; M. D. Anderson Cancer Center, Houston, TX

### Background

Control of acute chemotherapy-induced nausea and vomiting (A-CINV) is a positive predictor of control of D-CINV. First-generation 5-HT<sub>3</sub> receptor antagonists (RA) are highly effective in preventing A-CINV but less so in preventing D-CINV. PALO is a pharmacologically distinct 5-HT<sub>3</sub> RA with a

30+ fold higher binding affinity, a 40 hr plasma half-life, and has greater efficacy than ondansetron (OND) and dolasetron (DOL) in preventing both A-CINV and D-CINV in patients receiving moderately emetogenic chemotherapy (Aapro, ASCO '03, Rubenstein ASCO '03).

### Methods

Establishing whether this efficacy benefit in control of D-CINV is strictly a carryover effect from better control of A-CINV was analyzed using pooled data from 2 identically designed phase III trials where 754 patients received either a single IV

*continued on page 27*