An Indian real-world experience of Intravenous Fosnetupitant-Palonosetron (IV NEPA) in preventing delayed and extended delayed CINV

Authors: Amullya Pednekar[1], Pragya Shukla[2], Shaunak Valame[3], Siddhartha Nanda[4], Abhinandan Hanji[5], Naval Kishore Shakya[6], Arun Kumar Verma[7], Sagar B Bhagat[1], Saiprasad Patil[1], Sumit Bhushan[1], Hanmant Barkate[1]

[1]Glenmark Pharmaceuticals Ltd., Mumbai, India; Global Medical Affairs; [2]Delhi State Cancer Institute, Delhi, India; [3]Jawaharlal Nehru Cancer Hospital and Research Centre, Bhopal, India; [4]All India Institute of Medical Sciences, Raipur,India; [5]Hanji Cancer Hospital, Belgavi, India; [6]Lakshya Cancer Hospital and Research Centre, Lucknow, India; [7]Subharti Medical College and Hospital, Meerat, India.

Background

Nausea is still ranked as either the top or second most severe side effect of chemotherapy[1] with worst control compared to vomiting[2]

Nausea can only be measured subjectively and may be underreported by patients and underestimated by clinicians[3]

Report Nausea even on prescribing guideline based anti-emetic therapy[3]

Objective

To understand effectiveness and safety of fixed combination of IntraVenous (Fos)NEtupitant and PAlonosetron (IV NEPA) in preventing nausea in acute, delayed and extended delayed phase among patients receiving highly- and moderately emetogenic chemotherapy (HEC/MEC) regimens

Methods

Study Design

STOP CINV Study
(CTRI/2023/04/051951)

PHASE IV
Open label, single arm, multicenter, prospective

Study Population

- ≥18 years to ≤75 years of age
- Scheduled to receive their first chemotherapy cycle
- Receiving HEC/MEC regimen

Post-Hoc Analysis - Endpoints

Nausea was assessed during various phases using Visual Analog Scale (VAS)

2 COHORTS:
HEC and MEC

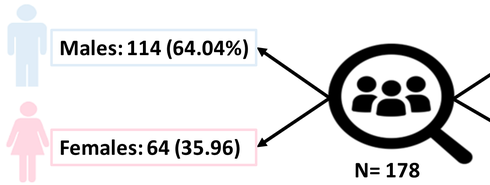
3 PHASES:
Acute Phase (0-24 hrs)
Delayed Phase (24-120 hrs)
Extended Delayed Phase (120-240 hrs)

EFFICACY PARAMETERS ASSESSED
- No nausea (<5mm on VAS)
- No significant Nausea (<25mm on VAS)
- Moderate nausea (25mm - <75mm on VAS)
- Severe nausea (75mm - 100mm on VAS)

SAFETY PARAMETERS ASSESSED
- Treatment emergent adverse events (TEAEs)

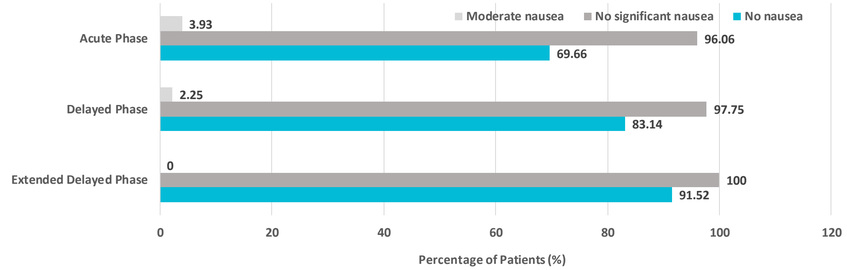
Results

Baseline charcteristics



Efficacy Assessment

Severity of nausea assessed in overall patients using VAS during various phases



No patient reported severe nausea in acute, delayed and extended delayed phases irrespective of regimen

Severity of nausea assessed in HEC/MEC regimen using VAS during various phases

PARAMETER	Acute Phase (0-24 hrs)		Delayed phase (>24-120 hrs)		Extended Delayed phase (>120-240 hrs)	
	HEC (N=90)	MEC (N=88)	HEC (N=90)	MEC (N=88)	HEC (N=90)	MEC (N=87)*
No nausea	48 (53.33%)	76 (86.36%)	66 (73.33%)	82 (93.18%)	78 (86.67%)	84 (96.55%)
No significant nausea	84 (93.33%)	87 (98.86%)	86 (95.55%)	88 (100.00%)	90 (100.00%)	87 (100.00%)
Moderate nausea	6 (6.67 %)	1 (1.14%)	4 (4.44 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

*1 patient lost to follow up

Safety Assessment

9.55% of patients experienced adverse events with headache (2.25%) and injection site reactions (1.68%) being most common.

Conclusion

>93%

Reported No Significant Nausea Irrespective of HEC/MEC Regimen or Phase

In the real-world Indian scenario, IV NEPA was found to be effective and well tolerated in preventing nausea in patients receiving HEC or MEC regimen.

References: 1. Rao KV et al. Am Health Drug Benefits. 2012 Jul; 5(4): 232–240. 2. Escobar Y et al. Support Care Cancer. 2015; 23(9): 2833–2840. 3. Aapro M. Support Care Cancer. 2018; 26(Suppl 1): 5–9.