

Questions to the Committee

September 10, 2001

NDA 21-236

IntraDose® (cisplatin/epinephrine) Injectable Gel
Matrix Pharmaceutical, Inc.

Indication: for the treatment of recurrent or refractory squamous cell carcinoma of the head and neck in patients who are not considered curable with surgery or radiotherapy

1. Do one-point changes on the palliative scale developed by the Applicant represent significant clinical benefit within the context of Clinical Trials 414 and 514?

If so, do the following data from the primary palliative goals represent significant evidence of clinical benefit that outweighs the toxicity of treatment with Cisplatin/Epinephrine Gel (CEG) in patients with symptomatic recurrent head and neck cancer?

Primary Palliative Goal, Study 414

	CEG	Placebo
Better	6% (3/51)	5% (1/20)
Worse	25% (13/51)	10% (2/20)

Primary Palliative Goal, Study 514

	CEG	Placebo
Better	19% (10/54)	3% (1/33)
Worse	22% (12/54)	12% (4/33)

2. Do the following data on response rate independently represent clinical benefit of treatment with CEG that outweighs its toxicity in the treatment symptomatic of recurrent head and neck cancer? [Note that 65% (22/34) of the patients with responding were from stratum one (tumors < 5cm³).]

	CEG	Placebo
Study 414	32% (20/62)	0% (0/24)
Study 514	23% (13/57)	3% (1/35)

3. Please discuss the clinical value of local treatments for head and neck cancer in patients with systemic disease or patients with locoregional progression.

4. Do these trials provide substantial evidence that Cisplatin Gel is safe and effective in the treatment of symptomatic recurrent head and neck cancer?