

SOCIETY OF  
INTERVENTIONAL  
RADIOLOGY

*Enhanced care through advanced technology®*

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22033 December 10, 2010

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Colin Lowrey, D.Phil.  
Director, Oncology Medical Strategy  
Bristol-Myers Squibb  
U.S. Pharmaceuticals  
100 Nassau Park Blvd.  
Princeton, NJ 08540

**RE: Platinol Discontinuation**

Dear Dr. Lowrey:

The Society of Interventional Radiology (SIR) is an organization comprised of more than 4,700 medical practitioners who perform chemoembolization (TACE) for treating hepatic malignancies. Some of our members were notified by letter dated November 29, 2010, that Platinol (Cisplatin) Powder produced by your company Bristol-Myers Squibb would no longer be manufactured after December 31, 2010. This decision is of great concern to our members, and it is believed that this decision will negatively impact patient care.

While Platinol powder has not been approved by the FDA for the treatment of liver tumors using the transarterial chemoembolization (TACE) approach, it has remained a component of one of the more common chemoembolization regimens used in TACE procedures for more than 30 years in the United States. There are no other chemotherapeutic agents that are currently FDA approved for this application, and new products being developed for TACE have not undergone rigorous clinical evaluation or FDA approval to replace existing regimens. Platinum compounds in general play a role in the treatment of a number of hepatic metastasis, particularly colorectal cancers which are by far the most common.


Carboplatinum was suggested by your company as a potential alternative agent. It is unclear at this point whether this agent will be a suitable replacement. The equivalent Carboplatinum dose is substantially greater than the traditional dose of Platinol used in TACE. How this will impact the reconstitution of the agent in terms of volume and how it will mix with other agents and Ethiodol/Lipiodol are unknown at this time. A one month notice is insufficient time to work these issues out prior to clinical introduction.

We would ask that Bristol-Myers Squibb reconsider discontinuing the production of Platinol powder or at a minimum delay this decision until a suitable alternative is available. We would appreciate the opportunity to discuss this matter further with a representative of your company. Please feel free to contact me at 786/596-5990 or [JamesB@baptisthealth.net](mailto:JamesB@baptisthealth.net), Michael Wallace, MD at 713/792-2713 or [mwallace@mdanderson.org](mailto:mwallace@mdanderson.org), or Tricia McClenny at 703/691-1805 or [tricia@sirweb.org](mailto:tricia@sirweb.org).

Sincerely



James Benenati, MD, FSIR  
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Michael Wallace, MD, FSIR  
Chair, SIR Interventional Oncology Service Line

cc: Tricia McClenny, SIR Interim Executive Director  
Bristol-Myers Squibb Customer Relations