

oncology NEWS INTERNATIONAL

News & Analysis

Melanoma: Rose bengal scores, ipilimumab sees delay

The experimental injectible drug PV-10 turned in positive results in a phase II study in metastatic melanoma, according to Provectus Pharmaceuticals. An objective response (OR) was observed in 49% of the 80 subjects, with 71% of subjects achieving locoregional disease control in their injected lesions. A mean progression-free survival of 11.7 months was observed among subjects achieving an OR.

These data, along with findings on changes in visceral and nodal metastases following chemoablation of cutaneous melanoma lesions with PV-10, were presented at the **2010 Melanoma Congress** in Sydney, Australia. The results build on interim data in 40 patients presented at the **2010 American Society of Clinical Oncology** meeting

(ASCO abstract 8534).

PV-10 is a form of rose bengal, a small-molecule agent that is used by ophthalmologists to assess damage to the eye. Provectus also reported that it is in talks with the Australian Therapeutic Goods Administration for the development of a phase III trial and the potential approval of PV-10 for use in metastatic melanoma.

“The consistently positive data on all 80 subjects in the PV-10 trial are very encouraging, particularly in light of the large number of patients in the second half of the study who had very significantly advanced melanoma,” said lead investigator **Sanjiv Agarwala, MD**.

“The excellent response rate in patients with cutaneous or nodal disease illustrates the potential of the drug for

these prime candidates for PV-10,” added Dr. Agarwala, who is chief of medical oncology and hematology at St. Luke’s Hospital and Health Network in Bethlehem, Penn.

Ipilimumab still under review

In other melanoma news, the FDA has requested additional time to complete its review of ipilimumab in patients with previously treated advanced melanoma.

The FDA is expected to render a decision in December 2010, according to ipilimumab manufacturer Bristol-Myers Squibb.

Results from the phase III MDX010-20 trial bolstered hopes for ipilimumab as a long-awaited new and effective agent in metastatic melanoma (ASCO 2010 abstract 4). ■