One-year Findings in Metastatic Melanoma Confirm Rose Bengal Benefit

By Walter Alexander

SYDNEY—One-year results in metastatic melanoma for PV-10 (Rose Bengal, Provectus Pharmaceuticals) confirm positive interim findings found earlier with the first 40 patients. The updated analysis of the full 80-patient cohort was presented by Sanjiv Agarwala, MD, at the 4th Interdisciplinary Melanoma & Skin Cancer Centres Meeting, held at the 2010 International Melanoma Research Congress. Interim findings had been presented at the annual meeting of the American Society of Clinical Oncology in June. All patients had stage III/IV melanoma.

PV-10 is a proprietary, injectable formulation of Rose Bengal, a small-molecule agent that has been in use for nearly 30 years by ophthalmologists as a diagnostic agent for assessing damage to the eye. It has also been used intravenously to diagnose liver ailments. Rose Bengal was initially developed in the 1870s as a coal tar–derived wool dye.

Agarwala, who is section chief of hematology/oncology at St. Luke's Hospital and Health Network in Bethlehem, Pennsylvania, stated that investigators treated up to 10 target lesions ≥0.2 cm in diameter and observed up to two untreated "bystander" lesions. Retreatment of new or partially responsive lesions was allowed.

Objective responses (ORs; complete response [CR] + partial response [PR]) were reported in 49% of patients (CR, 24%; PR, 25%), with 72% achieving locoregional control (stable disease [SD] or better) in their injected lesions. Among those with ORs, progression-free survival (PFS) was 11.7 months. Progressive disease, defined as ≥20% increase in tumor volume, was reported in 23%.

> "PV-10 is well tolerated, eliciting a robust response in a majority of patients." —Sanjiv Agarwala, MD

Among the 55 patients with cutaneous or nodal disease, OR and locoregional control were 55% and 78%, respectively. OR and locoregional control rates were considerably lower, at 37% and 55%, in the 25 patients with visceral metastases.

Among patients having an evaluable bystander lesion at baseline, an OR was achieved in 37%, with 55% achieving locoregional disease control. Bystander response in these untreated lesions was closely correlated with successful ablation of injected lesions, with 67% of patients achieving an OR of their bystander lesions if they achieved an OR in their injected lesions. The rate was only 5% in patients who did not achieve an OR in their injected lesions (P <.001). The respective locoregional control rates (CR + PR + SD) were 72% and 35% (P = .049).

Agarwala noted that two stage I patients with lung metastases experienced complete regression following PV-10 ablation of their cutaneous lesions. He commented, "The bystander effect, which appears to result from an immunologic response stimulated by PV-10 chemoablation, is especially intriguing. The immunologic processes whereby PV-10 produces systemic response are the topic of a phase 2B study." Agarwala also pointed out that responses were higher in patients with unresectable stage III disease (CR + PR, 53%; CR + PR + SD, 77%) than in those with stage IV M1c (27% and 55%, respectively). Mean PFS in these two groups was 8.8 months and 6.2 months, respectively.

Adverse events were generally mild to moderate, locoregional, and transient.

Agarwala concluded, "PV-10 is well tolerated, eliciting a robust response in a majority of patients." The safety and efficacy profiles compare favorably with those of existing and emerging therapies. He said further that PV-10 treatment is suitable for repeat treatment to maximize OR, ablate new lesions or to enhance long-term outcomes. Finally, he noted that with PV-10, it is quickly clear which patients are nonresponders, allowing rapid transition to alternate therapy. ●

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