Bosentan May Reduce Sclerotic Skin Fibrosis

BY BRUCE JANCIN

Berklin — Bosentan appears to be effective for the reduction of skin fibrosis in patients with systemic sclerosis.

Ten patients with systemic sclerosis showed a significant decrease in the skin thickness of forearm disease in response to treatment with bosentan (Tracleer) in a prospective open-label study, Dr. Annegret Kuhn reported at the annual congress of the European Academy of Dermatology and Venerology.

All 10 patients showed significant improvement, with a mean 6.4-point reduction in the Rodnan Skin Score at 24 weeks according to Dr. Kuhn of the University of Erlangen (Germany). Patients with diffuse systemic sclerosis had a mean 7.8-point reduction, while those with limited systemic sclerosis averaged a 6.3-point improvement in Rodnan Skin Score.

Participants in this small uncontrolled trial also experienced significant clearance of digital ulcers, with reduction in size and, in some cases, outright healing.

Favorable trends on the Scleroderma Health Assessment Questionnaire (Scleroderma Health Assessment Questionnaire, or SDAQ) were documented over the course of 24 weeks but did not achieve statistical significance.

There were no consistent changes over time in terms of 20-MHz ultrasound or histological testing as assessed by the fict closure test.

Bosentan was dosed at 62.5 mg twice daily for the first 4 weeks, then 125 mg twice daily. The dual endothelin receptor antagonist is approved for treatment of pulmonary hypertension.

Disclosures: Dr. Kuhn disclosed that her study was supported by Actelion, the manufacturer of bosentan.

Bosentan, a dual endothelin receptor antagonist, is approved for the treatment of pulmonary hypertension and, according to Dr. Kuhn, may be useful for the treatment of skin fibrosis.

In phase III trials for the treatment of pulmonary hypertension, bosentan improved exercise capacity and quality of life. The drug was well tolerated except for gastrointestinal side effects in some patients.

Dr. Kuhn reported that 10 patients with systemic sclerosis showed significant decrease in skin thickness, in response to bosentan treatment. The results were consistent with those seen in previous studies with bosentan treatment.

There is no specific

500 mg/kg in animals tested after cessation of dosing and, thus, were considered to represent long-term effects (deficits in learning and memory, altered locomotor activity, decreased auditory startle responding and habituation) and not be related to the presence or absence of circulating clonal T-cell populations in systemic sclerosis patients. Studies in the peripheral circulation of a single representative clone in limited cutaneous systemic sclerosis patients have been described.

In the present study, limited cutaneous systemic sclerosis patients were studied. The presence of circulating clonal T-cell populations was assessed in patients with limited cutaneous systemic sclerosis by polymerase chain reaction (PCR) analysis of skin-biopsy specimens.

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