

# Sitaxsentan May Offer Alternative Option for PAH

BY NANCY WALSH  
New York Bureau

VIENNA — Preliminary reports of safety and efficacy of the selective endothelin receptor antagonist sitaxsentan for pulmonary arterial hypertension associated with connective tissue disease have been confirmed in a double-blind study, Reda E. Girgis, M.D., reported in a poster session at the annual European congress of rheumatology.

Pulmonary arterial hypertension (PAH) related to connective tissue disease (CTD) is progressive and can be particularly problematic to manage. Prostacyclin regimens are complex and are generally reserved for critically ill patients.

One nonselective endothelin receptor antagonist, bosentan (Tracleer) is currently available but is not effective in all patients and has been associated with liver function abnormalities.

The Sitaxsentan to Relieve Impaired

Exercise (STRIDE-1) study randomized 178 patients to 12 weeks of treatment with 100-mg or 300-mg sitaxsentan or placebo.

The patients had either primary pulmonary hypertension or PAH related to congenital heart disease or CTD.

A post-hoc analysis of the subgroup of 42 patients with CTD-related PAH found improvements in the results of the 6-minute walk test, New York Heart Association (NYHA) functional class, and he-

modynamics.

Pooling of the 100-mg and 300-mg sitaxsentan groups found a treatment effect of 58 m on the 6-minute walk test; this was an increase of 20 m from baseline in the active treatment groups and a decrease of 38 m in the placebo group, according to Dr. Girgis of the department of medicine, Johns Hopkins University, Baltimore.

At baseline all patients were NYHA functional class II or III. By week 12, 8 of the 33 patients receiving the active treatment (24%) had improved by one NYHA functional class; none of the patients deteriorated.

In contrast, 1 of 9 (11%) placebo patients improved by one NYHA functional class and 1 of 9 (11%) deteriorated.

Among hemodynamic findings were an average increase in the cardiac index of 0.55 L/min per square meter, an average decrease in the mean pulmonary arterial pressure of 7.66 mm Hg, and an average fall in pulmonary vascular resistance of 320 dynes.sec.cm<sup>-5</sup>, Dr. Girgis said at the meeting, which was sponsored by the European League Against Rheumatism.

Sitaxsentan was well tolerated. No patients experienced liver abnormalities and no patients withdrew because of adverse events. ■

## If you could create a new way to treat RA, how would you do it?

Would you explore new pathways in RA immunopathology?

Would you try to selectively target one of these pathways in a way that could potentially leave other pathways largely intact?

Bristol-Myers Squibb is actively investigating strategies for the treatment of RA. Like you, we want to seize the moment and seek potentially new therapeutic approaches to RA.

**Bristol-Myers Squibb – Discovering the Next Future™**



**Bristol-Myers Squibb**

## Pimecrolimus 1% Cream Can Help Discoid LE

VIENNA — Pimecrolimus 1% cream proved safe and effective for the treatment of discoid lupus erythematosus in a small, uncontrolled patient series, Alberto Tlacuilo-Parra, M.D., reported at the annual European congress of rheumatology.

He reported on 10 patients with discoid LE of an average 3-year duration who were placed on 1% pimecrolimus cream twice daily for 8 weeks.

The mean age of the study population was 34 years. Four patients had previously received potent topical and/or systemic corticosteroids without therapeutic response.

The patients' mean clinical disease severity score fell significantly from a baseline of 6.1 to 2.9. Their score on a quality-of-life index improved by a mean of 46%, said Dr. Tlacuilo-Parra of the Mexican Institute of Social Security, Guadalajara.

Five patients rated themselves as having experienced marked improvement, four patients categorized their status as moderately improved, and one rated it as slightly improved, Dr. Tlacuilo-Parra added at the meeting, which was sponsored by the European League Against Rheumatism.

Adverse effects of the topical therapy were confined to several minutes of mild itching at treated sites.

—Bruce Jancin