gene analysis ties variant to psoriatic arthritis

**Phase II Efficacy Seen With New TNF Blocking Agent**

BY NANCY WALSH
New York Bureau

**Amsterdam** — The therapeutic options for patients with rheumatoid arthritis who do not respond to methotrexate alone continue to expand, with a new tumor necrosis factor-α blocker showing efficacy in a phase II trial.

In preclinical studies, the human monoclonal antibody golimumab was shown to be more effective at neutralizing tumor necrosis factor-α (TNF-α) than the other currently available biologic agents, Dr. Jonathan Kay wrote in a poster session at the annual European Congress of Rheumatology.

And while golimumab must be given subcutaneously, the dosing interval is once every 4 weeks rather than twice weekly as is the case with etanercept, or every other week as with adalimumab. Because the drug can be given once a month, it may provide a convenient alternative for patients, Dr. Kay told Rheumatology News in an interview.

The investigators randomly assigned 172 patients with rheumatoid arthritis (RA) of at least 3 months’ duration to placebo or treatment with golimumab with one of four dosages: 50 mg every 2 weeks, 50 mg every 4 weeks, 100 mg every 2 weeks, or 100 mg every 4 weeks. All patients also were on stable doses of methotrexate.

At week 16, 62% of patients who were receiving golimumab plus methotrexate achieved an ACR 20 response, compared with 37% of those receiving placebo plus methotrexate.

**Biomarker Predicts Joint Damage At 10 Years in Patients With RA**

BY NANCY WALSH
New York Bureau

**Amsterdam** — Baseline levels of the leucocyte protein calprotectin in patients with rheumatoid arthritis correlated with clinical and radiographic outcomes at 10 years in a prospective longitudinal study, suggesting that this biomarker may be a useful predictor of joint damage, Dr. Hilde Berner Hammer reported at the annual European Congress of Rheumatology.

A cohort of 145 patients with early rheumatoid arthritis (RA) were enrolled during 1991 and 1992—before the era of biologic treatment—from the rheumatology departments of Diakonhjemmet Hospital in Oslo and University Hospital Maastricht (the Netherlands). Baseline measurements included calprotectin levels, erythrocyte sedimentation rates (ESRs), and C-reactive protein levels. Radiographs of the hands were obtained, and modified Sharp scores were calculated. Damage was assessed according to the RA articular damage (RAAD) score and all measurements were repeated at 10 years. Dr. Berner Hammer wrote in a poster session at the meeting, sponsored by the European League Against Rheumatism.

The 88 patients with elevated levels of calprotectin (0.9 mg/L or more) at baseline and at 10 years also had high modified Sharp and RAAD scores at both time points. (See box.)

Moreover, patients who were rheumatoid factor positive had elevated calprotectin levels as well as high ESRs, modified Sharp scores, and RAAD scores according to Dr. Berner Hammer of Diakonhjemmet Hospital.

Calprotectin is one of the calcium-binding proinflammatory $\beta 100$ proteins released during cell activation. High levels of the protein have been found in the synovial fluid of RA patients. It is also up-regulated in other immunopathologic conditions, particularly in the setting of acute inflammation or Th1-mediated reactions (Physiol. Res. 2004;53:245-53).

An immunoadassay for the detection of fecal calprotectin in patients with inflammatory bowel disease—marketed as PhiCal by Genova Diagnostics Inc.—was recently approved by the Food and Drug Administration.

This marker has also been investigated as a measure of disease activity in polymyalgia rheumatica and temporal arthritis. A group of 47 patients, 33 with polymyalgia rheumatica, 10 with temporal arteritis, and 4 with both conditions, were followed prospectively for up to 3 years. Calprotectin was highly correlated with acute phase parameters and ESRs, and levels fell significantly after the initiation of prednisone therapy (Scand. J. Rheumatol. 2005;34:125-8).

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**Mean Marker Levels and Sharp Scores**

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<tr>
<th></th>
<th>At baseline</th>
<th>At 10-year follow-up</th>
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<tbody>
<tr>
<td>Calprotectin</td>
<td>3.7 mg/L</td>
<td>2.3 mg/L</td>
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<tr>
<td>CRP</td>
<td>11.7 mg/L</td>
<td>7.6 mg/L</td>
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<tr>
<td>ESR</td>
<td>25.3 mm/hr</td>
<td>18.0 mm/hr</td>
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<tr>
<td>Modified sharp score</td>
<td>7.3</td>
<td>36.1</td>
</tr>
</tbody>
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Note: Based on 88 rheumatoid arthritis patients. Source: Dr. Hammer