

# More Research Needed on Autoimmune Diseases

BY DIANA MAHONEY

WASHINGTON — Despite being a major public health threat, “the attention given to autoimmune diseases is not nearly proportional to the magnitude of the problem,” Dr. Noel R. Rose said at a meeting on autoimmune diseases organized by the American Autoimmune Related Diseases Association.

Fewer than 10% of the unique autoimmune or autoimmune-related diseases have currently available therapies, and new drug development programs target only about 30%, according to a recent report. The costs associated with the seven major autoimmune diseases—

**‘If we learn about a pathway that’s important in multiple sclerosis, it may also be important in lupus and 5 or 10 other autoimmune diseases.’**

Crohn’s disease, ulcerative colitis, lupus, multiple sclerosis, rheumatoid arthritis, psoriasis, and scleroderma—are estimated to be about \$50 billion.

The value of taking a global, collective view of autoimmune diseases is particularly obvious in the research and development setting, said Dr. Rose, director of the Johns Hopkins Autoimmune Disease Research Center in Baltimore. The most promise for broad application is likely to come from research programs that look for commonalities among groups of autoimmune diseases, he said.

Toward this end, the National Institutes of Health sponsors a range of basic translational and clinical research efforts focusing on autoimmune diseases. “That kind of research is tremendously valuable in autoimmune diseases, perhaps more than other diseases, because of the shared underlying mechanisms between the various conditions. If we learn about a pathway that’s important in multiple sclerosis, it may also be important in lupus and 5 or 10 other autoimmune diseases,” Dr. Daniel Rotrosen said at the summit.

One research focus is a stem cell transplantation program that is looking at bone marrow transplantation for systemic sclerosis and multiple sclerosis, reported Dr. Rotrosen, director of the Division of Allergy, Immunology, and Transplantation at the National Institute of Allergy and Infectious Diseases.

“Currently we have approximately 25-30 clinical trials going on in autoimmune diseases, about one-third of which are in type 1 diabetes, one-third for rheumatologic disease, and one-third for other conditions,” Dr. Rotrosen said, noting that clinical trials in this arena are notoriously difficult. “Often, patients go undiagnosed for years, so by the time subjects come into the trials, they have a history of years of established disease that is hard to arrest or reverse at that point. As a result, new therapies are of-

ten being tested in late-stage disease, usually after patients have gone through multiple therapy failures, where the chances for successful outcomes are not as good as they would have been with earlier intervention.”

Subject recruitment can also be challenging. “Once you define eligibility criteria for a particular trial, it may turn out that because of prior therapy or disease stage, the number of patients at a given

site is too small to power a study. This is especially true with the less common diseases,” Dr. Rotrosen explained. “In such cases, we have to do multisite studies, recruiting patients from around the country, and sometimes we have to go overseas, which introduces regulatory barriers and financial constraints.”

To alleviate some of the challenges, the NIAID provides support for multidisciplinary clinical research networks

in order to help facilitate long-term, multisite clinical trials, Dr. Rotrosen said. “This is especially important with relapsing and remitting diseases. Stable support over time is critical in order to see improvement against this background,” he said. ■

**Disclosures:** Dr. Rose and Dr. Rotrosen did not report conflicts of interest related to their presentations.

## NEW INDICATION

In high-risk\* patients who are unable to take an ACE-I,

# DOOM

## REDUCE THE RISK OF MI, STRO

### Important Safety Information

#### WARNING: AVOID USE IN PREGNANCY

When used in pregnancy, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, MICARDIS® (telmisartan) tablets should be discontinued as soon as possible (See Warnings and Precautions).

- MICARDIS is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.
- MICARDIS is indicated for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major cardiovascular events who are unable to take ACE inhibitors.
- High risk for cardiovascular events can be evidenced by a history of coronary artery disease, peripheral arterial disease, stroke, transient ischemic attack, or high-risk diabetes (insulin dependent or non-insulin dependent) with evidence of end-organ damage. MICARDIS can be used in addition to other needed treatment (such as antihypertensive, antiplatelet, lipid-lowering therapy, etc).
- Studies of telmisartan in this setting do not exclude that it may not preserve a meaningful fraction of the effect of the ACE inhibitor to which it was compared. Consider using the ACE inhibitor first, and, if it is stopped for cough only, consider retrying the ACE inhibitor after the cough resolves.

- Use of telmisartan with an ACE inhibitor is not recommended.
- Volume depletion and/or salt depletion should be corrected in patients before initiation of therapy or start treatment under close medical supervision with a reduced dose, otherwise symptomatic hypotension may occur.
- In patients with impaired hepatic function, initiate telmisartan at low doses and titrate slowly.
- Monitor carefully in patients with impaired renal function, especially in patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (eg, patients with severe congestive heart failure or renal dysfunction); treatment of these patients with ACE inhibitors and ARBs has been associated with oliguria and/or progressive azotemia and, rarely, with acute renal failure and/or death. In patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen may occur.
- Dual blockade of the renin-angiotensin-aldosterone system (eg, by adding an ACE-inhibitor to an ARB) should include close monitoring of renal function. Use of MICARDIS with ramipril is not recommended.

Please see Brief Summary of Prescribing Information on following pages.