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—

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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 often 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.*