A team of researchers from Charité - Universitätsmedizin Berlin and the Deutsches Rheuma-Forschungszentrum (DRFZ) Berlin, a Leibniz Institute, have successfully treated two patients with the autoimmune disease systemic lupus erythematosus. Using daratumumab, a monoclonal antibody which targets specific immune cells known as plasma cells, the researchers were able to modulate the abnormal immunological memory processes found in these patients. Treatment induced sustainable clinical responses and resulted in a reduction in systemic inflammation. The results of this research have been published in the *New England Journal of Medicine*.

The body’s immunological memory enables the immune system to respond more rapidly and effectively to pathogens that have been encountered before. This immune response is mediated by both memory T lymphocytes and antibodies, which are produced by cells known as ‘plasma cells.’ Mature memory plasma cells reside in special niches in the bone marrow and are able to produce large amounts of antibodies for decades or even life-time. In autoimmune diseases, the immune system mistakes part of the body as foreign and considers it a danger. In a process that is assisted by the body’s immunological memory, the immune system mounts a response using ‘autoantibodies.’ Systemic lupus erythematosus (SLE) is a prototypical autoimmune disease in which antibodies are produced against components of the body’s cellular nuclei. This autoimmune response is associated with inflammation that may affect the skin, joints, or internal organ systems such as the kidneys, heart, or central nervous system. Traditionally, treatments have relied on the long-term suppression of the immune response. Until now, however, they have not been targeted at mature memory plasma cells.

For the first time – and working alongside colleagues from the DRFZ, led by Prof. Dr. Andreas Radbruch, Charité researchers, led by Dr. Tobias Alexander, have studied the effectiveness and tolerability of a plasma cell-specific treatment in two lupus patients who failed to respond to conventional therapies. “In a certain proportion of patients, the disease cannot be controlled using currently available treatments. As a result, there is a desperate need for novel and targeted treatment approaches,” explains study lead Dr. Alexander, who is Head of Rheumatology Outpatient Services at Charité’s Department of Rheumatology and Clinical Immunology and also conducts research at the DRFZ.

The researchers focused their efforts on the monoclonal anti-CD38 antibody daratumumab, which has been used for years to successfully treat patients with plasma cell cancer. The role of plasma cells in autoimmune diseases has been a major focus of the work conducted by the research group led by Dr. Alexander and his co-author, Prof. Dr. Falk Hiepe. “CD38 surface protein is considered a classic plasma cell marker. However, our preliminary investigations have shown that, in patients with lupus, increased levels of this marker can also be detected in other active immune cells such as memory T lymphocytes, as well as in the blood and urine,” explains Dr. Alexander. This makes CD38 an ideal target for treatment, which aims to eliminate the pathologically altered immune cells.

“The promising results seen in SLE may be transferable to other autoimmune diseases in which autoantibodies play a role,” says first author Lennard Ostendorf, a doctoral student at the DRFZ. The next step, however, will be to test the safety and efficacy of daratumumab in a larger group of lupus patients. For this, the researchers are planning to conduct a pilot clinical study, which will be led by Dr. Alexander and conducted at Charité.

As the year comes to a close, AARDA and our autoimmune community can reflect on the challenge of the COVID-19 coronavirus pandemic and our resiliency and support for each other through lockdown and loss.

In April, AARDA hosted one of the first large-scale briefings with the Centers for Disease Control and Prevention (CDC) to better understand the threat posed by the virus to persons with autoimmune disease. We convened throughout the year to share learning and offer support. This Fall, leading experts from the National Institute of Health (NIH), Harvard, and Johns Hopkins joined AARDA to share the latest news about COVID-19 infection, treatment, and prevention. Now, with FDA approval of vaccines underway and Americans being vaccinated, there is reason to believe that we will get past this pandemic and its devastating toll on lives lost, economic hardship, and disruption.

For people with autoimmune diseases, COVID-19 has caused understandable concern over the threat of infection, serious illness, and significant interruptions in access to medicines and care. As vaccines becoming available to the general public, people with autoimmune conditions must continue to take measures to avoid infection and discuss with their doctors how best to approach vaccination for themselves and their families. Look to AARDA to remain a trusted source of information and support on COVID-19 treatment and prevention in the year ahead.

Many of AARDA’s priorities and related activities in 2020 will continue into the new year, including seeking increased investment in medical research to better understand the underlying causes of autoimmunity and promote new and better therapies to manage and cure autoimmune conditions. AARDA’s investment in scientific colloquia on key topics and in grants to young autoimmune researchers and minority interns continues despite the pandemic.

And AARDA remains steadfast in promoting public policy and insurance practice reforms to guarantee patient access medicines as prescribed by their doctors - by working to eliminate step therapy, prior authorization, contracting arrangements, and other barriers that harm patients. AARDA is actively encouraging lawmakers to protect copay assistance programs to help patients better afford their medicines, limit out of pocket spending in Medicare and private plans, and support the innovation pipeline for developing new medicines for persons with autoimmune and rare diseases.

Assuring equity in health care for persons with autoimmune disease who experience discrimination and disparities in access, treatment, and outcomes has been an AARDA priority that gained greater importance and momentum during 2020. AARDA recently endorsed the National Health Council’s Consensus Statement on Health Equity, and going forward, will continue to collaborate with partners and other organizations to close damaging and persistent gaps in health care for Black, Hispanic, Native American, Asian/Pacific Islander, LGBTQ, and other persons in our autoimmune community who have suffered the effects of systemic racism and neglect due to poverty, rural/urban isolation, and stigma.

AARDA has welcomed many new individual, foundation, and corporate donors to our cause, and added nearly a dozen of the nation’s leading innovation companies to our Autoimmune Partnership Council to provide valuable insight and support. In addition, we have strengthened our internal capacity to advance AARDA’s compelling mission by adding key professional staff, adopting new tools for education and engagement, and updating our technology infrastructure. All made possible by your much appreciated support.

Thank you friends of AARDA for your partnership this past year, as we faced unprecedented difficulties and meaningful accomplishments together. I am optimistic about the future of AARDA and our autoimmune community. Together, we are a match for any challenge and a formidable force for positive change to benefit everyone living with an autoimmune condition, their families, and communities.

Best wishes for a safe and enjoyable holiday season, Randall Rutta
As Chair of AARDA’s Scientific Advisory Board, I was honored to moderate AARDA’s October 30th National Briefing on COVID-19 and Autoimmune Disease: Research Insights, Treatment, and Prevention. Many thanks to my esteemed colleagues on the forefront of autoimmune disease and the COVID-19 virus for sharing their findings and expertise with the autoimmune community.

Dr. Zachary Wallace, a rheumatologist and clinical researcher at Massachusetts General Hospital and Assistant Professor of Medicine at Harvard Medical School, presented findings on COVID-19 susceptibility and severity in persons with rheumatic disease, inflammatory bowel disease, psoriasis, and on racial disparities in outcomes.

Dr. Arturo Casadevall, Chair of the Department of Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health, discussed his experience with patients during the pandemic and provided insights on how to best manage health during the COVID-19 pandemic with particular emphasis on the use of convalescent serum.

Dr. Daniel Rotrosen, Director of the Division of Allergy, Immunology, and Transplantation at the National Institutes of Health, presented critical information and guidance directly from the NIH, describing a pathway for vaccine development and dissemination to prevent infection. Of note, he emphasized that the vaccine would be free to all who want it.

The participation and feedback received from the briefing is a sure indication of the need for timely and accurate information surrounding COVID-19 for the autoimmune disease community.

I also want to welcome to AARDA the new members of the Scientific Advisory Board including David Hafler, M.D., FANA, Andrea Knight, M.D., MSCE, Nina Luning Prak, M.D., Ph.D., Jerrold Turner, M.D., Ph.D., Lucienne Chatenoud, M.D., Ph.D., DSc, and Thomas Huizinga. Their expertise, experience, and energy will enrich our efforts. I also want to thank those who are rotating off the Board for their dedicated help over the years, including: Bevra H. Hahn, M.D., Caroline Whitacre, Ph.D., Michelle Petri, M.D., M.P.H., Nicholas Chiorazzi, M.D., Parviz Lalezari, M.D., Yaron Tomer, M.D., FACR, and Yehuda Schoenfeld, M.D.

For more information, resources, and a link to the full briefing, please visit www.aarda.org.

The American Autoimmune Related Diseases Association is dedicated to the eradication of autoimmune diseases and the alleviation of suffering and the socioeconomic impact of autoimmunity through fostering and facilitating collaboration in the areas of education, public awareness, research, and patient services in an effective, ethical, and efficient manner.
ARDA understands that the COVID-19 pandemic represents a serious health threat to persons with autoimmune diseases, who are among those with underlying conditions, that are at risk of serious illness if they contract the virus. The mental stressors of thinking through the implications of contracting COVID-19 can be overwhelming, and we recognize this pandemic has introduced new challenges such as barriers to accessing medication or frustration and fear of the risks associated from others that may not take the proper precautions to keep others safe. Daunting obstacles to treatments, including care locations compromised or closed due to COVID-19, shortages of medicines, coverage uncertainty and costs, and real fear of contracting this deadly disease all contribute to increased anxiety.

There are also physical considerations. Those on immunosuppressive medication and corticosteroids are more at risk for infections, and it is also likely that individuals on immunosuppressive therapy who develop the virus may not exhibit a fever. Corticosteroids and immunosuppressive therapies lessen the activation of those immune cells which are responsible for a fever. Therefore, individuals with autoimmune diseases requiring these therapies need to know that a cough, fatigue, and certainly any difficulty breathing are reason enough to contact your physician -- with or without a fever. Emergency rooms come with additional risk, so consider establishing in advance how you will seek professional medical assistance should you develop symptoms or have concerns about potential exposure to someone infected by the virus.

At AARDA, we are standing with you and continue to advocate for legislation to protect high-risk populations during the COVID-19 crisis and provide resources including our webinar on mental health and coping through the pandemic for autoimmune patients. You can find more resources at https://www.aarda.org/aarda-covid-19/.

AARDA RECOMMENDATIONS TO NASEM

AARDA is pleased to announce that The National Academies of Sciences, Engineering, and Medicine convened an ad hoc committee to conduct a congressionally mandated study of NIH research on autoimmune diseases. In November, AARDA Founder and Past President Virginia Ladd addressed the committee on the need for cross institution collaboration and for increased funding for autoimmune diseases.

The study will:

- Provide a general overview (with particular focus on NIH research efforts) of epidemiologic trends in autoimmune diseases.
- For common autoimmune diseases (including those that are overrepresented in women), evaluate the NIH research portfolio with particular attention to issues such as risk factors; diagnostic tools; barriers to diagnoses; treatments; and prospects for cures.
- Review NIH’s research activities related to specific autoimmune diseases, the occurrence of multiple autoimmune diseases in individuals, and the interplay of autoimmune diseases and comorbidities.
- Assess trends in the focus of NIH research and address whether the trends are reflective of the changes in epidemiology as compared to other factors such as availability of research tools and technologies, and emerging biomedical knowledge and concepts.
- Identify barriers to NIH-sponsored research and research gaps for autoimmune diseases.
- Identify promising areas for future NIH-sponsored research for autoimmune diseases that would benefit the greatest need.
- Evaluate Institute and Center structure in support of NIH autoimmune disease research to identify where needs are met and where coordination could be enhanced.
- Produce and publish a final consensus committee report summarizing the committee’s findings, conclusions, and recommendations. The report must address NIH accomplishments, challenges that NIH faces, as well as possible solutions to the challenges.
2021 POLICY PRIORITIES

As the Biden Administration continues to move forward with its transition, AARDA has been hard at work continuing to advocate for patients during the pandemic. No matter the leadership in Washington, or in your locale, we continue to act as your voice for important matters in the autoimmune space.

As we look to new leadership in the White House and in Congress, AARDA has identified four main policy priorities to guide our work and set the stage for the decisionmakers everywhere to follow as they enact laws that impact individuals across the nation. AARDA’s 2021 Policy Priorities include:

1. Put Patients First: Allow Patients and Their Clinicians to Make Treatment Decisions
2. Protect Copay Assistance Programs for Life-Saving Medicines
3. Address Healthcare Disparities in Autoimmune Disease
4. Invest in Autoimmune Disease-Specific Research

At a time when we should all be working to help patients with complex diseases to obtain and maintain access to the prescribed care and treatment that they need, AARDA continues to encourage policymakers and regulators to avoid policies that impede—rather than improve—such access. AARDA is committed to putting patients first. 2020 highlights include:

Copay Assistance Campaign

In November, AARDA highlighted the importance of protecting copay assistance programs by authoring a letter addressed to congressional caucus leadership representing autoimmune disease, chronic illness, people of color, and other underrepresented populations. Our message is simple: protect copay assistance programs during a time when patients need it the most. In a recent rule passed by the Administration, certain provisions would affect access and increase costs for those who rely on it the most.

NCAPG in Action

The National Coalition of Autoimmune Patients Groups met in December to amplify the voice of autoimmune disease patients and to promote increased awareness, education, and research into all aspects of autoimmune disease. This collaborative approach from over 40 national patient organizations representing a single autoimmune disease or a group of autoimmune diseases included discussions of 2020 post-election plans, 2021 strategies, and highlights some of the top issues patients struggling with autoimmune disease during the pandemic.

NCAPG welcomes its newest member, the Global Liver Institute. The Global Liver Institute works to improve the lives of individuals and families impacted by liver disease through promoting innovation, encouraging collaboration, and scaling optimal approaches to help eradicate liver diseases.

NCAPG is currently accepting new members and welcomes groups that work to promote the voice of autoimmune disease patients. Together we have been able to amplify our voices and work toward advancing shared goals during such a vital time. If you, or someone you know may be interested in joining the NCAPG, please contact Brett McReynolds at bmcreynolds@aarda.org for more information.
History likely will record 2020 as a year of great challenges and unfathomable losses — a year of invention driven by necessity. AARDA had its challenges and losses, too, and was compelled to re-engineer programs and operations to meet the needs of the autoimmune community. Through it all, we were fortunate to have the support of good friends — long-term, committed donors and new supporters — who helped to keep our most essential programs funded and functioning for people living with autoimmune disease.

Thanks to donor support:

- **56,000 people** utilized our “COVID-19 and Autoimmune Disease” webpage
- **30,000** received AARDA InFocus, INSIGHT, and Inspired publications every quarter
- **7,200** attended AARDA virtual educational events including national public forums, webinars and briefings with the CDC and NIH
- **2,100** individuals and families received informational materials including connected to vital resources
- **41** members joined AARDA’s National Coalition of Autoimmune Patient Groups to participate in advocacy campaigns on behalf of patients nationwide

Now, we face 2021. AARDA is planning for the year ahead with continued support and confidence in our ability to maintain our strategic programs and fulfill our mission. Our goal is to restore all programs in the near future to their pre-pandemic levels and meet the ever-growing demand for AARDA’s services. It’s a journey full of challenges — a journey we ask you to take with us.

Annual Appeal donations to AARDA by check, credit/debit card, QCD (Qualified Charitable Distribution) or through your DAF (Donora Advised Fund) made before midnight on December 31, 2020 will provide a dependable, secure way forward for AARDA research, education, advocacy, and awareness programs in 2021 and an important tax benefit for donors.

**Please make your one-time gift or become a monthly sustainer with a smaller, ongoing contribution and support AARDA all year long!** Every gift will help us make a positive and powerful difference.
Outwardly, Inga C. did not look ill when she was little, but she felt ill. When doctors questioned her adoptive mom about her, she would describe Inga as a lively, active little girl; nothing slowed her down. “They were judging a book by its cover,” Inga said. “I felt ignored by the physicians and my adoptive parents. They wanted to believe everything was perfect. My mom had lost three children to ectopic pregnancies. It was just too scary for her [to think that she could lose me, too]. But ignoring my symptoms forced me to be a Type A personality to survive. It forced me to be tough.”

From an early age, Inga had a strong interest in the human body. Her illness only made that interest keener. “I read a lot,” she said. “And by the time I was 15, I’d decided that I had lupus. In college, I loved physiology class and the clinical training. I thought, I’m going to be a health care professional and knew that I would have to fight among my colleagues for my patients.”

Inga went on to become a registered nurse, earning her BSN at Indiana University and her MSN from Ball State University. Still, she did not have a diagnosis for what ailed her. “I worked in newborn ICU in a large urban area. I saw a lot of autoimmune women go through there. I think women don’t get diagnosed until adulthood because doctors blow it off. I would see women lose two and three pregnancies before someone tested them for autoimmune.”

At age 36, Inga had a “near death” experience — a huge blood clot in the subclavian vein in her neck. Doctors suggested it might be caused by trauma to her arm, a long plane flight, or a kink in her vein anatomy. Inga informed them that she had had no trauma to her arm, she had not been on a long flight, and that if there had been a kink in her vein anatomy, it would have shown up long ago. “They weren’t paying attention. They told me, ‘you work 16 hours a day on your feet,’ as if that was the answer.” It was discouraging. “Sometimes you get complacent. You get tired of pushing the doctors for answers. You start to believe you’re crazy,” she said. But Inga soldiered on.

She had blood clots before, which doctors had attributed to many things, but not autoimmune disease. She had mild strokes. She had classic lupus rashes as a child. If the doctors couldn’t enlighten her, who could?

Inga decided to find her biological family. What Inga discovered was that several members had autoimmune disorders, including what she was ultimately diagnosed with – Mixed Connective Tissue Disease, demyelinating disease, and MS.

Becoming an advocate for herself inspired Inga to advocate for her patients and encourage them to advocate for themselves. “The nurse is often the team leader,” she said, “being at the bedside and interacting with patients more — listening to them.” And in her current role as adjunct professor of nursing at a community college, Inga is also sharing her knowledge and experiences with a new generation of nursing professionals. “What I try to do as a clinical instructor is to find patients on the floor and show them to students and point out symptoms that might be autoimmune related. That’s a good thing for all of us,” she said, “patients, professionals and students.”

“As a child, I spent summers in Germany with my adoptive mom and her family. She emigrated to the U.S. from there. And what I noticed was stark differences in how their health care system manages autoimmune disease. They start early so that there is less impact on the patient. That’s what frustrates me about health care in the U.S.” Still, she is hopeful for the future. “I’ve been excited to see in the last five or six years that children are getting diagnosed earlier,” she said. “I think there’s hope on the horizon for autoimmune patients, but it depends on where you live. Rural areas, for instance, need more attention, more information, services and access. We have to get out there and really be more vocal.”

Inga says she supports AARDA financially because she values the organization’s mission, especially advocacy and education. Currently, she is working remotely, conducting virtual clinical simulations from her home near Indianapolis, which she shares with her husband, Tim.

DONOR PROFILE

Name: Inga C.  Profession: MSN, RN, Adjunct Nursing Faculty  Interests: Awareness, Education & Advocacy

From: Shelbyville, IN  Donor Since: 2002
PLANNED GIVING RESOURCES – FREEWILL

New Resources for our Community to Plan for the Future

AARDA is committed to providing autoimmune disease patients and their families with the resources they need to create as bright a future as possible. As part of these efforts, AARDA is excited to announce a new partnership with FreeWill, a social venture featured in Forbes and The New York Times, to support our community by offering free estate planning resources.

Caring.com reports that nearly 70 percent of American adults don’t have an updated legal will. Having an estate plan in place is essential. It helps to protect the people and causes you love and allows you to take your health and safety decisions into your own hands. But for the average person, the cost of estate planning services can be prohibitive.

This partnership allows individuals to write your will and plan for your future in 20 minutes or less, at no personal cost. Visit FreeWill.com/AARDA to find out just how quick and easy this can be done – again – at no cost!

We hope this resource brings some peace of mind to members of our AARDA family. In addition, we’ve partnered with FreeWill to provide another planned giving service: a free tool to create a tax-free gift from your IRA. If you’re 70.5 or older, you’re eligible to make this gift and further the work and mission of AARDA in this critical moment and receiving tax benefits. Visit FreeWill.com/QCD/AARDA to learn more.

PROGRAM NEWS

TED AWARENESS WEEK

This November, AARDA participated in the first-ever Thyroid Eye Disease (TED) Awareness Week to increase recognition of thyroid eye disease, a serious, progressive and vision-threatening rare autoimmune disease. Thanks to the collaboration of AARDA and other leading advocacy organizations, the first TED Awareness Week helped increase recognition of TED and educate people who are at risk to better understand the symptoms, learn how to find a TED Specialist, and feel empowered to get support and proper care.

AARDA President & CEO Randall Rutta was featured on "TED Today," an online talk show that shares valuable tips and resources for people living with TED and their caregivers.

Hear more from Randall Rutta and Horizon Therapeutics CEO Tim Walbert in AARDA’s most recent issue of INSIGHT: Conversations with Thought Leaders here.
Tips for Health During the Holidays

Robert H. Phillips, Ph.D., Director, The Coping Counselors at the Center for Coping, Hicksville, NY. Member, AARDA National Board of Directors

The holidays can be a stressful time of year, regardless of a pandemic. This year, we are grappling with figuring out how to see family, travel, and still celebrate the holidays in a safe manner, augmenting everyone’s stress. All the while, coronavirus (COVID-19) is still present and has been causing increased stress for most people. Both the known facts about the virus, as well as the unknown concerns, can be overwhelming and anxiety-inducing for adults and children.

It can be helpful to recognize that the way we are affected by anything going on around us is directly related to the way we think about it. Therefore, an important category of coping strategies involves working on your thinking.

We are all dealing with the coronavirus and its impact on society. However, if you think about the people you know, you’ll realize that they’re all dealing with it differently. How can that be if we’re all dealing with the same situation? It’s because each person thinks differently. So if you work on your thinking, you can improve the way you deal with it, even while we’re waiting for it to run its course.

So what can you do? Here are two simple suggestions for how you can start working on your thinking.

Focus on Positive Thoughts Instead of Negative Thoughts

If you were to have a “transcript” of every thought going through your mind, you’d be amazed to see how negative your thinking is. And you get into trouble if you are overwhelmed with negative thoughts, and you don’t “fight back” with realistic positive thoughts.

So work on that. Try to identify as many of your negative thoughts as you can about what’s going on. Then, instead of allowing them to become “a runaway train”, try to jump in and come up with some positive responses. For example, instead of thinking, “I can’t deal with the stress; everything is falling apart,” you might think, “I’m working to deal with the stress better, and I’m going to do the best I can until the problem peaks and then starts to wane.”

Try to Relax

Relaxation is the opposite of tension, so the more you’re able to relax, the more you can control your anxiety in check. The relaxation techniques I’m suggesting are clinical strategies, not the typical ways people think of relaxing such as walking, listening to music, reading, etc. Instead, I’m referring to strategies such as deep breathing, progressive muscle relaxation, meditation, among many others.

Here’s the link to a simple relaxation technique that only takes two minutes to do. It’s an effective technique that I developed more than 30 years ago, and has helped people all over the world.

Examples of positive affirmations that some people find helpful would be, “I am doing the best I can;” “I can get through this one day at a time;” and “I’m going to continue to focus on the positive things going on in my life.”

Use Positive Affirmations

Positive affirmations are encouraging statements, directed at yourself, that you either say out loud or think to yourself. They are designed to strengthen you, help you to think more positively, and better offset debilitating negative thoughts.

It’s important that these affirmations be realistic and believable, and that you keep repeating them to yourself. In this way, even if you don’t believe them at first, the repetition will help them to become a greater part of the way you think.

Examples of positive affirmations that some people find helpful would be,