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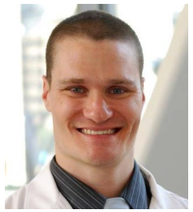
JANSSEN ADDS IMMUNOLOGY EXPERTISE TO SEARCH FOR LUPUS TREATMENT

A conversation with **SHAWN ROSE**, Director of Immunology Global Clinical Development, Janssen Research & Development, LLC



Lupus is an autoimmune disease in which the body's immune system attacks healthy tissues. There is no cure for the disease, which affects about 5 million people worldwide. Symptoms of lupus include painful swollen joints, fever, rashes and chest pain. When a lupus advocacy organization contacted the Janssen Pharmaceutical Companies of Johnson & Johnson to share findings that suggested one of the company's existing approved medicines might be effective against lupus, Janssen embraced the opportunity. Shawn Rose describes the company's focus in continuing its innovation path for the disease.

How did Janssen get involved in lupus research?
The Lupus Research Alliance (LRA) contacted us about a scientific analysis they conducted, reviewing the potential of currently available therapies in the treatment of lupus. This included an existing Janssen treatment, STELARA® (ustekinumab), which is approved for the treatment of other inflammatory and autoimmune diseases. The LRA provided scientific support and rationale for its potential in lupus.

What happened next?
The LRA encouraged Janssen to conduct a trial of STELARA in systemic lupus erythematosus (SLE). We initiated a Phase 2 study which showed positive results with clinically relevant findings. As a result, we have progressed a Phase 3 study evaluating the efficacy and safety of STELARA in the treatment of SLE.

Why might STELARA be a good candidate to treat lupus?
STELARA is a monoclonal antibody that selectively targets p40, which is a shared subunit of the cytokines interleukin (IL)-12 and IL-23. Together, these cytokines affect a number of immune cell types and cellular pathways that have been found to be abnormal in lupus. In addition, IL-12 and IL-23 signalling occurs upstream in the inflammatory processes that may contribute to the development and progression of lupus. We believe that in order to bring the immune system back to a more homeostatic state, we will need to disrupt those upstream pathways. This is something we are very excited about — addressing a potential root cause of the disease — rather than just symptoms.

Do you have other candidates beyond STELARA for the treatment of lupus?
Janssen has many other molecules in the early development portfolio that focus on numerous pathways ranging from the innate immune system to the adaptive immune system. The goal is to realize what molecules may be useful as therapeutic agents, either in isolation or in combination, to treat lupus.

How does Janssen's history in immunology research benefit its lupus programme?
We have been pioneers in immunology research for more than 30 years and are driven to build upon our foundation of developing novel molecules to treat diseases of high unmet need, including lupus. We are bringing our knowledge and expertise from years of studying and developing therapies to treat other immune-mediated diseases such as psoriasis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, Crohn's disease and ulcerative colitis. Our mission is to find targeted therapies that provide an important clinical benefit with an acceptable safety profile.

Why is lupus a good prospect for Janssen's research portfolio?
It's a complex disorder that greatly disrupts the lives of patients and their families. We are focused on developing new targeted innovative therapies that meet the needs of those whose lives are significantly impacted by a chronic, devastating and life-altering disease like lupus.

What infrastructure is Janssen building to take on lupus?
We are building upon strong internal and external infrastructure. Internally, that means continuing to inspire and motivate our scientists and attract new talent who are looking to make a difference for patients. We are focusing our efforts on understanding the pathogenesis of lupus, undertaking internal research and leveraging collaborations with scientific leaders in the field.

What skills are you recruiting for?
We are looking for people with expertise in lupus to serve in roles such as clinical trial director. We are also looking at lab-focused scientists who are experts in immunology research, or those who can apply their skills in big data analysis. Similarly, our medical affairs team continues its growth in this area.

What about external collaborations?
We are working with partners from multiple organizations, such as the LRA and the Lupus Foundation of America. We are also looking for collaborators to help us address key scientific questions that their labs may be in the best position to support. Further, we see an opportunity to work with the broader lupus community to improve patient support.

Any examples?
We're working with Eric Morand at Monash University in Australia, whose group is looking at a novel measure called the Lupus Low Disease Activity State (LLDAS). Achieving this state has been shown to correlate with a reduction in organ damage. We are helping to support the collaboration and hope to use data from it to better understand treatment goals in lupus.

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