Back in Balance

Drug candidate shows promise as immune system modulator

By Jenny Thorn Palter

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When the results of a Phase II study for edratide were published in August, lupus experts and patients alike felt a sense of hope. Although the drug did not meet its primary endpoint, its secondary endpoint results using the BILAG system—an organ-specific disease activity measure that captures partial improvement, unlike global score indices that capture only complete improvement—were encouraging. The safety and side effects profiles were also encouraging. While more research must be done on edratide, those in the lupus community are ready to be optimistic.

Developed by Prof. Edna Mozes of the Department of Immunology at the Weizmann Institute of Science in Israel, edratide is an immunomodulator—a drug designed to influence the overactive immune system that is the hallmark of lupus.

Normally, the immune system activates T and B cells to protect the body from foreign agents, such as bacteria and viruses. But in a person with an autoimmune disease, these activated cells go after healthy tissue. To combat the autoimmune process, which causes an increase of activated B cells, scientists seek to interrupt the immune system pathway. But we can't do without B cells entirely, and it has proved to be very difficult to suppress the B cell attack without destroying them altogether. Edratide takes a different approach.

"Our drug is a little bit different," says Joshua Levine, CEO of XTL Biopharmaceuticals Ltd., based in Israel. "It tries to increase the amount of regulatory T cells, which will decrease the amount of activated T cells, which will then lead to a lowering of the amount of activated B cells and help the body resume immune balance."

Levine sees another advantage to a drug that can modulate "T-regs," as researchers have nicknamed the regulatory T cells. "Lupus can be very, very difficult to treat. Clinicians believe that to combat the disease fully, they may need a combination therapy. They like edratide as a stand-alone treatment, as well as a potential combination treatment down the road."

"Down the road" may be getting closer if the U.S. Food and Drug Administration (FDA) acts favorably toward the company's next clinical trial proposal.

"We expect to go to the FDA before the end of the year and show them the data and the clinical trial protocol that we propose," says Levine. "Because of the relative lack of effective available treatments for lupus, and after the recent clinical trial setbacks for the biologic lupus drugs under development at UCB and Eli Lilly, and others before that, we are hopeful that the FDA will be receptive to our proposed study and endpoints. We're going to them with different kinds of designs, and hopefully we'll get their blessing."

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