SLE Drug Pipeline: An Embarrassment of Riches

BY BRUCE JANCIN
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SNOWMASS, COLO. — The drug pipeline has no lack of options for lupus. Since the last approval of a new therapy for SLE, some important new options have emerged, including the first biologic agent to treat lupus — rituximab, which was approved by the FDA in 1998.

“Rituximab has been a significant step forward,” said Dr. Wofsy, who serves as a consultant to Serono and ZymoGenetics. “But it is a disservice to the community. It doesn’t translate into anything meaningful to anyone who takes care of lupus patients.”

Belimumab was found to have no effect on time to flare or SLE Disease Activity Index in a randomized trial involving 449 patients with mild to moderate active SLE. In response, sponsor Human Genome Sciences Inc. created a novel combined end point, applied it retroactively, and declared the study a success. The new combined end point is being used in two ongoing phase III trials of the anti-Biys agent, each double the size of the earlier one.

“I think this novel end point is a disservice to the community. It doesn’t translate into anything meaningful to anyone who takes care of lupus patients,” said Dr. Wofsy, who did the original animal studies.

“Current or upcoming clinical trials include a trial of My specials Co.-sponsored studies of abatacept in SLE patients without nephritis and abatacept plus mycophenolate mofetil in lupus nephritis, as well as an NIH-sponsored study of abatacept plus short-course cyclophosphamide vs. cyclophosphamide alone for lupus nephritis to be conducted by Dr. Wofsy and coworkers.”

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