Jeffrey Bluestone's 'Breakthrough' Drug is Back and Being Steered to the FDA

var addthis_share = { templates: { twitter: "" } }

Originally published in Endpoint News, by John Carroll

The diabetes drug Teplizumab has taken another step forward in the long, painfully slow trek out of the research and development wilderness, and the next stop could be the FDA.

Banished from the shelves 9 years ago at Eli Lilly, the drug from the lab of UCSF scientist and Parker Institute chief Jeffrey Bluestone has now won the FDA's Breakthrough Therapy Designation—an elite regulatory status that should speed its way into the hands of reviewers—based on a study called "At-Risk," which highlighted evidence of its ability to de lay the onset of Type 1 diabetes in a high-risk group. ProventionBio execs now say that the trial could be the basis of an NDA. And that spurred an 8% hike in its share price ahead of the bell on Monday.

"With this designation in place, we plan to leverage that landmark data, as well as the robust safety database from prior Teplizumab studies, to support a registration filing," says ProventionBio CEO. Healthcare investment bank SVB Leerink likes the sound of an accelerated filing, and ProventionBio's chances of success after the drug spent years in the wilderness.

"There are lots of reasons to work on a drug for 30 years," Bluestone said. "If you believe a drug helps patients, that's why you do it."

Campus News

News