TOURLITE
CAPITAL MANAGEMENT

Opportunity to buy a stock whose drug has been approved by the FDA before it's been announced

Long Provention Bio (PRVB)

We believe there is significant upside for Provention Bio $PRVB as approval for its Teplizumab drug is approaching.

Teplizumab is the first treatment designed to delay the onset of clinical Type 1 Diabetes (T1D) diagnosis. This would be the first innovation in the T1D space in decades, which will mark a huge leap forward in how T1D is treated and managed.

The official FDA approval date is November 17th; however, the Company has stated that if no major deficiencies are identified during the review period, the FDA plans to communicate proposed labeling by October 17, 2022. The company would likely disclose any problems as they have in the past.

Provention Bio Announces Extension of FDA User Fee Goal Date for Teplizumab to November 17, 2022

June 30, 2022

RED BANK, N.J., June 30, 2022 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB) (the "Company"), a biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced that the U.S. Food and Drug Administration (FDA) has extended its review period by three months for the Biologics License Application (BLA) for teplizumab. The extended User Fee Goal date is November 17, 2022.

The Company was also informed that if no major deficiencies are identified during the review period, the FDA plans to communicate proposed labeling and, if necessary, any post-marketing requirement or commitment requests by October 17, 2022.

As part of its ongoing review and communications, the FDA informed the Company yesterday that it considers a timely response to an information request made earlier this month to be a Major Amendment to the BLA resubmission, requiring additional time for the Agency's review.

"We are committed to collaborating closely with the Agency as it completes its review," said Ashleigh Palmer, Co-Founder and CEO of Provention Bio. "We want to thank the FDA for its continued diligence as we continue to work towards bringing this potential first disease modifying therapy to patients with type 1 diabetes in the United States, for whom there is currently no approved treatment other than a life-time of exogenous insulin therapy."

Source: press release

As of Friday afternoon, Provention posted several job openings on their website and LinkedIn page related to Teplizumab. We believe this is a positive sign for potential conversations with the FDA regarding labeling discussions for Teplizumab.

Job postings from October 14th, 2022

Associate Director/Director – Healthcare Provider (HCP) Marketing

VIRTUAL

Summary Of Major Responsibilities:

As the Associate Director/Director – Healthcare Provider (HCP) Marketing, you will make significant contributions to the successful launch of Teplizumab, the first treatment designed to delay the onset of clinical Type 1 Diabetes (T1D) diagnosis. This would be the first innovation in the T1D space in decades, which will mark a huge leap forward in how T1D is treated and managed. In this role, you will be responsible for executing strategies for multiple HCP segments across all personal and non-personal channels. There is an immediate need to contribute to launch readiness for Provention Bio. To be successful in this role, you should possess a good understanding of marketing in the biotech space and be passionate about delivering best-in-class tactical execution supporting the launch of Teplizumab. Attributes that set the successful candidate up for success are: being adaptable, thinking strategically, having a bias for action and committing to making a difference to T1D patients and their families. Rare disease experience is a plus.

Source: Company website posting / LinkedIn Job Positing

Additional October 17th Job Postings mentioning of "Teplizumab"

Associate Director/Director, Marketing - *Company website* / *LinkedIn*
Associate Director, Forecasting, Secondary Data and Insights - *Company website* / *LinkedIn*
Executive Director Field Market Access - *Company website* / *LinkedIn*
Associate Director of Biostatistics - *Company website* / *LinkedIn*

The Company is not required to announce a positive sign from the FDA this week, however, management would notify shareholders of material event including if Teplizumab was not approved, or if there are any further complications. **This means, if there is no word from the Company, in all likelihood, we believe the drug will receive approval.**

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