UK: +44 (0)207 989 0813
NA: +1 646 896 3065
AU +61 2 9280 0700
action@proactiveinvestors.com

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Baird 'more cautious' on Karyopharm Therapeutics getting quick FDA approval for cancer drug selinexor

Baird analysts saw slimmer chances of Karyopharm Therapeutics Inc (NASDAQ:KPTI) getting accelerated approval for its new cancer drug selinexor aimed at treating multiple myeloma.

On Friday, the Food and Drug Administration released disappointing selinexor briefing documents highlighting "limited efficacy and significant toxicity."

Shares in the Newton, Massachusetts, pharma company nosedived Friday after the FDA briefing documents were released but recovered some ground Monday, rising 5.5% to $5.30 in morning trade.

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"As such, we are more cautious on accelerated approval in triple class-refractory multiple myeloma and await clarity from the Oncologic Drugs Advisory Committee (ODAC) panel (February 26)," wrote Baird analysts Michael E Ulz and Colleen M Hanley to clients in a note over the weekend.

"However, based on the draft questions, the FDA seems to suggest waiting for data from the randomized, Phase 3 BOSTON study (2L+: SVd vs. Vd) YE19 as a potential option, which could address many concerns, in our view," they added.

The analysts at Baird maintained an Outperform rating on Karyopharm Therapeutics shares.

"Though we expect near-term volatility, given potential for approval, we maintain our Outperform rating," wrote the analysts. "Overall, at current levels, limited value is being assigned to selinexor (cash: approximately $3/share) even in the more meaningful 2L+ population and any signs of positive developments could drive upside."

Status of New Drug Application

Karyopharm Therapeutics submitted a new drug application for a combination of selinexor and dexamethasone that is being evaluated for penta-refractory multiple myeloma. Selinexor functions by binding with and inhibiting the nuclear export protein XPO1, resulting in the accumulation of tumor suppressor proteins in the cell nucleus.

The new drug application (NDA) was made based on Part 2 of the Phase 2b trial dubbed STORM. The FDA accepted the application on October 5, according it Priority Review status, cutting the review period to six months.

However, the FDA's concerns highlighted on Friday have dampened expectations linked to speedy approval.

"The FDA highlighted selinexor's toxicity profile, indicating 60.2% of Part 2 STORM patients experienced a serious adverse event, 88.6% required dose modification due to a treatment emergent adverse events (TEAE) and 28.5% discontinued due to a TEAE," wrote the analysts.

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Additionally, 23 deaths occurred within 30 days of study treatment, and the FDA indicated 10 were due to treatment emergent adverse events, although only two of these were assessed as related to selinexor by the investigator, said the analysts.

"The FDA also used data from a prior study in acute myeloid leukemia (development discontinued) to highlight toxicity, where selinexor resulted in a worsening trend on overall survival compared to physician's choice (HR=1.18). Overall, given selinexor's safety profile, we are not surprised by the FDA's focus on toxicity," wrote the analysts.

The FDA's Oncologic Drugs Advisory Committee is set to discuss the NDA at a meeting on Tuesday, February 26.

Contact Uttara Choudhury at uttara@proactiveinvestors.com

Follow her on Twitter: **@UttaraProactive**