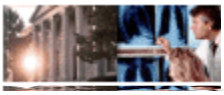

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Mesothelioma Articles

Merck & Co: Zolinza becomes first approved HDAC inhibitor

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By Dr Benjamin Friedmann

FDA approves first-in-class Zolinza (vorinostat) for cutaneous T-cell lymphoma.

Merck & Co's Zolinza has been approved by the FDA for cutaneous T-cell lymphoma patients who have progressive, persistent or recurrent disease on or following failure of two systemic therapies, making the oral drug the first in its class to reach the market. However, with similar drugs not far behind, Merck will need to work hard to ensure Zolinza capitalizes on its first-to-market lead advantage.

'Content In some cancer cells, excess amounts of the enzyme histone deacetylase (HDAC) prevent the activation of genes that control normal cell activity. As an inhibitor of HDAC, Zolinza (vorinostat) allows for the activation of genes that may help to slow or stop the growth of cancer cells, although the exact mechanism of Zolinza's anticancer effect has not been fully characterized.

Cutaneous T-cell lymphoma (CTCL) is a rare form of non-Hodgkin's lymphoma which affects the skin. Approval of the once-daily drug was based on two clinical studies in which refractory CTCL patients were evaluated to determine their response rate to oral Zolinza. In the open-label, single-arm, pivotal study, the overall objective response rate was 29.7% in all patients treated with Zolinza.

In addition to CTCL, Zolinza is being investigated in other indications including myeloma, mesothelioma and a variety of other cancers that have entered phase I and II clinical trials since June 2005. Zolinza's wide application reflects the assertive approach Merck is taking to maximize the potential use of the drug as the gold-standard HDAC inhibitor in as many indications as possible.

Furthermore, the strong global sales and marketing power of Merck should provide the commercial strength necessary to drive market uptake of Zolinza successfully in CTCL and in any other indications Zolinza is subsequently approved for.

The future role of HDAC inhibitors is likely to be in combination with existing or novel chemotherapeutic agents. Merck is therefore exploring the effects of Zolinza as a single agent and its use in combination with both other targeted therapies such as Genentech/Roche's Avastin (bevacizumab) and OSI/Genentech/Roche's Tarceva (erlotinib), and with conventional chemotherapy treatment regimens.

Although Zolinza is now the only approved HDAC inhibitor, Merck may potentially face intense competition from Gloucester Pharmaceuticals' romidepsin (FK-228), another HDAC inhibitor also in development for both CTCL and myeloma. Merck will, therefore, need to work hard if it is to ensure Zolinza capitalizes on its first-to-market advantage. 'End Intelliext

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