

FACT SHEET

Pr ZOLINZA™ (vorinostat capsules)

About ZOLINZA™

- ZOLINZA™ is the first of its kind of a new generation of targeted treatments for advanced cutaneous T-cell lymphoma (CTCL) that has demonstrated benefits in previously treated patients.
- ZOLINZA™ is approved for the treatment of cutaneous manifestations in patients with advanced cutaneous T-cell lymphoma who have progressive, persistent or recurrent disease subsequent to prior systemic therapies.
- ZOLINZA™ is a once a day oral treatment, administered on an outpatient basis.
- Treatment with ZOLINZA™ decreases the activity of the enzyme HDAC (histone deacetylase) to allow for the activation of genes that may help to slow or stop the growth of cancer cells.
- ZOLINZA™ is the first HDAC inhibitor and currently the only oral anti-tumor treatment approved for treatment of cutaneous manifestations of advanced CTCL in Canada.
- Health Canada approved ZOLINZA™ on June 11, 2009. ZOLINZA™ is now available to Canadian patients.

Efficacy

- ZOLINZA™ provides effective improvement of the appearance of skin symptoms of CTCL, with a median time to response of less than two months.
- In patients with Stage IIB and higher CTCL, an overall objective response rate of 29.5% (18/61) was observed in the pivotal study.
- In patients with Stage IIB and higher CTCL with pruritus (score of 3 or more) at the beginning of the trial, nearly one third (30%) of patients treated with ZOLINZA™ experienced pruritus relief, a condition that is extremely difficult to treat in patients with advanced stage CTCL. 11% (6/53) had complete resolution. Improvement of pruritus was noted in both responders and non-responders.

Safety

- ZOLINZA™ is generally well tolerated.
- The safety profile of ZOLINZA™ was evaluated in 107 CTCL patients in two single-arm clinical studies in which 86 patients received ZOLINZA™ 400 mg once daily.

- The most common adverse reactions occurring in clinical trials with ZOLINZA™ are:
 - Gastrointestinal symptoms (diarrhea, nausea, anorexia, weight loss, vomiting, constipation, decreased appetite)
 - Constitutional symptoms (fatigue, chills)
 - Hematologic abnormalities (thrombocytopenia, anemia)
 - Taste disorders (dysgeusia, dry mouth)

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For more information, please contact:

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