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EMA says no to risky schizophrenia drug

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EMA raises red flag to schizophrenia drug Fanaptum



Singapore: European Medicines Agency's (EMA) Committee for Medicinal Product for Human Use (CHMP) has issued a negative opinion recommending against approval of US-based Vanda Pharmaceuticals's Fanaptum (oral iloperidone tablets) for the treatment of schizophrenia in adult patients in the European Union.

The CHMP was of the opinion that the benefits of Fanaptum did not outweigh its risks and recommended against marketing authorization at this point in time. Vanda intends to appeal this opinion and request a re-examination of the decision by the CHMP.

Vanda Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders.