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At its meeting in late July 2012, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) gave positive recommendations for a number of new medicines. EAHP presents a round-up.

The CHMP gave positive recommendations for:

- the granting of a conditional marketing authorisation for Takeda's Adcetris (brentuximabvedotin), licensed from Seattle Genetics, for the treatment of adults with relapsed or refractory CD30+ Hodgkin lymphoma.
- approval of Janssen-Cilag International NV's DACOGEN® (decitabine) for Injection, indicated for the treatment of adult patients (age 65 years and above) with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.
- conditional marketing authorisation for Pfizer's crizotinib drugfor the treatment of adults with previously treated anaplastic lymphoma kinase-positive advanced non-small cell lung cancer.

The CHMP's positive opinions are now referred to the European Commission for approval.

The CHMP issued a negative opinion for Celgene'sIstodax (romidepsin), intended for the treatment of peripheral T-cell lymphoma, saying the way a study was designed did not allow the committee to conclude on the clinical benefit of Istodax as it was not compared with any other treatment. It also noted that, due to an oversight, the company failed to provide an adequate certificate of Good Manufacturing Practice for the site where the medicine is manufactured, which is legally required.

More information **here** [1]

3 August 2012

Links
[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/07/news_detail_001568.jsp&am