Cladribine (Litak)

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Sackler SOM MS4
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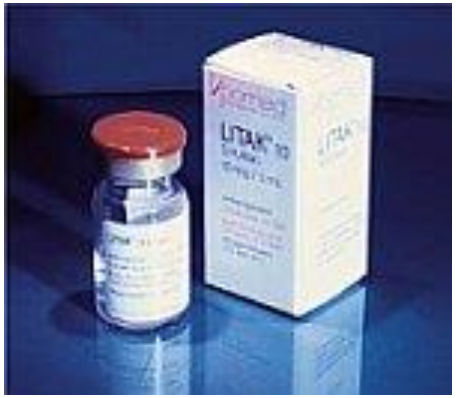

- MOA: Nucleoside ADENOSINE analogue
  - Inhibits adenosine deaminase
  - Targeted to hematopoietic cell lines
- Thought to be further specific in ability to (preferentially) inhibit certain lines of T-cells

- Approved Indications (EU)
  - Hairy cell leukemia
  - Waldenstroem macroglobulinemia
  - Further investigation- other leukemias and lymphomas, MS, histiocytosis

- ‘Orphan drug’ designation in Australia
- Adverse events: Anemia, thrombocytopenia, neutropenia

Cladribine – use in MS

- First approved in Russia (July 2010)
- Pending approval in EU and US- second review cycle
- Study funded by MERCK at London School of Mecicine, to be marketed as 'Mylinax'; 900 million/year
- Phase III trial(CLARITY trial, Jan 2011) – 96 week placebo-controlled study, 1,326 people, that showed efficacy on clinical and neuroimaging outcomes in relapsing-remitting MS.
- Reduces relapses by 50%, 30-40% less disability, 88% reduction in MRI lesions.
- It's a PILL!!!!

- Jan 21st- EU rejects Cladribine due to SAE (2% people developed shingles, 4 people developed cancer)
- FDA to make ruling at end of February
- Competitor- Novartis's Gilenya(fingolimod) FTY-720 (48,000/year tx)