# NEW DRUG APPROVALS

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| **Amevive®** alefacept 1/31/03 | **Indication:** Treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.  
**Claim to fame:**  
- First biologic therapy for psoriasis  
- Designed to target only the harmful memory T cells, not all T-lymphocytes  
**Studies:** FDA based its approval on the results of two randomized, double-blind, placebo-controlled studies that enrolled over 1000 adults with chronic plaque psoriasis (covering at least 10 percent of their bodies). Both studies showed that a significantly higher percentage of patients receiving Amevive responded to treatment compared to those receiving placebo based on pre and post-treatment measurements of the percentage of affected skin surface area and severity of scaling and inflammation.  
**Retreatment:** Additional 12-week course may be initiated provided that CD4+ T lymphocyte counts are within the normal range, and a minimum of a 12-week interval has passed since the previous course of treatment. Data on re-treatment beyond two cycles is limited.  
**Side Effects:** Lymphopenia, malignancies, serious infections requiring hospitalization, hypersensitivity reactions, longer-term risks unknown.  
Amevive induces dose-dependent reductions in circulating cd4+ and cd8+ T lymphocyte counts.  
**Pregnancy:** Risk of harm to the developing fetus is unknown, and many psoriasis patients are women of childbearing age. Doctors are encouraged to list patients who become pregnant while using the drug for participation in a Biogen pregnancy registry, by calling 1-866-AMEVIVE.  
**Cost:** $7,000 to $10,000 for a 12-week course of treatment; each weekly dose is given in a doctor’s office. |
| **Dosage:**  
7.5 mg given once weekly as an IV bolus or 15 mg given once weekly as an IM injection.  
| **Regimen:** course of 12 weekly injections. |
| **Monitoring Parameters:** cd4+ T lymphocyte counts should be monitored weekly throughout the course of the 12-week dosing regimen. |

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**Did you know that in 2002...**

- Only 17 new molecular entity approvals (NME’s) were approved in 2002, down from 24 in 2001 and 27 in 2000.
- The 2002 tally marks the lowest number of approvals since 1983, when 14 NMEs were approved. The all time high of NME approvals was 53 in 1996.
- The median review time for the FDA was 18.3 months in 2002, up from 18.1 in 2001; the average was 21.5 months.
- Excluding resubmitted applications, Zetia® (ezetimibe) received the shortest review with an approval in 9.9 months. The longest approval time was 50 months for the migraine agent Relpax® (eletriptan).