FDA Approves New Cancer Treatments

The Food and Drug Administration gave the green light to Tecelra (afamitresgene autoleucel) and Lymphir (denileukin diftitox).

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In August, the Food and Drug Administration (FDA) granted accelerated approval of Tecelra (afamitresgene autoleucel)— the first T-cell receptor therapy for solid tumors—for people with inoperable or metastatic synovial sarcoma. Tecelra is a gene therapy created from a patient's own T cells. A sample of cells is removed and genetically modified to express a natural T-cell receptor that targets MAGE-A4, an antigen expressed on cancer cells. In the Phase II SPEARHEAD-1 trial, the overall response rate was 43%, and 39% of responders were still doing well a year later.

The FDA also gave the green light to Lymphir (denileukin diftitox), a new type of immunotherapy for relapsed or refractory cutaneous T-cell lymphoma, a rare type of non-Hodgkin lymphoma. Lymphir is a recombinant protein that targets the IL-2 receptor on malignant T cells and carries a diphtheria toxin to kill the cells. In a Phase III study, the overall response rate was 36%, and about half of these responders had a durable response lasting at least six months.

In September, the FDA approved the first injectable immune checkpoint inhibitor, giving patients an alternative to IV infusions. The new formulation of Tecentriq (atezolizumab), administered via subcutaneous injections in the thigh, reduces treatment time to about seven minutes compared with up to an hour for infusions. The injectable and IV formulations had similar overall response rates, overall survival, progression-free survival and safety in a study of people with lung cancer. What's more, about 70% preferred the injectable version, citing increased comfort and reduced emotional distress.