

Cancer Beats All Other Fields for New Drug Approvals in 2012

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Eleven new drugs for the treatment of cancer were approved by the US Food and Drug Administration (FDA) in 2012 (so far). Only a few of these agents have been approved in Europe; most are still under review there.

"This is more than any other therapeutic category," Stephanie Yao, from the FDA Office of Public Affairs, told *Medscape Medical News*. So far this year, the FDA has approved 34 new molecular entities and new biologic agents this year, 11 of which were oncology drugs, she explained. And Yao pointed out that there are still 2 weeks left in this calendar year.

This is slightly more than last year, she said. In 2011, the FDA approved 30 new products, 8 of which were oncology drugs. That was also more than any other therapeutic category, she added.

Eleven New Cancer Drugs

Axitinib (*Inlyta*, Pfizer) is used to treat patients with advanced renal cell carcinoma who have not responded to other therapies. It was approved [in the United States](#) in January and [in Europe](#) in September.

Vismodegib (*Erivedge*, Genentech) is used to treat patients with locally advanced basal cell cancer who are not candidates for surgery or radiation and to treat patients whose cancer has metastasized. It [was approved](#) in the United States in January.

Pertuzumab (*Perjeta*, Roche) is used to treat patients who have *HER2*-positive metastatic breast cancer and to treat patients who have not received any previous *HER2*-targeted therapy or chemotherapy in combination with trastuzumab (*Herceptin*) and docetaxel. It [was approved](#) in the United States in June and was just [recommended for approval](#) in Europe.

Carfilzomib (*Kyprolis*, Onyx Pharmaceuticals) is used to treat patients whose multiple myeloma has progressed despite at least 2 previous therapies, including bortezomib (*Velcade*, Millennium Pharmaceuticals) and an immunomodulatory agent. It [was approved](#) in the United States in July.

Ziv-aflibercept (*Zaltrap*) is used to treat patients with metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin-containing regimen, in combination with the FOLFIRI regimen (5-fluorouracil, leucovorin, and irinotecan). The drug [was approved](#) for colorectal cancer in the United States in August. In November 2011, an ophthalmic solution (*Eylea*) [was approved](#) for use in age-related macular degeneration.

Enzalutamide (Xtandi, Astellas/Medivation) is used to treat men with metastatic castration-resistant prostate cancer who previously received docetaxel. It [was approved](#) in the United States in August.

Regorafenib (*Stivarga*, Bayer) is used to treat patients with metastatic colorectal cancer that has progressed despite standard treatment. It [was approved](#) in the United States in September.

Bosutinib (*Bosulif*, Pfizer) is used to treat patients with chronic myeloid leukemia who have developed resistance or tolerance to previous therapy with tyrosine kinase inhibitors. It [was approved](#) in the United States in September.

Omacetaxine mepesuccinate (*Synribo*, Teva Pharmaceuticals) is used to treat patients with chronic myeloid leukemia who have progressed after treatment with at least 2 tyrosine kinase inhibitors. It [was approved](#) in the United States in October.

Cabozantinib (*Cometriq*, Exelixis) is used to treat patients with metastatic medullary thyroid cancer, which accounts for about 4% of all of thyroid cancers. It [was approved](#) in the United States in November.

Ponatinib (*Iclusig*, Ariad) is used to treat patients with chronic myeloid leukemia or Philadelphia-chromosome-positive acute lymphoblastic leukemia who are resistant to other therapies, and in those who carry *T315I* mutations. It [was approved](#) in the United States in December.

Three Other Approvals

The FDA approved another 3 agents for use in cancer patients this year, either for supportive care or for imaging.

Glucarpidase (*Voraxaze*, BTG International) is used to treat patients with high levels of methotrexate in their blood due to renal impairment. It [metabolizes methotrexate](#) and leads to a rapid and sustained reduction of methotrexate blood levels. It [was approved](#) in the United States in January.

Tbo-filgrastim (*Neutroval*, Sicor Biotech), a colony-stimulating factor, is used to increase the production of neutrophils in cancer patients with nonmyeloid malignancies who are receiving chemotherapy drugs that cause severe neutropenia. It [was approved](#) in the United States in August.

Choline C 11 injection (manufactured and distributed by the Mayo Clinic PET Radiochemistry Facility in Rochester, Minnesota) is an imaging agent used in positron emission tomography scanning to detect recurrent prostate cancer. These scans are performed in men who have elevated prostate-specific antigen levels after previous treatment for prostate cancer. It [was approved](#) in the United States in September.

Targeted Agents

In its annual report, the American Society of Clinical Oncology notes that nearly all of the new drugs are targeted agents, designed to block the activity of specific proteins involved in tumor growth.

That report highlights the fact that vismodegib has a novel mechanism of action, and is the first approved drug to target the Hedgehog signaling pathway, which plays an important role in tissue growth and repair. Vismodegib, currently marketed for basal cell skin cancer, is also being investigated in clinical trials of patients with colorectal, stomach, and pancreatic cancers.

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