Cancer drug approvals grew from 4% of U.S. total in the 1980s to 27% in 2010-18

Share grew each decade, outpacing anti-infectives, cardiovascular, and CNS drugs

- The cancer drug share of new approvals increased by 50% from the 1990s to the 2000s, and nearly doubled from the 2000s to the 2010-18 period.
- Solid tumor cancer drug approvals have increased more than blood cancer approvals during 1993-18.
- Regulatory approval phase time for cancer approvals during 1999-18 was 48% shorter on average vs. non-cancer approvals.
- Total clinical development and approval phase times during 1999-18 was 17% longer on average for hematologic drugs (8.8 years) compared to drugs for solid tumors (7.5 years).
- Substantially higher percentages of new cancer drug approvals received priority ratings and had orphan drug status during 1999-18, compared to new non-cancer drug approvals.

Oncology drug development has skyrocketed in the last 38 years, reflecting strong demand coupled with an explosion in new scientific knowledge about the pathophysiology of the disease. In the 2010-18 period, cancer drug approvals in the United States accounted for the greatest share (27%) of all U.S. drug approvals among major four therapeutic classes. In contrast, in the 1980s, oncology drugs accounted for the smallest share (4%) of U.S. approvals among the same four classes. New approaches to development helped to drive the surge in new oncology products, including improvements in clinical trial design, novel drug formats, and a focus on new and validated targets. Those efforts appear to have paid off, as cancer patients today have many more effective treatment options.

Pressure for more new oncology drugs is likely to continue, driven in part by the demand for personalized medicines to treat a host of currently untreated or inadequately treated cancers. Developers will be challenged to meet that demand while controlling development costs, particularly those tied to recruiting sufficient numbers of patients for clinical trials involving rare cancers, and managing payer pressure to control drug prices and contain pharmaceutical spending in the U.S.