The Oncology Race in Biotech: Road to First Approval

Development in oncology has increased dramatically with multiple approvals across many cancers. Many biotechs are looking for their first approval, including those with large clinical programs in the US and EU and ongoing Phase III trials.

Alternative Approval Pathways:

- **Accelerated Approval pathway**: The Accelerated Approval pathway by the FDA (Conditional Approval by the EMA) allows the ability to approve drugs that treat serious conditions with high unmet need, based on surrogate endpoints and often in smaller Phase 1 and 2 trials. Since 2017, there have been an amazing 60 accelerated approvals in oncology by the FDA.

Studies Conducted Outside of the US and EU:

- In 2019, Beigene was the first to gain an FDA approval (zanubrutinib in mantle-cell lymphoma) based mainly on a pivotal study conducted in China. Currently several submissions in front of the FDA include trials exclusively done in China. These include submissions by Innovent, and by Akeso / Sino, and Junshi / Coherus in nasopharyngeal cancer. In February 2022 the FDA ODAC recommended against approval of sintilimab (Innovent) in NSCLC, however the other applications remain pending.