Biomarker-directed drug development in oncology-20 years and counting

Baolin Zhang
Food and Drug Administration, USA

Most recently approved oncology drugs target discrete molecular aberrations or pathways in tumor cells and consequently are active on a subset of the patient population. The problem mainly lies in the vast heterogeneity that exists between tumor types, individuals with the same type of tumor, and within one tumor of a patient at any given time. The Predictive biomarkers, measured using *in vitro* companion diagnostics (IVD), help identify patients likely to respond to treatment and are increasingly integrated into drug development programs. This presentation will provide an update of biomarker-directed oncology drugs approved by the US Food and Drug Administration. Case studies will be presented on therapeutic monoclonal antibodies selectively targeting HER2, EGFR, or PD-1/PD-L1 signaling pathways. This information will be further discussed with respect to biomarker qualification in the development of novel cancer therapeutics.

e: baolin.zhang@fda.hhs.gov