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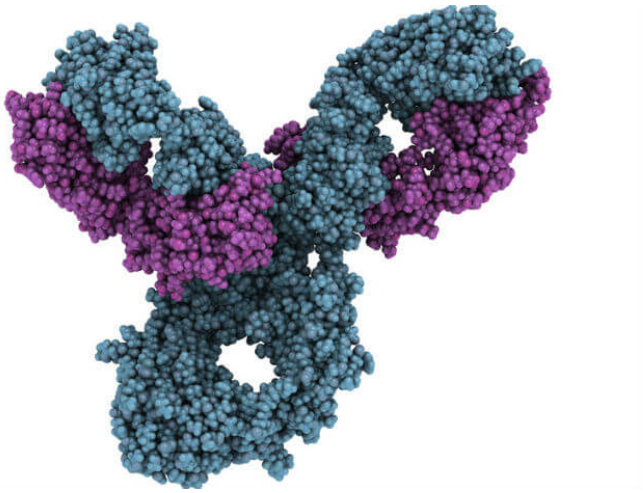
Merck’s KEYTRUDA receives approval in China

02 April 2019 | News

KEYTRUDA is First Anti-PD-1 Therapy to be approved in multiple tumor types in China



Merck, known as MSD outside the United States and Canada, has announced that KEYTRUDA, Merck’s anti-PD-1 therapy, has been approved by the National Medical Products Administration (NMPA) in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.

This new indication was granted conditional approval based on overall survival (OS) and progression-free survival (PFS) data from the pivotal Phase 3 KEYNOTE-189 trial in patients regardless of PD-L1 tumor expression status. Continued approval may be contingent upon verification and description of clinical benefit in Chinese patients in a confirmatory trial.

With this approval, KEYTRUDA is the first anti-PD-1 therapy approved for more than one tumor type in China, following its initial approval in July 2018 for advanced melanoma, and the first anti-PD-1 therapy approved in the first-line treatment setting for metastatic nonsquamous NSCLC.