Keytruda Receives Five New Approvals in Japan, Including 3 Expanded Uses for Lung Cancer

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Keytruda (pembrolizumab) has simultaneously received five new approvals in Japan, including four expanded uses — three for advanced non-small cell lung cancer (NSCLC) and one for melanoma — and a new indication for advanced microsatellite instability-high tumors.

“These five simultaneous approvals of Keytruda in Japan represent a significant achievement that involved extensive collaboration with the Japan Pharmaceuticals and Medical Devices Agency,” Roy Baynes, senior vice president and head of global clinical development, and chief medical officer of Merck Research Laboratories, said in a press release.

“We appreciate the Agency’s efforts to expedite availability of this important medicine to more patients living with cancer in Japan,” Baynes added.

Keytruda, developed by Merck (known as MSD outside the United States and Canada), is an anti-PD-1 antibody that blocks the binding of PD-1 with its ligands. This activates T-cells and boosts the ability of the immune system to identify and fight tumor cells.

Among the new approvals are three indications for first-line treatment of NSCLC patients who cannot undergo surgery.

The first is for patients with nonsquamous NSCLC with any level of PD-L1 expression, and is based on promising overall survival and progression-free survival data from the KEYNOTE-189 Phase 3 trial (NCT02578680). The approval is for Keytruda in combination with Alimta (pemetrexed) and platinum-based chemotherapy – Platinol (cisplatin) or Paraplatin (carboplatin) — a first-line treatment that has also been cleared in Europe.

The second approval – based on data from the KEYNOTE-407 Phase 3 trial (NCT02775435) — is for squamous NSCLC, regardless of PD-L1 levels. For these patients, Keytruda is to be used in combination with Paraplatin (carboplatin) plus Taxol (paclitaxel) or Abraxane (nab-paclitaxel) — a treatment that was also approved in the U.S.

In addition, Keytruda was approved for patients with locally advanced or metastatic NSCLC, whose tumors have at least 1 percent of cells producing the PD-L1 factor. The approval was based on data from a pivotal Phase 3 trial, KEYNOTE-042 (NCT02220894), in which Keytruda outperformed chemotherapy in extending patients' lives.

The U.S. Food and Drug Administration is currently reviewing Merck's application seeking Keytruda's label extension for this NSCLC patient population. The application has been granted priority review and a decision is expected by Jan. 11, 2019.

The Japanese authorities have also extended the label of Keytruda for an additional melanoma indication. Based on clinical evidence from the pivotal KEYNOTE-054 Phase 3 trial (NCT02362594), Keytruda may now be given to patients with advanced melanoma who have undergone complete surgical removals of their tumors.

Finally, Keytruda was approved as a stand-alone agent for the treatment of microsatellite instability high solid tumors — those presenting a high frequency of mutations in their DNA — who failed to respond to prior chemotherapy treatment. Data from two ongoing Phase 2 studies, the KEYNOTE-164 (NCT02460198) and KEYNOTE-158 (NCT02628067), supported the approval by Japanese regulatory authorities.

“KEYTRUDA was first approved in Japan almost two years ago and has rapidly become an important therapy in a number of different types of cancer,” said Jannie Oosthuizen, managing director of MSD in Japan. “Cancer is the leading cause of death in Japan, so with these new approvals, we are proud to bring renewed hope to even more people with cancer in Japan and their families.”

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