

[FDA OKs Imfinzi for unresectable stage III NSCLC](#)

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March 13, 2018—[AstraZeneca](#) and MedImmune, its biologics research and development arm, announced the FDA has approved Imfinzi (durvalumab) for the treatment of patients with unresectable stage III non-small cell lung cancer whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

“This is the first treatment approved for stage III unresectable non-small cell lung cancer to reduce the risk of the cancer progressing, when the cancer has not worsened after chemoradiation,” Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence and acting director, Office of Hematology and Oncology Products, FDA Center for Drug Evaluation and Research, said in a statement. “For patients with stage III lung cancer that cannot be removed surgically, the current approach to prevent progression is chemoradiation.... Patients now have an approved therapy that has been shown to keep the cancer from progressing for a longer time after chemoradiation.”

Approval of Imfinzi is based on the positive progression-free survival data from the phase three PACIFIC trial, in which Imfinzi demonstrated an improvement in median PFS of 16.8 months compared with 5.6 months on placebo, representing a 48 percent reduction in relative risk of progression or death versus placebo in all patients, regardless of PD-L1 status. The PACIFIC trial is ongoing to evaluate overall survival in unresectable stage III NSCLC. Detailed interim results of the PACIFIC trial were published in the *New England Journal of Medicine* (Antonia SJ, et al. 2017;377[20]:1919-1929).

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