

バイオマーカーで何が変わるのか\*\*  
—Cetuximab におけるバイオマーカー—

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—Clinical Development of Cetuximab and Biomarkers—

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**Summary**

In July 2008, Cetuximab was approved in Japan, 4 years after its approval in the EU and US. Thus, we have been able to embrace the world standard treatment strategy for colorectal cancer (CRC). There has also been remarkable progress in studies of biomarkers, such as KRAS gene status. As a result, cetuximab has been positioned as the first personalized therapy for CRC. Specifically, if cetuximab is not used in patients with mutated KRAS, in whom it would be ineffective, patients are not exposed to the risk of adverse events and the cost of treatment is reduced. However, in Japan, there were serious delays in introducing tests for fundamental biomarkers, such as the EGFR IHC test and KRAS gene test. In the future development of molecular-targeting drugs, it will be important to consider related biomarkers as well.

**Key words**

Cetuximab, Biomarker, KRAS