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——抗悪性腫瘍薬開発フォーラム——

承認から臨床への安全な導入—現場での対応—**
—セツキシマブ（アービタックス）承認における問題と当院における診療体制—

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Clinical Problems in Approval and Introduction of Cetuximab
—From the Viewpoint of Our In-house System and Experience—

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Summary

Cetuximab (ERBITUX(R)) has received marketing authorization in Japan for use in treating patients with epidermal growth factor receptor (EGFR)-positive mCRC. This approval allows the use of cetuximab + irinotecan as second-line and subsequent treatment. To ensure proper clinical use, safety monitoring and postmarketing survey have been conducted by companies and government and this has imposed a significant burden on investigators. This conditional approval may also lead to confusion due to the differences of clinical conditions (indications, combination regimen, etc.) between Japan and elsewhere in the world. We set up an organizing committee in our hospital to ensure successful introduction of cetuximab. This in-house system works well and has resulted in safe clinical use.

Key words

Cetuximab, Approval