Novartis implements manufacturing adjustments for ribociclib to ensure alignment with latest regulatory standards in eBC by end of Q2

Apr 09, 2024

In light of recently evolving regulatory guidance on intake limits for nitrosamines in medications, enrollment of new patients in ribociclib early breast cancer (eBC) studies has been paused in alignment with health authorities.

This does not impact patient use or commercial supply of Kisqali® in its approved indication of metastatic breast cancer (mBC).

We are implementing manufacturing adjustments to ensure alignment with the latest regulatory standards in eBC by the end of Q2.

We currently expect regulatory review of ribociclib in eBC to proceed as planned.
