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Date: October 28, 2021
Panel: Breast Cancer

As an addendum to the submission for Verzenio® (abemaciclib) to the NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines) for breast cancer dated October 14, 2021, we are enclosing overall survival data from the monarchE study published online as a letter to the editor in *Annals of Oncology* for your consideration.¹⁻² This survival information was not included in the recently published study update, due to immaturity of the data.³ However, detailed overall survival data (which remain immature) were published in the enclosed letter to allow the medical community access to this information so that they may better understand the rationale for the indication approved by the Food and Drug Administration (FDA).¹

FDA Approval

On October 12, 2021, the FDA approved abemaciclib in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score $\geq 20\%$ as determined by an FDA approved test. Please refer to the product prescribing information for the full FDA-approved indications and safety information for abemaciclib, available at <http://pi.lilly.com/us/verzenio-uspi.pdf>.⁴

Literature Support

1. Harbeck N, Rastogi P, Shahir A, et al. Letter to the Editor for "Adjuvant abemaciclib combined with endocrine therapy for high-risk early breast cancer: Updated efficacy and Ki-67 analysis from the monarchE study". *Ann Oncol*. Published online October 28, 2021. [https://www.annalsofoncology.org/article/S0923-7534\(21\)04551-8/fulltext](https://www.annalsofoncology.org/article/S0923-7534(21)04551-8/fulltext)
2. Additional Verzenio® (abemaciclib) phase 3 monarchE trial data published in the *Annals of Oncology*. Press release. Eli Lilly and Company; October 28, 2021. Accessed October 28, 2021. <https://www.prnewswire.com/news-releases/additional-verzenio-abemaciclib-phase-3-monarche-trial-data-published-in-the-annals-of-oncology-301411243.html>.
3. Harbeck N, Rastogi P, Martin M, et al. Adjuvant abemaciclib combined with endocrine therapy for high-risk early breast cancer: Updated efficacy and Ki-67 analysis from the monarchE study. *Ann Oncol*. Published online October 14, 2021. [https://www.annalsofoncology.org/article/S0923-7534\(21\)04494-X/fulltext](https://www.annalsofoncology.org/article/S0923-7534(21)04494-X/fulltext).
4. Verzenio [package insert]. Indianapolis, IN: Eli Lilly and Company; 2021.

We appreciate this opportunity to provide this additional information for consideration by the NCCN Breast Cancer Panel. Please do not hesitate to contact me with any questions.

Sincerely,

Jack Goodpasture
Vice President, Global Medical Affairs, Lilly Oncology