



**For Immediate Release**

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**National Advertising Division Finds Novartis Breast Cancer Drug Claim Supported in Physician-Directed Messaging, But Not in Ads to Consumers**

New York, NY – Jan. 19, 2023 – The National Advertising Division (NAD) of BBB National Programs determined that Novartis Pharmaceutical provided a reasonable basis for the claim that its Kisqali breast cancer treatment drug is “The only CDK4/6 inhibitor with statistically significant overall survival proven across 3 phase III trials” when directed to an audience of health care professionals (HCPs).

However, NAD recommended that a substantially similar claim in consumer-facing advertising, along with several implied comparative superiority claims, be discontinued.

Eli Lilly, manufacturer of the competing Verzenio drug to treat metastatic breast cancer, had challenged survival benefit claims made in Novartis’ advertising campaign for Kisqali.

Metastatic breast cancer is presently incurable, however, current treatments can reduce the spread of cancer to other parts of the body, consequently extending time without disease progression (known as progression-free survival) and enabling patients to live longer—an outcome referred to as “overall survival.” Treatments include blocking the estrogen pathway (hormonal therapy), chemotherapy, and targeted treatments, including treatments that function as CDK4/6 inhibitors.

At issue before NAD was whether Novartis’ claims about Kisqali’s overall survival outcomes in clinical trials convey a message of superior survival benefits over other CDK4/6 inhibitors and imply that patients will live longer with Kisqali than when taking any other competitor’s drug in class.

**HCP-Directed Advertising**

NAD considered the claim that Kisqali is “The only CDK4/6 inhibitor with statistically significant overall survival proven across 3 phase III trials” that appears in health care professional-directed advertising. NAD has long recognized that health care providers and specialists are a sophisticated audience and are better equipped to decipher the advertised results of clinical data than the general consumer, especially when provided with appropriate context and detail.

NAD concluded that clinical experience and the context provided in the advertiser’s HCP-directed brochures would both inform the physician’s takeaway of the claim and limit it to the recited facts, and that this audience would interpret the comparative claim here simply as

reporting that Kisqali is unique in achieving a statistically significant overall survival benefit across Novartis' three phase III clinical trials.

After assessing the results of the advertiser's three clinical trials published in the New England Journal of medicine, NAD determined that the advertiser had provided a reasonable basis for the HCP-directed claim.

### **Consumer-Directed Advertising**

With respect to the consumer-directed claim, "Only drug in class with consistently proven survival benefit in HR+/HER2- metastatic breast cancer" \* \* "across three Phase III trials," NAD determined that the claim was inherently comparative. NAD therefore concluded that one message reasonably conveyed to consumers, who NAD determined lack the medical knowledge or experience to understand nuances in clinical trial design or outcomes, is that Kisqali is more effective and provides superior survival benefits.

Further, NAD determined that due to the numerous variations in trial design and other key metrics across clinical trials, the studies submitted are not similar enough to compare the overall survival data or other results. NAD noted that where express or implied comparative performance claims are being made, head-to-head studies of the products at issue constitute the most reliable and persuasive substantiation.

NAD therefore recommended that in consumer-facing advertising, the advertiser discontinue the claim "Only drug in class with consistently proven survival benefit in HR+/HER2- metastatic breast cancer" \* \* "across three Phase III trials" as well as the implied claims that:

- Kisqali provides superior survival benefits as compared to any other available treatment in the CDK4/6 inhibitor class generally and to Verzenio specifically.
- Patients will live longer with Kisqali as compared to any other available treatment in the CDK4/6 inhibitor class generally and to Verzenio specifically.

During the proceeding, the advertiser permanently discontinued several challenged express and implied survival benefit claims. Therefore, NAD did not review these claims on the merits.

In its advertiser statement, Novartis stated that although it respectfully disagrees with NAD's findings, pursuant to NAD's recommendation, Novartis plans to discontinue the claim in consumer-facing advertising.

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