אוגוסט 2026

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

שלום רב,

הנדון: **<u>עדכונים בעלון לרופא של התכשיר</u>**

Kisqali 200 mg/ קיסקלי 200 מ"ג

Film Coated Tablets/ טבליות מצופות

חברת נוברטיס ישראל בע"מ מבקשת להודיע על עדכון בעלון לרופא של התכשיר Kisqali 200 mg.

למידע מלא יש לעיין בעלוני התכשיר.

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פניה לבעל הרישום.

התוויות התכשיר:

<u>Early breast cancer</u>

Kisqali in combination with an aromatase inhibitor is indicated for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer at high risk of recurrence (see sections 4.2 and 5.1 for selection criteria).

In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

<u>Advanced or metastatic breast cancer</u>

Kisqali is indicated in combination with:

- a non-steroid aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, as initial endocrine-based therapy; or
- fulvestrant for the treatment of men and postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

In pre- or perimenopausal women, the endocrine therapy should be combined with a LHRH agonist.

חומר פעיל:

Ribociclib (as succinate) 200 mg

Novartis Israel Ltd.
6 Tozeret Haaretz street, Tel Aviv
Tel: 972-3-9201111

עידכונים בעלון לרופא:

4. CLINICAL PARTICULARS

.....

4.4 Special warnings and precautions for use

Critical visceral disease

~~The efficacy and safety of ribociclib have not been studied in patients with critical visceral disease.~~ A longer time to response (TTR) has been observed in patients treated with ribociclib plus a non-steroidal aromatase inhibitor (NSAI) compared to those treated with combination chemotherapy in a clinical study (see section 5.1). This should be considered by the treating physician managing patients with critical visceral disease who may be considered for ribociclib plus NSAI therapy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Study CLEE011A3201C (RIGHT Choice)
RIGHT Choice was a randomised, open-label, phase II study (N=222) comparing the combination of ribociclib plus NSAI (letrozole or anastrozole) plus goserelin (n=112) versus combination chemotherapy (docetaxel plus capecitabine, paclitaxel plus gemcitabine, or capecitabine plus vinorelbine, n=110) in pre-/perimenopausal women with HR-positive, HER2-negative advanced breast cancer for whom combination chemotherapy was indicated. Patients had not received prior hormonal therapy, except LHRH agonist, nor chemotherapy for advanced breast cancer.

The primary endpoint of progression-free survival (PFS) was met at the time of primary analysis (12 April 2022 cut-off), with a statistically significant improvement in PFS in the ribociclib plus NSAI arm compared to the combination chemotherapy arm (HR: 0.536, 95% CI: 0.363, 0.793 at one-sided stratified log-rank test p-value=0.000727). The median PFS was 24.0 months in the ribociclib plus NSAI arm versus 12.3 months in the combination chemotherapy arm.

Secondary endpoints included overall response rate (ORR) and time to response (TTR) as determined by local investigator assessment without image confirmation. The unconfirmed ORR was 65.2% in the ribociclib plus NSAI arm versus 60.0% in the combination chemotherapy arm. The median TTR was 4.9 months in the ribociclib plus NSAI arm versus 3.2 months in the combination chemotherapy arm.

OS data was immature at final data cut-off date (10 May 2023) with 34 deaths (30.4%) in the ribociclib plus NSAI arm and 29 deaths (26.4%) in the combination chemotherapy arm. The median OS was not reached in the ribociclib plus NSAI arm (95% CI, 38.6 months, NE) or the combination chemotherapy arm (95% CI: 30.8 months, NE); HR: 0.92, 95% CI: 0.56, 1.52.

בברכה,

נוברטיס ישראל בע"מ

Novartis Israel Ltd.
6 Tozeret Haaretz street, Tel Aviv
Tel: 972-3-9201111