משרד ראשי

רח' החרש 45240 הוד השרון 45240 ת.ד. 10 ת"א 61000

Head Office

4 Haharash St. Hod-Hasharon 45240 P.O.Box 10 Tel-Aviv 61000 Israel

Tel. +972-9-7626333 Fax. +972-9-7626300 רופא/ה, רוקח/ת נכבד/ה,

הנדון: **עדכון עלון לרופא של ולטסה 8.4 גר', ולטסה 16.8 גר' VELTASSA 8.4 G, VELTASSA 16.8 G**

אנו מבקשים להודיעכם כי העלון לרופא של התכשיר שבנדון עודכן.

:ההתוויה המאושרת

Veltassa is indicated for the treatment of hyperkalaemia in adults.

הרכב וחוזק חומר פעיל:

PATIROMER (AS SORBITEX CALCIUM) 8.4 G, 16.8 G

בפירוט שלהלן מובא המידע בו בוצעו <u>שינויים מהותיים בלבד</u>. תוספת טקסט או טקסט בעל שינוי משמעותי מסומן בצבע. מחיקת טקסט מסומנת בקו חוצה.

<u>העדכונים בעלון לרופא נעשו בסעיפים הבאים:</u>

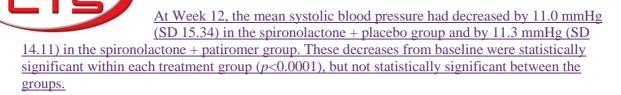
5.1 Pharmacodynamic properties

The ability of patiromer to enable concomitant spironolactone treatment in patients with resistant hypertension and CKD was further investigated in a randomised, double-blind, placebo-controlled study over 12 weeks. Normokalaemic patients initiated spironolactone at 25 mg QD together with their randomised treatment (patiromer 8.4 g QD or placebo). Patiromer/placebo was titrated weekly (up to 25.2 g QD) to maintain serum potassium \geq 4.0 mEq/L and \leq 5.1 mEq/L. At week 3 or after, spironolactone dose was increased to 50 mg QD for subjects with systolic blood pressure \geq 120 mmHg and serum potassium \leq 5.1 mEq/L.

Of the 295 randomized patients receiving study treatment (patiromer 147; placebo 148), mean age was 68.1 years, 51.9% were men, 98.3% were Caucasian, and mean eGFR was 35.73 mL/min/1.73m2. At randomization, mean baseline serum potassium values were 4.74 mEq/L for patiromer and 4.69 mEq/L for placebo. The primary efficacy endpoint, the proportion of subjects remaining on spironolactone at Week 12, was significantly higher (*p*<0.0001) in the patiromer group (85.7%) compared to the placebo group (66.2%). Significantly more patients received spironolactone 50 mg/day (69.4% versus 51.4%).

Overall, patients in the patiromer group remained on spironolactone 7.1 days longer (95% CI 2.2–12.0; *p*=0.0045) compared to the placebo group and received significantly higher cumulative doses of spironolactone (2942.3 (SE 80.1) mg vs 2580.7 (SE 95.8) mg, *p*=0.0021).

There were also significantly fewer patients in the patiromer group with serum potassium values \geq 5.5 mEq/L (35.4% vs. 64.2%, p<0.001).



Overall, in the phase 2 and 3 clinical studies, $99.4\underline{5}\%$ of patients were receiving RAAS inhibitor therapy at baseline, $\underline{81.287}\%$ had CKD with eGFR <60 mL/min/1.73 m², $\underline{72.865.6}\%$ had diabetes mellitus and $\underline{48.747.5}\%$ had heart failure.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות http://www.health.gov.il. ניתן לקבלם מודפסים על ידי פניה לחברת כצט בע"מ, רח' החרש 4 הוד השרון, 09-7626323

> בברכה, אלון אופיר רוקח ממונה כצט בע"מ