

תאריך 28/6/2017

שם תכשיר באנגלית **Cerdelga**

מספר רישום 1575634703

שם בעל הרישום **sanofi aventis Israel ltd**

טופס זה מיועד לפרוט ההחמרות בלבד!

מוזכרים כאן רק תתי הסעיפים בהם נעשה שינוי בטיחות. מידע מלא ניתן למצוא בעלון המלא.

ההחמרות המבוקשות מסומנות על רקע צהוב.  
טקסט שהוסר מסומן בקו אדום

פרטים על השינויים המבוקשים		
פרק בעלון	טקסט נוכחי	טקסט חדש
PHARMACOLOGICAL PROPERTIES	<p><b>5.1 Pharmacodynamic properties</b></p> <p>During an open-label extension period, patients who continued to receive Cerdelga (n=18) showed further improvements (change from baseline) in haemoglobin level (1.02 g/dL), platelet count (58.16%) and spleen and liver volumes (-44.61% and -11.18% respectively) after 18 months of treatment. All patients had <math>\geq 20\%</math> reduction in spleen volume after 18 months, and the vast majority (16/18) of patients achieved <math>&gt; 30\%</math> reduction in spleen volume.</p> <p><u>Effects on skeletal pathology</u></p> <p>In Study 02507, the total Bone Marrow Burden (BMB) score as assessed by MRI in lumbar spine and femur in Cerdelga-treated patients decreased by a mean of 1.1 points after 9 months (n=20) and 2.15 points after 18 months (n=18). The percentage of Cerdelga-treated patients with a significant reduction of at least 2 points in the total BMB score increased from 26% (n=5) after 9</p>	<p><b>5.1 Pharmacodynamic properties</b></p> <p>During an open-label long term treatment period with Cerdelga (extension period phase), all patients with complete data who continued to receive Cerdelga (n=18) showed further improvements (change from baseline) throughout the extension phase. Results (change from baseline) after 18 months, 30 months and 4.5 years of exposure to Cerdelga on the following endpoints were: absolute change in haemoglobin level (g/dL) 1.1 (1.03) [n=39], 1.4 (0.93) [n=35], and 1.02 g/dL (1.31) [n=12]; mean increase in platelet count (<math>\text{mm}^3</math>) <del>(58.5</del> <del>+6%</del>) (40.57%) [n=39], 74.6% (49.57%) [n=35], and 86.8% (54.20%) [n=12]; and mean reduction in spleen volume (MN) 46.5% (9.75%) [n=38], 54.2% (9.51%) [n=32], and 65.6% (7.43%) [n=13]; and mean reduction in liver volumes <del>(-44.61% and -11.18% respectively)</del> (MN) 13.7% (10.65%) [n=38], 18.5% (11.22%) [n=32], and 23.4% (10.59%) [n=13]. <del>after 18 months of treatment. All patients had <math>\geq 20\%</math> reduction in spleen volume after 18 months, and the vast majority (16/18) of patients achieved <math>&gt; 30\%</math> reduction in spleen volume.</del></p> <p><u>Effects on skeletal pathology</u></p> <p>After 9 months of treatment, in Study 02507, bone marrow infiltration by Gaucher cells, as determined by the total Bone Marrow Burden (BMB) score as (assessed by MRI in lumbar spine and femur) <del>in Cerdelga-treated patients</del> decreased by a mean of 1.1 points in Cerdelga treated patients (n=19) compared to no change in patients receiving placebo (n=20). Five Cerdelga-treated patients (26%) achieved <del>after 9 months (n=20) and 2.15 points after 18 months (n=18).</del> The percentage of Cerdelga-treated patients with a significant a reduction of at least 2 points in the total BMB score <del>increased from 26% (n=5) after 9</del></p>

<p><del>months to 44% (n=8) after 18 months.</del></p> <p>After 18 and 30 months of <b>Cerdelga</b> treatment, <b>BMB</b> score had decreased by a <del>the</del> mean 2.2 points (n=18) and 2.7 (n=15), respectively for the patients originally randomised to Cerdelga, compared to a mean decrease of 1 point (n=20) and 0.8 (n=16) in those originally randomised to placebo. <del>(SD) lumbar spine bone mineral density (BMD) T-score increased from -1.06 (0.82) (n=17), to -0.91 (0.88) (n=15).</del></p> <p>After 18 months of Cerdelga treatment in the open-label extension phase, the mean (SD) lumbar spine Bone Mineral Density T-score increased from -1.14 (1.0118) at Baseline (n=34) to -0.918 (1.1601) (n=33) in the normal range. After 30 months and 4.5 years of treatment, the T-score further increased to -0.722 (1.1250) (n=27) and -0.533 (0.8031) (n=9), respectively.</p>	<p>BMB score increased from 26% (n=5) after 9 months to 44% (n=8) after 18 months.</p> <p>After 18 months of Cerdelga treatment, the mean (SD) lumbar spine bone mineral density (BMD) T-score increased from -1.06 (0.82) (n=17), to -0.91 (0.88) (n=15).</p>	
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מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב ועדכוני נוסח בצבע אפור (עדכונים מעלון מ- SPC המאושר ע"י USA) טקסט שהוסר מסומן בקו מחיקה.

העלון, שבו מסומנים השינויים המבוקשים הועבר בדואר אלקטרוני בתאריך 28/6/2017.