רופא/ה רוקח/ת נכבד/ה,

חברת GSK Israel שמחה לבשר על התחלת שיווקה של תרופה חדשה לטיפול בנשאי HIV- **TIVICAY®** (Dolutegravir). **TIVICAY®** הינה תרופה המעכבת אינטגראז (Integrase Inhibitor) הניתנת פעם ביום*.

Indication [2]**:**

TIVICAY® is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents aged 12 years and older and weighing at least 40 kg.

החל מינואר 2014 נכללת **TIVICAY ®** ***בסל הבריאות*** לטיפול בנשאי HIV בהתקיים אחד התנאים הבאים[1]:

- נשא נגיף ה-HIV פיתח תסמונת הכשל החיסוני הנרכש.
- נשא נגיף ה-HIV טרם טופל למחלתו והוא אסימפטומטי עם ערך CD4 קטן מ-500 או ערך עומס נגיפי גדול מ- 100,000 עותקי RNA בסמ"ק.
- נשא נגיף ה-HIV שכשל בטיפול קודם.
- מתן התרופה ייעשה לפי מרשם של מנהל מרפאה לטיפול באיידס במוסד רפואי שהמנהל הכיר בו כמרכז AIDS.

Efficacy and tolerability [3-8]**:**

The efficacy and tolerability of **TIVICAY®** demonstrated in extensive clinical development program with 3041 patients across 5 phase III trials including:

✓ Treatment naïve patients (people living with HIV who were new to treatment): SINGLE[3], SPRING-2[4-5] and FLAMINGO[6] studies

✓ Treatment experienced patients (people who had already been treated with other HIV medicines): SAILING[7] study

✓ Heavily treatment experienced patients (people who were infected with a virus that had developed resistance to previously available integrase inhibitors): VIKING-3[8] study

In the above clinical trials TIVICAY® demonstrated [3-8] **:**

Rapid and sustained efficacy.

High barrier to resistance.

Well tolerated with few discontinuation.

Few drug-drug interactions (DDIs).

* TIVICAY should be administered twice daily when co-administered with certain medicines. For patients with resistance to the integrase class (documented or clinically suspected), the recommended dose of TIVICAY is one 50-mg tablet twice daily

Tivicay® (dolutegravir) 50 mg tablets

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Administration [2]:

TIVICAY® tablets are available in one dose of strength

- ✓ Naïve patients -50 mg (one tablet) once daily
- ✓ Treatment-experienced, and integrase inhibitor naïve- 50 mg (one tablet) once daily
- ✓ Integrase inhibitor resistant- 50 mg (one tablet) twice daily.

- ✓ Small tablet size
- ✓ No food or fluid restrictions**
- ✓ No time-of-day restrictions
- ✓ No boosting required

** In the presence of INI-class resistance, TIVICAY should preferably be taken with food to enhance exposure (particularly in patients with Q148 mutations)[2]

Tablet and packaging not actual size

נשמח לעמוד לרשותכם בכל שאלה בנושא זה,

בכבוד רב,

ד"ר איל עוז
יועץ רפואי

הילה ברוך
מנהלת מוצרים

Succinct safety information: **Contraindication**: Coadministration with dofetilide. Hypersensitivity to DTG (Dolutegravir) or to any of the excipients. **Warning and Precaution**: Integrase class resistance of particular concern: The decision to use DTG in the presence of integrase class resistance should take into account that the activity of DTG is considerably compromised for viral strains harbouring . Hypersensitivity reactions: Hypersensitivity reactions have been reported with DTG, and were characterized by rash, constitutional findings, and sometimes, organ dysfunction, including severe liver reactions. DTG and other suspect agents should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop. Immune Reactivation Syndrome: an inflammatory reaction to asymptomatic or residual opportunistic pathogens may arise and cause serious clinical conditions, or aggravation of symptoms. Any inflammatory symptoms should be evaluated and treatment instituted when necessary Drug interactions: Factors that decrease DTG exposure should be avoided in the presence of integrase class resistance. Patients should be monitored during therapy and a dose adjustment of metformin may be required Osteonecrosis: Although the aetiology is considered to be multifactorial cases of osteonecrosis have been reported in patients with advanced HIV-disease and/or long-term exposure to CART. **Adverse Reactions**: Very common: headache, nausea, diarrhoea. Common: insomnia, abnormal dreams, dizziness, vomiting, flatulence, upper abdominal pain, rash, pruritus, fatigue, Alanine aminotransferase (ALT) and/or Aspartate aminotransferase (AST) elevations, Creatine phosphokinase (CPK) elevations.

למידע מלא נא עיין בעלון לרופא שאושר ע"י משרד הבריאות. גלקסוסמיתקליין (ישראל) בע"מ, רחוב בזל 25, פתח-תקוה. לדיווח תופעות לוואי il.safety@gsk.com או בטלפון: 03-9297100. שירות מידע לרופא il.medinfo@gsk.com

1. 2/14 בינואר מספר 12, משרד הבריאות, חוזר המנהל הכללי,"ב בשבט,תשע"ד. 2. TIVICAY MOH approved Prescribing Information 3. Walmsley S et al. N Engl J Med 2013;369:1807-18. 4. Raffi F et al. Lancet 2013;381:735–43. 5. Raffi F et al. Lancet 2013. doi.org/10.1016/S1473-3099(13) 70257-3. 6. Feinberg J et al. Slides presented at ICAAC Sept 10-13, 2013 Abstract H-1464a. 7. Cahn P, et al. *Lance*t 2013;382(9893):700-708. 8. Nichols G et al. Journal of the International AIDS Society 2012, 15(Suppl 4):18112.