

6 בפברואר 2024

הנדון: נייר עמדה – השפעת מלחמת "חרבות ברזל" על מחקרים קליניים בינ"ל למטופלות מחלות הסרטן הגינקולוגי

מבוא ותקציר מנהלים

1. עמותת "הבית של בר – למען נשים עם סרטן גינקולוגי" (ע"ר) נוסדה מתוך חזון להיות בית לכל הנשים שמתמודדות והתמודדו עם סרטן רירית הרחם, סרטן השחלה, סרטן צוואר הרחם, סרטן העריו וסרטן הלדן ("מחלות הסרטן הגינקולוגי"). לפי נתוני רשם הסרטן הלאומי, כ- 1644 נשים מאובחנות בשנה עם מחלות הסרטן הגינקולוגי, ועוד אלפי נשים מאובחנות עם מחלות טרום סרטן גינקולוגי.¹
2. עם פרוץ מלחמת "חרבות ברזל", היינו ערות למגמה מדאגה של דחיית הטיפול ושגרת המעקב בקרב חולות סרטן, בעיקר מאובחנות חדשות. מגמה זו הובילה להקמת "חמ"ל נשים למען נשים" ב-22 באוקטובר 2023. מאז הקמתו, החמ"ל טיפל בכ-100 נשים אשר נזקקו להעברות לבתי חולים במרכז הארץ ובירושלים ואשר נזקקו להכוונה כללית, רפואית ומשפטית בהתאם למצבן.
3. מגמה נוספת שנצפתה הינה סגירת מחקרים קליניים אשר הציעו אופציות טיפוליות חדשניות למחלות אשר להן אין אופציות טיפוליות טובות אחרות. מפרוץ המלחמה, נסגרו 4 מחקרים קליניים בין-לאומיים, "מחשש לאספקת תרופות", והעמותה הובילה את קו השיח הישראלי בשיתוף פעולה עם החברה הישראלית לגינקולוגיה אונקולוגית למול חברות התרופות שסגרו את המחקרים ולמול איגודי המחקר הבינ"ל התומכים במחקר. לאחר פניות מטעמנו, פרסמו חלק מהאיגודים הודעות תמיכה בישראל ובחוסנה של מערכת הבריאות הישראלית.
4. להלן תובא בהרחבה סקירת פעילות החמ"ל ואירועים נוספים אשר השפיעו על מטופלות סרטן גינקולוגי.

סגירת מחקרים קליניים

5. מאז תחילת המלחמה התקבלו בחברה הישראלית לגינקולוגיה אונקולוגית הודעות מ-4 מחקרים קליניים שונים, המודיעות על הפסקת המחקר במדינת ישראל, "בשל החשש מאספקת תרופות". מיותר לציין כי החשש המדובר כלל לא קיים. השמיים נשארו פתוחים לאורך כל המלחמה ומטוסי תובלה המשיכו לטוס כרגיל. עוד, מספר חברות התרופות התאגדו להוציא מטוסי שילוח מיוחדים על מנת להבטיח את אספקת התרופות לישראל. הערכתנו היא שבכל חודש שפעילות מחקרית זו נעצרת, כ-15 נשים ישראליות נפגעות.
6. במסגרת מאמצי העמותה שיגרנו בחודש דצמבר 2023 מכתב חריף להנהלת חברות התרופות שעצרו את המחקר, וכן להנהלת האיגוד האירופי לגינקולוגיה אונקולוגית. במכתב הסברנו כי לא קיימת סיבה ממשית להפסקת המחקר וקשה להתעלם מעיתוי ההודעה, בוודאי כשמדינת ישראל הינה בין המדינות היחידות במזרח התיכון המציעה מערכת רפואית ציבורית איכותית ומתקדמת.
7. בעקבות המאמצים המשותפים, חלק מהפעילות המחקרית הייתה אמורה לחזור לישראל השבוע, ואף 2 איגודים אונקולוגיים גדולים פרסמו הודעות תמיכה בישראל (ראו נספחים), אך חברות התרופות ממאנות מלהמשיך את הפעילות בישראל. מכתב דומה נוסף נשלח בסוף השבוע האחרון, והעמותה מתכוונת להמשיך להפעיל לחץ על האיגודים על מנת שחיי נשים ישראליות לא יפגעו.

¹ מערכת נתוני רשם הסרטן הלאומי (שנת 2020).

8. יש לציין כי מחקרים שנעצרו הינם מחקרים קליניים מטעם חברות תרופות שאין להן נציגות ישראלית מקומית, ולכן התקשורת עימן מתבצעת למול ההנהלה העולמית בלבד, דבר אשר מקשה בצורה משמעותית על חזרת המחקרים ארצה.


סיכום והמלצות

9. "הבית של בר – למען נשים עם סרטן גינקולוגי" (ע"ר) עברה מפעילות שגרה לפעילות חירום כמעט מיידית. נקטנו באמצעים שונים להבטחת הרצף הטיפולי לעשרות נשים, תוך ניהול העברתן מהצפון ומהדרום לבתי חולים במרכז הארץ לבחירתן, והגשת מידע לכל דורשת.

10. עוד, פעלנו בזירה הבין-לאומית לשם הבטחת חוסנה המחקרי של ישראל, ואנו נמשיך לפעול על מנת להבטיח חזרה מלאה ותקינה של כלל הפעילות המחקרית, קטנה כגדולה.

11. אני רוצה להודות לכלל מתנדבות העמותה על העבודה המאומצת במתכונת חירום (24/7), לחברה הישראלית לגינקולוגיה אונקולוגית על התמיכה בנו והפעילות המשותפת הענפה, לבתי החולים אשר עובדים איתנו בשיתוף פעולה, וכן לחברות התומכות פיננסית בפעילות החמ"ל.

12. בתפילה לשלום החטופים והנעדרים ולחזרתם הביתה, לשלום חיילות וחיילי צה"ל, ושיבואו עלינו ימים טובים ושקטים במהרה.

בברכה,

בר לוי
מנכ"לית

נספחים:

1. מכתבו לחברת Alkermes (Mural Oncology) בדבר סגירת מחקר קליניים
2. מכתבינו לאיגוד האירופי לגינקולוגיה אונקולוגית
3. הודעות תמיכה של האיגוד העולמי לגינקולוגיה אונקולוגית והאיגוד האמריקני לאונקולוגיה קלינית



נספחים – מכתב לחברת Alkermes (Mural Oncology) בדבר סגירת מחקר קליני

HaBait Shel Bar
Israel Women's Cancer Association
In remembrance of Sarit Levy and Bracha Rosenberg z"l (RA)



December 4, 2023

Mr. Laurent Gauzargues

Clinical Trial Manager

Medpace, France

Email: L.Gauzargues@medpace.com

Ms. Elizabeth Keane

Clinical Program Management Director

Mural Oncology, USA

Email: clinicaltrials@muraloncology.com

Subject: Clinical Trials Withdrawals in Israel due to the War Situation

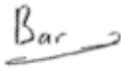
1. On October 7th our nation has suffered a brutal attack by Hamas, a terrorist organization, in which more than 1,400 people lost their lives thousands of people were injured and 250 people were kidnapped from their homes. Hundreds of thousands of Israelis have been evacuated from their homes and became refugees without being able to return to their homes for nearly two months. However, **none of these affected nor harmed the high standard of the Israeli medicine.**
2. Sadly, in these hard times of our nation, even though the entire healthcare system is working hard with great success to ensure the continuity of Israel's top notch healthcare system operations, it came to our attention that you announce ARTISTRY-7 will be withdrawn from Israel.
3. This announcement was made despite the fact that five sites have conducted the feasibility phase, and prepared for starting patients enrollment. **Several patients have already been screened for the study, and we understood that one patient even sent a biopsy.**
4. In your announcement letter, the reason for withdrawing the trial was stated as **"interruptions to medicine supply" and the company cannot proceed the opening of the trial in Israel.** However, we, the Israeli Ministry of Health and pharma companies in Israel can all confirm no such interruptions were recorded in the past 2 months and are not expected in the future.
5. Gaining access and participating in clinical trials is a key priority for the Israeli healthcare system. This announcement is distressing especially now days as the entire healthcare system has declared that ensuring continuity within the healthcare system remains top priority, including the continuity of existing and initiating new clinical trials. Nevertheless, Israeli patient associations teamed up with governmental health authorities and other significant Israeli healthcare organizations, to ensure treatment continuity for all patients in Israel.

HaBait Shel Bar
Israel Women's Cancer Association
In remembrance of Sarit Levy and Bracha Rosenberg z"l (RA)



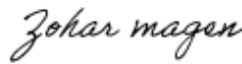
- 6. It is hard for us to accept this decision and it comes with great disappointment. Israel is one of the only countries in the Middle East that provides a public affordable healthcare system and grants opportunities to all residents (including Gaza strip and the west bank) to enroll to such studies.**
- 7. We urge you to reconsider your decision. The Israeli government has vouched for the continuity of clinical trials. No interruptions are anticipated. We are happy to offer support in any way that may be needed as we are committed to our patients together with our Israeli doctors and the entire healthcare system.**

Sincerely,



Bar Levy

Founder and CEO



Dr. Zohar Magen

Medical Strategy Director

Appendix:

1. Mural Oncology letter, November 27, 2023
2. ISGO letter, November 9, 2023
3. Ministry of Health letter, October, 2023



נספחים – מכתבינו לאיגוד האירופי לגינקולוגיה אונקולוגית

HaBait Shel Bar
Israel Women's Cancer Association
In remembrance of Sarit Levy and Bracha Rosenberg z"l (RA)



December 4, 2023

Prof. Nicoletta Colombo	Ms. Renata Brandtnerova
Chair	Executive Director
ENGOT	European Society for Gynecologic Oncology
Email: nicoletta.colombo@ieo.it	Email: renata.brandtnerova@esgomail.org

Subject: Clinical Trials Withdrawals in Israel due to the War Situation

1. On October 7th our nation has suffered a brutal attack by Hamas, a terrorist organization, in which more than 1,400 people lost their lives thousands of people were injured and 250 people were kidnapped from their homes. Hundreds of thousands of Israelis have been evacuated from their homes and became refugees without being able to return to their homes for nearly two months. However, none of these affected nor harmed the high standard of the Israeli medicine.
2. Sadly, in these hard times of our nation, even though the entire healthcare system is working hard with great success to ensure the continuity of Israel's top notch healthcare system operations, several companies announced they are about to withdraw Israel from the list of countries participating in their clinical trials:
 - a. **Artistry-7 / ENGOT-OV-68** – initiation phase, one patient has already enrolled and a biopsy was sent to Alkermes (Mural Oncology). The trial was withdrawn.
 - b. **STRO-002 / ENGOT -OV-79** – initiation phase, after several communication with the pharma company, and with help from Prof. Anna Oaknin, we understand that initiation phase will resume again.
 - c. **Kartos / ENGOT EN-21** – initiation phase was paused.
 - d. **Glorosia / ENGOT OV-76** - initiation phase was paused with no formal communication.
3. Gaining access and participating in clinical trials is a key priority of the Israeli healthcare system. These announcements are distressing especially now days as the entire healthcare system has declared that ensuring continuity within the healthcare system remains top priority, including the continuity of existing and initiating new clinical trials. Nevertheless, Israeli patient associations teamed up with governmental health authorities and other significant Israeli healthcare organizations, to ensure treatment continuity for all patients in Israel.

3 Shmuel Shnitzer st., Tel Aviv, Israel \ www.women-cancer.org \ +972-50-9585275

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HaBait Shel Bar
Israel Women's Cancer Association
In remembrance of Sarit Levy and Bracha Rosenberg z"l (RA)



HaBait Shel Bar
Israel Women's Cancer Association

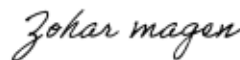
4. **These decisions come with great disappointment. Israel is one of the only countries in the Middle East that provides a public affordable healthcare system and grants opportunities to all residents (including Gaza strip and the west bank) to enroll to such studies.**
5. **We would like to kindly ask your support, of both ENGOT and ESGO, to reopen the trials that are currently being held or withdrawn and help us ensure the continuity of clinical trials in Israel and the initiation of new ones.**
6. **We are happy to offer support in any way that may be needed as we are committed to our patients together with our Israeli doctors and the entire healthcare system.**

Sincerely,



Bar Levy

Founder and CEO



Dr. Zohar Magen

Medical Strategy Director

Appendix:

1. Mural Oncology letter, November 27, 2023
2. ISGO letter, November 9, 2023
3. Ministry of Health letter, October, 2023



HaBait Shel Bar
Israel Women's Cancer Association
In remembrance of Sarit Levy and Bracha Rosenberg z"l (RA)



February 2, 2024

Prof. Nicoletta Colombo

Chair, ENGOT

Email: nicoletta.colombo@ieo.it

Prof. Nicole Concin

ESGO President

Email: nicole.concin@i-med.ac.at

Dear Prof. Concin and Prof. Colombo,

Re: Clinical Trials Withdrawals in Israel due to the ongoing War Situation

We would like to thank you for reading our previous letter and sharing your thoughts and concerns with us.

Unfortunately, the subject of our previous letter remains as it came to our attention that some of the ENGOT clinical trials did not resume in Israel.

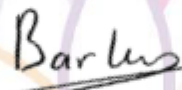
We can confirm that the Israeli healthcare system is functioning with great success ensuring the continuity of all planned and non-planned treatments and diagnostic procedures. Nevertheless, we can confirm there is no shortage of any needed resource for maintaining the same top notch health services that were provided prior to October 7th.

As patient advocacy group which is in touch with thousands of patients each year, we can reflect the patients' voice and ensure that no woman is left behind and is treated according to all ESGO guidelines and enjoys the top notch Israeli health services.

Participating in clinical trials is a key priority for the Israeli healthcare system. HaBait Shel Bar, on behalf of the Israeli patients, shares this key priority and we support our Israeli clinicians (ISGO).

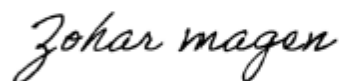
The ENGOT support together with ISGO and Israeli patients in the call for the continuance of existing clinical trials and initiating new ones in Israel will be highly appreciated.

Sincerely,



Bar Levy

Founder and CEO



Dr. Zohar Magen

Medical Strategy Director

הבית של בר -
העמותה לסרטן האישה
ע"ש שרית לוי וברכה רוזנברג ז"ל (ע"ר)



The International Global Cancer Society (IGCS) stands committed to its mission of advancing gynecologic cancer care and support, regardless of geographic or geopolitical challenges. The recent crisis in Israel and Gaza has brought significant disruptions to the lives of countless individuals, including our colleagues and patients in need of care. In these challenging times, we are reminded of the critical importance of our global community.

Our commitment to you, our members, is unwavering, and we are actively seeking avenues to provide assistance in the affected areas. Things such as collaborating with local healthcare providers to assist in making connections to practitioners in the region who might be able to help, facilitating access to necessary medical supplies, and supporting initiatives that ensure the continuation of cancer care services.

We also encourage our members to share any insights, challenges, or ideas they may have related to the current situation. Your experiences and recommendations are invaluable to us, and they will help us tailor our support to meet the specific needs of the cancer care community in Israel and Gaza during these trying times. If you have any information, suggestions, or requests related to how the IGCS can support you or our colleagues in Israel and Gaza during this crisis, please do not hesitate to contact us at igcs@igcs.org.

Those of you who are preparing for your journey to Seoul to attend the IGCS Annual Global Meeting, please know that the safety and well-being of our participants is, and always has been, our utmost concern. We are closely monitoring the situation in Israel, Gaza, and other parts of the world during uncertain times and are actively taking measures to ensure that your travels to Seoul and your stay during the conference are as safe and comfortable as possible.

The IGCS is in close contact with relevant authorities, local partners, and the appropriate agencies to assess the situation and implement any necessary precautions. We are committed to providing you with up-to-date information and guidance regarding your travel plans and the conference itself. Rest assured, our priority is to make your experience at IGCS 2023 secure and enjoyable.

It is our belief that even in trying times, the exchange of knowledge and the connections made at the IGCS Annual Global Meeting can play a vital role in advancing cancer care and research across the world. We value your participation and dedication to our shared mission, and we remain committed to making this year's conference a success.

We look forward to welcoming our members to Seoul and to collectively making a difference in the field of global cancer care.

Warm regards,



Keiichi Fujiwara, MD, PhD
IGCS President



Mary Eiken, MS
IGCS CEO



הבית ש"ל ב"ר -
העמותה לסרטן האישה
ע"ש שרית לוי וברכה רוזנברג ז"ל (ע"ר)



ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

Dear Bar,

Our thoughts are with you and those close to you enduring the unimaginable devastation of the intensifying crises in Israel and Gaza. While ASCO is not the institution from which a resolution will emerge, we remain steadfast in our commitment to help you preserve cancer care in your community.

As a global organization whose vision is a world where cancer is prevented or cured and every survivor is healthy, we abhor violence of any kind—particularly when it affects the most vulnerable populations, such as patients living with cancer, and health care workers like you who are trying to provide the best possible, lifesaving care. We remain deeply concerned about the interruption of cancer treatment for patients and the additional burdens and unnecessary suffering that places upon them and you as their health care providers. The events that led to the war are complex, but the suffering is real and enduring.

We are following the events closely to understand their impact on cancer care and to determine if and how ASCO may be of assistance to members in the region and the patients they serve. We encourage you to help us by sharing your perspective on what is happening with regard to oncology care and specific suggestions for how we may help. You can reach our member support team at: international@asco.org.

In solidarity with you and other members in the region, we plan to publicly issue the statement below:

"The terrorist attacks by Hamas on Israel and the violence in Gaza remind us that the cost of conflict and war is borne most heavily by innocent victims wishing to simply live their lives in peace. As a global professional oncology society, we turn to our community in times like these, as heroic colleagues and members continue to try to provide the best possible care for their patients. We embrace and encourage the larger health care community who provide aid and comfort under the most devastating circumstances. We strive to support them the best we can, which includes providing resources, when possible, to preserve cancer care."

We stand ready to support you, other members, and the larger oncology community in the affected region and around the globe, and we hope for a resolution that minimizes further loss of life and suffering for innocent victims.

Sincerely,

Clifford A. Hudis, MD, FACP, FASCO
Chief Executive Officer
Office of the CEO
American Society of Clinical Oncology
Association for Clinical Oncology