



## EXHIBIT - AN EXPERT OPINION REPORT

October 22<sup>nd</sup> 2016

Dear [REDACTED]

Thank you for reaching out to Tata Memorial Centre (TMC) and nationally acclaimed experts of the National Cancer Grid (NCG). Navya is pleased to offer this online expert consultation service for assessing your treatment options.

We converted your case reports into a structured summary to be reviewed by three surgical oncologists, one medical oncologist, and one radiation oncologist in the Breast Disease Management Group at Tata Memorial Centre, one radiation oncologist in the Gynecology Disease Management Group at Tata Memorial Centre, and one expert medical oncologist in the National Cancer Grid, a consortium of 85+ cancer centers with the mandate to standardize cancer care nationally.

We asked the following question(s) on your behalf:

1. Given the Early Endometrial Cancer (i.e. uterine cancer, i.e. presence of cancer cells/lesions in the uterus), is surgery with Total Abdominal Hysterectomy (TAH) (i.e. surgical removal of the uterus/womb and the cervix) and Bilateral Salpingo-Oophorectomy (BSO) (i.e. surgical removal of both the fallopian tubes and ovaries) recommended at this time?
2. Additionally, given the Ductal Carcinoma In Situ (DCIS) (i.e. presence of tumor(s)/lesion(s) within the milk ducts, with precancerous cells i.e. abnormal cells that are not currently cancer cells but could in the future become cancer cells) in the right breast, what is recommended:
  - A. Radiation therapy to the right breast, or
  - B. Modified Radical Mastectomy (MRM), which includes Mastectomy (i.e. complete removal of the right breast) with Axillary Lymph Node Dissection (i.e. axillary clearance)).
  - C. Sentinel Lymph Node Biopsy (i.e. a surgical procedure to assess the presence of cancer cells/lesion(s) in the lymph nodes in the axilla to which an injected dye first drains, indicating the first lymph node with the likely presence of cancer cells).
3. Given the Invasive Ductal Carcinoma (i.e. presence of cancer cells/tumor(s)/lesion(s)) in the left breast, and completion of prior treatment with MRM, what further treatment(s) is recommended at this time?
4. Are diagnostic tests such as Oncotype Dx (i.e. to assess probability of recurrence i.e. reappearance of cancer cells after therapy) or Ki67 (i.e. assess probability/pace of proliferation of cells/cancer cells) recommended?
5. Is adjuvant chemotherapy and/or hormone therapy recommended? If yes, what is the regimen?



The TMC NCG Navya opinion is summarized as follows:

1. Total Abdominal Hysterectomy (TAH) with Bilateral Salpingo-Oophorectomy (BSO) is recommended at this time.
2. Additionally, at the time of the above-mentioned surgery, Axillary Lymph Node Sampling (i.e. a surgical procedure to assess the presence of cancer cells/lesion(s) in the lymph nodes under the arm /axilla) in the right axilla, is also recommended.
3. Given the negative surgical margins (i.e. no cancer cells at the edge/border of the tissues removed) after lumpectomy (i.e. removal only of the tumor/lump) in the right breast, Modified Radical Mastectomy (MRM), and Sentinel Lymph Node Biopsy in the right axilla, are not indicated/not recommended.
4. Diagnostic tests to assess the value of Oncotype Dx and/or Ki67 are recommended at this time.
5. If the right axillary lymph node sampling suggests positive lymph nodes (i.e. presence of cancer cells/lesion(s) in the axillary lymph nodes), then after completion of surgery with TAH, BSO, and right axillary lymph node sampling, adjuvant chemotherapy is recommended. Prior to administering chemotherapy, assessment of the heart/cardiac function is recommended.
6. If the right axillary lymph node sampling suggests negative lymph nodes (i.e., no cancer cells/lesion(s) in the axillary lymph nodes), and the value of Oncotype Dx indicates a high risk of recurrence or the value of Ki67 is greater than 14 percent, then adjuvant chemotherapy is recommended. Prior to administering chemotherapy, assessment of the heart/cardiac function is recommended.
7. If the right axillary lymph node sampling suggests negative lymph nodes and the value of OncotypeDx and/or Ki67 is low, then adjuvant chemotherapy is not indicated/not recommended.
8. After completion of surgery, or after completion of surgery followed by adjuvant chemotherapy, adjuvant Loco Regional Radiation therapy (LRRT) with a hypofractionated schedule for the whole right breast at a dosage of 40 Gy in 15 fractions over three weeks and Tumor Bed Boost (TBB) at a dosage of 12.5 Gy in 5 fractions over one week, is recommended.
9. After completion of radiation therapy, hormone therapy with Letrozole 2.5 mg daily for five years is recommended.
10. No additional treatment is recommended for the left breast cancer, other than hormone therapy with Letrozole (as mentioned above).
11. Pathological review of the slide/ block of the surgical specimen(s) (i.e. sample of tumor(s)/lesions(s) surgically removed from an area/organ with cancer cells), of the prior and recommended/imminent surgeries, at Tata Memorial Centre is recommended.

We hope that the expert opinion is helpful in determining the course of your treatment.



Please discuss this opinion with your treating oncologist(s).

Navya is pleased to provide the following information on treatment recommendations per the National Comprehensive Cancer Network (NCCN), which lists the globally accepted guidelines for the treatment of cancers, and the Navya Experience Engine based on the collective experience of experts at Tata Memorial Centre.

1. If the right axillary lymph node sampling suggests negative lymph nodes, and the value of Oncotype Dx indicates a high risk of recurrence and/or the value of Ki67 is greater than 14 percent, then after completion of surgery with TAH, BSO, and right axillary lymph node sampling, adjuvant chemotherapy with either one of the options is recommended.
  - a. Chemotherapy with Epirubicin 90 mg/m<sup>2</sup> and Cyclophosphamide 600 mg/m<sup>2</sup> every three weeks (i.e. in a 21 day cycle) for six cycles.  
OR
  - b. Chemotherapy with Epirubicin 100 mg/m<sup>2</sup> and Cyclophosphamide 830 mg/m<sup>2</sup> every three weeks (i.e. in a 21 day cycle) for eight cycles.  
OR
  - c. Chemotherapy with Adriamycin 60 mg/m<sup>2</sup> and Cyclophosphamide 600 mg/m<sup>2</sup>, every three weeks (i.e. in a 21 day cycle) for four cycles.
2. If the right axillary lymph node sampling suggests positive lymph nodes, then adjuvant chemotherapy with Adriamycin 60mg/m<sup>2</sup> and Cyclophosphamide 600 mg/m<sup>2</sup>, every two weeks (i.e. in a 14 day cycle) for four cycles, followed by Paclitaxel 80 mg/m<sup>2</sup> every week for twelve cycles is recommended.

If you would like to send your slides/blocks for review at Tata Memorial Centre, the information to do so is at <https://tmc.gov.in/tmh>. If you have additional questions on the process of having your pathology sides/blocks reviewed, please call the hospital at +91 22 24177000.

Further, Navya is pleased to provide the following information and responses to your question(s). For your convenience, we have reproduced your question(s) in italics and within quotes.

*“What are the outcomes of the results can I live normal after fighting two cancers at same time.”*

Through this online consultation service, Tata Memorial Centre, National Cancer Grid, and Navya cannot provide direct responses on curability of a disease or life span of a patient.



However, following the recommendations in the expert opinion above, in consult with and under the care of your treating oncologist(s), provides a strong path forward in managing your clinical diagnosis at this time.

If you are interested in an in-person consultation with an oncologist at Tata Memorial Centre, please register online <https://tmc.gov.in/> or call +91 22 24177000 for assistance.

Please note that Tata Memorial Centre does not generally offer prescheduled appointments for in-person consultations. Patients are advised to visit the Out-Patient Department (OPD) of the relevant Disease Management Group, between 9am to 5pm, on a business day, to consult with the oncologists in the OPD.

Please do not hesitate to write to us or call us with any questions.

Sincerely,

Gitika Srivastava



**CASE SUMMARY Navya ID [REDACTED] Expert Opinion ID [REDACTED] Ms. [REDACTED]**

**Current Diagnosis:** Synchronous Bilateral Breast Cancer And Early Endometrial Cancer

**Age:** 64 Years Old

**Gender:** Female

**Menopausal Status:** Post-Menopausal

**Past Medical History:** Obesity

**Past Medical History:** High Cholesterol

**Past Medical History:** Hypothyroid

**Complaint(s):** Lump in the Lt breast for 10-12 days [September 2016]

**Breast Cancer Laterality:** Bilateral

**Ipsilateral Breast MRI:** 2.2\*2.1\*2.0 cm Lt breast UQ metabolically active nodule at 12'O clock with early washout kinetics. No regional lymphadenopathy [October 1st 2016]

**MRI BIRADS:** VI

**Contralateral Breast MRI:** Sub cm Rt breast UQ metabolically inactive nodule at 11'O clock with washout kinetics, LQ non mass like enhancement. No regional lymphadenopathy [October 1st 2016]

**MRI BIRADS:** V (UQ)

**MRI BIRADS:** III (LQ)

**FDG-PET CT:** 1.6\*1.5 cm Lt breast UQ nodule at 11-12'o clock (SUV-6); 0.8 cm Rt breast nodule at 11 O'clock (SUV-1.5); bulky uterus & increased metabolic activity in endometrial cavity (SUV-10.7) [October 1st 2016]

**Hysteroscopy:** Hyperplastic endometrium. Endometrial cavity with calcification and hypervascularity [October 3rd 2016]



**Prior Surgery #1:**

Timing	Surgery	Surgery Date
Primary	Mast- Left Modified Radical Mastectomy (MRM) + BCS- Right Breast Lumpectomy or Wide Excision (UQ)+ BCS- Right Breast Lumpectomy or Wide Excision (LQ) 7 O'clock + Endometrial Curettage	October 3rd 2016

**Laterality: Left**

**Diagnosis Made By:** Mast- Left Modified Radical Mastectomy (MRM)

**Pathological Tumor Size (cm):** 2.2\*2.0\*1.5

**Final Margins- Surgery1:** Negative (>10mm)

**Number of Positive Axillary Pathological Lymph Nodes Resected/Examined:** 0/18

**Malignant Breast Disease:** Invasive Ductal Carcinoma (IDC)

**Modified Richardson Bloom Score:** 9

**Cancer Grade:** III

**Ductal Carcinoma In Situ:** No

**Lymphovascular Invasion:** Negative

**Estrogen Receptors ER - Status:** Positive (90%) [October 24th 2016]

**Progesterone Receptors PR - Status:** Positive (10%) [October 24th 2016]

**HER 2 NEU Receptors - Status:** Negative [October 24th 2016]

**HER 2 NEU Receptors - IHC:** 0



**Pathological TNM Stage:** Stage IIA- T2 N0 M0 (Left Breast)

**Laterality:** Right (UQ)

**Diagnosis Made By:** BCS- Right Breast Lumpectomy or Wide Excision (UQ)

**Pathological Tumor Size (cm):** 1.2\*0.8\*0.6

**Final Margins- Surgery1:** Negative (>10mm)

**Malignant Breast Disease:** Invasive Ductal Carcinoma (IDC)

**Cancer Grade:** II

**Modified Richardson Bloom Score:** 7

**Ductal Carcinoma In Situ:** Yes

**Lymphovascular Invasion:** Negative

**Estrogen Receptors ER - Status:** Positive (90%) [October 24th 2016]

**Progesterone Receptors PR - Status:** Positive (70%) [October 24th 2016]

**HER 2 NEU Receptors - Status:** Negative [October 24th 2016]

**HER 2 NEU Receptors - IHC:** 0

**Pathological TNM Stage:** Stage IA- T1 Nx M0 (Right Breast)

**Laterality:** Right (LQ)

**Diagnosis Made By:** BCS- Right Breast Lumpectomy or Wide Excision (LQ)

**Malignant Disease:** Ductal Carcinoma In Situ (DCIS)

**Cancer Grade:** II

**Note:** Solid & Cribriform. Microcalcification noted in situ component. Surgical margins not mentioned.

**Diagnosis Made By:** Endometrial Curettage



**Malignant Disease:** Endometrioid Adenocarcinoma

**FIGO Grade:** II

**Bone Marrow (Hematologic) Function:** Adequate [October 2016]

**Kidney (Renal) Function:** Adequate [October 2016]

**Liver (Hepatic) Function:** Adequate [October 2016]

**Heart (Cardiac) Function:** Not Available

**Functional Status- ECOG Score:** 1

**General Condition:** Pt is able to care for self, able to clothe, bathe, walk across a room, and carry out all independent activities of daily living





Navya is a Cambridge, MA based company with offices in Bangalore, India. Navya is founded by graduates of Harvard University, MIT Sloan School of Management, and the Stanford School of Medicine. Navya's innovative and scalable decision making system is a technology powered solution for complex medical questions. Navya's software solutions are efficient engines to gather and synthesize individual goals of care, evidence specific to an individual medical case, and expert opinion, for evaluating treatment alternatives. Navya's goal is to assist in bringing clarity to the complexity of evaluating treatment alternatives. Navya's system collects the best available information and expertise from several worldwide sources relevant to a specific previously diagnosed medical case and assesses treatment decisions. For more information, please visit [www.navyanetwork.com](http://www.navyanetwork.com)

If you have any questions, please call +91 7022009550 or email [gitika@navyatech.in](mailto:gitika@navyatech.in)

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