forward-looking statements

This presentation contains certain forward-looking statements with respect to the business of Novocure and certain of its plans and objectives, including with respect to the development and commercialization of its lead product candidate, Optune, for a number of oncology indications. These forward-looking statements can be identified in this presentation by the fact that they do not relate only to historical or current facts. Forward-looking statements often use words “expect”, “intend”, “anticipate”, “plan”, “may”, “should”, “would”, “could” or other words of similar meaning. These statements are based on assumptions and assessments made by Novocure in light of industry experience and perception of historical trends, current conditions, expected future developments and other appropriate factors. By their nature, forward-looking statements involve risk and uncertainty, and Novocure’s performance and financial results could differ materially from those expressed or implied in these forward-looking statements due to general financial, economic, regulatory and political conditions as well as more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 22, 2018, or in subsequent quarterly filings with the U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this presentation. Novocure assumes no obligation to update or correct the information contained in this presentation, whether as a result of new information, future events or otherwise, except to the extent legally required.

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As of the date of this presentation, Optune is only FDA-approved for the treatment of adults with supratentorial glioblastoma, or GBM, and its approval for other indications is not certain. Novocure can provide no assurances regarding market acceptance of Optune or its successful commercialization, and can provide no assurances regarding the company’s results of operations or financial condition in the future. This presentation is for informational purposes only and may not be relied upon in connection with the purchase or sale of any security.
agenda and speakers

1. Opening remarks
   William Doyle, Executive Chairman, Novocure

2. Tumor Treating Fields, a platform therapy
   Eilon Kirson, MD, PhD, Chief Science Officer and Head of R&D, Novocure

3. STELLAR final results
   Giovanni L. Ceresoli, MD and Principal Investigator, Humanitas Gavazzeni Hospital

4. Mesothelioma in clinical practice
   Charles B. Simone II, MD, University of Maryland Medical System

5. The path forward
   Eilon Kirson, MD, PhD, Chief Science Officer and Head of R&D, Novocure

6. Question and answer session
Tumor Treating Fields, a platform therapy

Eilon Kirson, MD, PhD
we can leverage physics to fight cancer

AN ELECTRIC FIELD
EXERTS FORCES ON CHARGED OBJECTS

AN ELECTRIC FIELD
EXERTS FORCES ON CHARGED OBJECTS

TUMOR TREATING FIELDS USES ELECTRIC FIELDS
TO DISRUPT CELL DIVISION

MISALIGNED TUBULINS
INTERFERE WITH
FORMATION OF
MITOTIC SPINDLE

MISALIGNED SEPTINS
INTERFERE WITH
FORMATION OF
CONTRACTILE RING

ALTERNATING ELECTRIC FIELDS
DISRUPT CANCER
CELL DIVISION

CANCER CELL DEATH

TUMOR TREATING FIELDS DESCRIBES ELECTRIC FIELDS
THAT ALTERNATE 100,000 TO
300,000 TIMES PER SECOND
TO TARGET CANCER CELLS
**CANCERS OF THE CENTRAL NERVOUS SYSTEM**
- Glioblastoma
- Brain metastases from non-small cell lung cancer
- Brain metastases from breast cancer
- Brain metastases from melanoma
- Ependymoma
- Gliosarcoma
- Medulloblastoma
- Meningioma

**CANCERS OF THE CHEST**
- Mesothelioma
- Non-small cell lung cancer
- Small cell lung cancer

**CANCERS OF THE ABDOMEN**
- Pancreatic cancer
- Ovarian cancer
- Cervical cancer
- Colorectal carcinoma
- Gastric adenocarcinoma
- Liver cancer
- Renal cell adenocarcinoma
- Urinary transitional cell carcinoma

**OTHER**
- Breast cancer
- Malignant melanoma

---

**single therapy provides multiple opportunities in solid tumor cancers**

<table>
<thead>
<tr>
<th>Cancers</th>
<th>Pre-Clinical Evidence</th>
<th>First in Human Evidence</th>
<th>Clinical Evidence</th>
<th>FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cancers of the Central Nervous System</strong></td>
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<tr>
<td>Glioblastoma</td>
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<td>Brain metastases from non-small cell lung</td>
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<tr>
<td>Brain metastases from breast cancer</td>
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<td>Brain metastases from melanoma</td>
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<td>Ependymoma</td>
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<td>Gliosarcoma</td>
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<td>Medulloblastoma</td>
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<td>Meningioma</td>
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<td><strong>Cancers of the Chest</strong></td>
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<td>Mesothelioma</td>
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<td>Non-small cell lung cancer</td>
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<td>Small cell lung cancer</td>
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<td><strong>Cancers of the Abdomen</strong></td>
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<td>Pancreatic cancer</td>
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<td>Ovarian cancer</td>
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<td>Cervical cancer</td>
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<td>Colorectal carcinoma</td>
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<td>Gastric adenocarcinoma</td>
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<td>Liver cancer</td>
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<tr>
<td>Renal cell adenocarcinoma</td>
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<tr>
<td>Urinary transitional cell carcinoma</td>
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<tr>
<td><strong>Other</strong></td>
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<tr>
<td>Breast cancer</td>
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<tr>
<td>Malignant melanoma</td>
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</tbody>
</table>
Tumor Treating Fields induced severe spindle damage in cancer cell lines

A549 cells in lung tissue were treated with Tumor Treating Fields for 24 hours.

Tubulin fluorescence images were inverted and pseudocolored so that increasing fluorescence intensity is indicated from blue to red (scale bar represent arbitrary units). Dashed lines define the region between the two spindle poles (white) and overall tubulin fluorescence within the cell (Red).

Tumor Treating Fields resulted in abnormal chromosomal segregation

A2780 cells were treated with TTFields for 96 hours. Chromosome number was evaluated every 24 hours. Horizontal bars indicate median values (p<0.0001; Brown-Forsythe test).

Spectral karyotyping of A2780 cells showing numerical aberrations following TTFields treatment.

Tumor Treating Fields interfered with DNA damage response

TTF+IR triggers multinucleation and mitotic abnormalities in glioblastoma cells. Cells were exposed to 24 h of TTF, 5 Gy of $\gamma$-rays or 5 Gy of $\gamma$-rays followed by 24 h of TTF, indicated as the TTF, IR and TTF+IR treatments, respectively.

Immunofluorescence microscopy image of cells stained for $\alpha$-tubulin (green) and DAPI. The histograms summarize the results of three independent experiments (with at least 100 cells counted in each experiment in each column). The values represent the means of three experiments ± SD; *$p < 0.05$, **$p < 0.001$. Cells were scored for the presence (abnormal) or absence (normal) of chromosome alignment and se.

Tumor Treating Fields inhibited metastases and activated an immune response.

Exemplary photos of surface lung metastases in Tumor Treating Fields treated versus sham control rabbits.

Treatment was initiated on day 12 from implantation of the kidney tumor. The average total number (±SD) of surface metastases in control versus treated rabbits.

Discrete intra-tumoral infiltration of CD45 positive T cells in control tumors and abundant intra tumoral CD45 positive T cells in Tumor Treating Fields treated tumors. Scale bar 100 lm

Tumor Treating Fields offered additive or synergistic benefits in combination with chemotherapy

A2780  OVCAR3  Caov-3

Combination of Tumor Treating Fields and paclitaxel chemotherapy

Ovarian Cancer Cells were treated for 72 hr with paclitaxel alone (1–100 nM) and in combination with TTFields (2.7 V/cm pk-pk, 200 kHz). Dose–response plots of A2780, OVCAR-3 and Caov-3 cells. CI: combination index.

Tumor Treating Fields has repeatedly increased survival without systemic toxicity

- Tumor Treating Fields exhibited increased survival across a range of solid tumors
  - FDA approval in newly diagnosed GBM with unprecedented 5-year survival
  - Registration trial data in mesothelioma
  - Phase 2 pilot trial data in non-small cell lung cancer, pancreatic cancer and ovarian cancer
- No significant increase in serious adverse events has been seen with the addition of Tumor Treating Fields to standard treatments across clinical trials
- In newly diagnosed GBM, patients treated with Optune and temozolomide maintained quality of life for up to one year and across predefined daily functioning domains
increasing visibility of Tumor Treating Fields in the clinical and research communities

**Publications on Tumor Treating Fields**

- 2016: 16 Primary Papers, 5 Reviews
- 2017: 20 Primary Papers, 14 Reviews
- 2018 YTD: 21 Primary Papers, 6 Reviews

**Abstracts at four key congresses**

- AACR: 3 Primary Papers, 24 Reviews, 35 Abstracts
- ASTRO: 4 Primary Papers, 13 Reviews, 4 Abstracts
- EANO: 10 Primary Papers, 53 Reviews, 10 Abstracts
- SNO: 60 Primary Papers, 38 Reviews, 65 Abstracts
## Advancing Clinical Pipeline

<table>
<thead>
<tr>
<th>Disease Type</th>
<th>Phase II Pilot</th>
<th>Phase III Pivotal</th>
<th>In Registration</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesothelioma</td>
<td></td>
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<td>HDE application to the FDA in 2H 2018</td>
</tr>
<tr>
<td>Brain metastases</td>
<td></td>
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<td>METIS trial last patient in 2019 with final data collection in 2020</td>
</tr>
<tr>
<td>Non-small cell lung cancer</td>
<td></td>
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<td></td>
<td>LUNAR trial last patient in 2019 with final data collection in 2021</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
<td></td>
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<td>PANOVA 3 trial last patient in 2020 with final data collection in 2022</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td></td>
<td></td>
<td></td>
<td>phase three pivotal trial open in 2H 2018</td>
</tr>
<tr>
<td>Liver cancer</td>
<td></td>
<td></td>
<td></td>
<td>HEPANOVA trial first patient in 2H 2018</td>
</tr>
</tbody>
</table>

**Legend:**
- Trial ongoing
- Trial complete
STELLAR final results

Giovanni L. Ceresoli, MD
Malignant pleural mesothelioma overview

- Malignant pleural mesothelioma arises from the mesothelial lining covering the external surface of lungs and inside of chest wall.
- Vast majority of cases attributed to asbestos exposure.
  - Asbestos used commonly in 1940s-1970s for insulation, textiles, heat protectors, filters, construction materials.
  - Long latency period of at least 20-30 years following exposure.
- Mesotheliomas belong to three main histological subtypes: epithelioid (60-80%), sarcomatoid (10%) or mixed (10-20%).

malignant pleural mesothelioma epidemiology

<table>
<thead>
<tr>
<th>Location</th>
<th>Incidence</th>
<th>Eligible Patient Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>3,000</td>
<td>2,400</td>
</tr>
<tr>
<td>Germany</td>
<td>1,400</td>
<td>1,100</td>
</tr>
<tr>
<td>Japan</td>
<td>1,000</td>
<td>800</td>
</tr>
</tbody>
</table>

current standard of care

- Only 15-20% of mesothelioma patients are candidates for surgical resection
- Most patients treated in the first-line setting with chemotherapy
  - Since 2003, pemetrexed plus platinum-based therapy (cisplatin or carboplatin) has been the standard of care for patients with malignant pleural mesothelioma
  - Pemetrexed plus cisplatin (median OS 12.1 months)\(^2\); pemetrexed/carboplatin show similar outcomes\(^3,4\)
- No standard treatment in the second-line setting
- Radiation therapy can play a role throughout treatment pathway
- New treatments are urgently needed

1. Bueno R et al., J Thorac Oncol 2018
5. Kindler et al., J Clin Oncol 2018
STELLAR - Final Results of a Phase 2 Trial of TTFields with Chemotherapy for First-Line Treatment of Malignant Pleural Mesothelioma

Giovanni L. Ceresoli1, Joachim Aerts2, Jaroslaw Madrzak3, Rafal Dzidziuszko3, Rodryg Ramlau4, Susana Cedars5, Birgitta Hiddinga6, Jan P. Van Meerbeeck6, Manlio Mencoboni7, David Planchard8, Antonio Chella9, Lucio Crinò10, Maciej Krzakowski11, Federica Grosso12

1Cliniche Humanitas Gavazzeni, Bergamo; 2Erasmus MC, Rotterdam; 3Medical University of Gdansk, Gdansk; 4Poznan University of Medical Science, Poznan; 5Vall d’Hebron University Hospital, Barcelona; 6University Hospital Antwerp, Edegem; 7Villa Scassi Hospital, Genova; 8Gustave Roussy, Villejuif; 9Ospedale di Pisa, Pisa; 10Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori – IRCCS, Meldola; 11Maria Sklodowska Curie Memorial Cancer Centre, Warsaw; 12SS Antonio e Biagio Hospital, Alessandria
STELLAR study design & patient characteristics

Unresectable malignant pleural mesothelioma N=80

The sample size provides 80% power (α, 0.05) to detect an increase in median OS of 5.5 months vs historical data1 (i.e. mOS of 17.6 mo, HR of 0.67)

Key Inclusion Criteria:
- Pathological evidence of unresectable MPM
- At least one measurable lesion (mRECIST)
- ECOG PS score 0-1

Key Exclusion Criteria:
- Candidate for curative treatment
- Significant comorbidities
- Implanted electronic medical devices

Primary Endpoint: OS
Secondary Endpoints: ORR, PFS, Safety

Median age, years (range) 67 (27–78)
Male 67 (84%)
ECOG PS 0 45 (56%)

Epithelioid histology 53 (66%)
Sarcomatoid/Biphasic 21 (26%)
Unspecified histology 6 (8%)

TTFields (150kHz, ≥ 18 h/day) + Pemetrexed/Cisplatin or Pemetrexed/Carboplatin x 6

- Pemetrexed IV, 500 mg/m² day 1
- Cisplatin 75 mg/m² day 1
- Carboplatin AUC 5 day 1 q3w up to 6 cycles

TTFields alone until Disease Progression

Follow-up for survival

- Follow-up q3w
- CT scan q6w: Modified RECIST

TTFields cycles: Median (range): 8.0 (2–41)
Chemotherapy cycles: Median (range): 6.0 (1–7)
Carboplatin: 50 patients (63%)

STELLAR efficacy results: primary endpoint met

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median OS (all pts)</td>
<td>18.2 months (95% CI 12.1-25.8)</td>
</tr>
<tr>
<td>1-year OS (all pts)</td>
<td>62.2% (95% CI 50.3%-72.0%)</td>
</tr>
<tr>
<td>Median OS (epithelioid pts only)</td>
<td>21.2 months (95% CI 13.2-25.8)</td>
</tr>
<tr>
<td>Median PFS</td>
<td>7.6 months (95% CI 6.7-8.6)</td>
</tr>
<tr>
<td>mRECIST PR; DCR*</td>
<td>29 (40%); 70 (97%)</td>
</tr>
</tbody>
</table>

* Investigator-assessed partial response & disease control rate (PR + stable disease)

The threshold for significant extension in OS compared to historical control\(^1\) was met (HR 0.663; 95% CI 0.558-0.826; p=0.043).

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STEELLAR safety results

<table>
<thead>
<tr>
<th>Adverse event reported in &gt;1 patient</th>
<th>Grade ≥3 AE</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with ≥1 AE, n(%)</td>
<td>21 (26)</td>
<td></td>
</tr>
<tr>
<td>Hematologic Disorders</td>
<td></td>
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<tr>
<td>Anemia</td>
<td>6 (8)</td>
<td></td>
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<tr>
<td>Leukopenia</td>
<td>3 (4)</td>
<td></td>
</tr>
<tr>
<td>Neutropenia</td>
<td>6 (8)</td>
<td></td>
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<tr>
<td>Thrombocytopenia</td>
<td>2 (3)</td>
<td></td>
</tr>
<tr>
<td>Non-hematologic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>3 (4)</td>
<td></td>
</tr>
<tr>
<td>Skin-related toxicity</td>
<td>4 (5)</td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>2 (3)</td>
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</tr>
</tbody>
</table>

- Thirty-seven patients (46%) had TTFields-related skin toxicity
- Four patients (5%) had Grade 3 skin toxicity (rash or skin irritation)
  - Resolved after treatment with topical corticosteroids or a short treatment break
- No serious adverse event was related to TTFields

Median compliance with TTFields was 68% (16.3 hours/day)

Cerasoli, G.L. International Association for the Study of Lung Cancer. MA 12.06 – STEELLAR Final Results of a Phase 2 Trial of TTFields with Chemotherapy for First-Line Treatment of Malignant Pleural Mesothelioma. Mini Oral Abstract Session: Mesothelioma Surgery and Novel Targets for Prognosis and Therapy. Tuesday, Sept. 25, 2018, 10:30 a.m. ET.
## Comparison of STELLAR and recent studies

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>STELLAR pem+platinum</th>
<th>Vogelzang et al. pem+cis</th>
<th>MAPS pem+cis</th>
<th>LUME-Meso pem+cis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of patients</strong></td>
<td>80</td>
<td>226</td>
<td>225</td>
<td>229</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>84%</td>
<td>81%</td>
<td>76%</td>
<td>74%</td>
</tr>
<tr>
<td><strong>Median age</strong></td>
<td>67 (27-78)</td>
<td>61 (29-85)</td>
<td>66 (61-70)</td>
<td>66</td>
</tr>
<tr>
<td><strong>Epithelioid histology</strong></td>
<td>66%</td>
<td>68%</td>
<td>81%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Sarcomatoid/mixed histology</strong></td>
<td>26%</td>
<td>24%</td>
<td>19%</td>
<td>-</td>
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<tr>
<td><strong>Outcomes</strong></td>
<td></td>
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</tr>
<tr>
<td>mOS (months, 95% CI)</td>
<td>18.2</td>
<td>12.1</td>
<td>16.1</td>
<td>16.1</td>
</tr>
<tr>
<td>mOS epithelioid (months, 95% CI)</td>
<td>21.2 (13.2-25.8)</td>
<td>7.6</td>
<td>7.3</td>
<td>16.1</td>
</tr>
<tr>
<td>mPFS</td>
<td>8.3 (7.1-9.7)</td>
<td>5.7</td>
<td>7.0</td>
<td>7.0</td>
</tr>
</tbody>
</table>

Cerasoli, G.L. International Association for the Study of Lung Cancer. MA 12.06 – STELLAR Final Results of a Phase 2 Trial of TTFields with Chemotherapy for First-Line Treatment of Malignant Pleural Mesothelioma. Mini Oral Abstract Session: Mesothelioma Surgery and Novel Targets for Prognosis and Therapy. Tuesday, Sept. 25, 2018, 10:30 p.m. ET.
TTFields in combination with pemetrexed and a platinum agent showed improved outcomes compared to historical controls for the treatment of unresectable malignant pleural mesothelioma

- Median OS (18.2 months) was significantly longer than historical control (12.1 months)
- Despite the lower rate of patients with epithelioid histology, OS was better than the pemetrexed/platinum arm in recent trials (MAPS, LUME-Meso)
- There was no increase in systemic toxicity with TTFields
- Only TTFields-related adverse event was skin irritation beneath the transducer arrays
mesothelioma in clinical practice

Charles B. Simone, II, MD
malignant pleural mesothelioma presentation

- Male predominance (male:female = 5:1)
- Median age of 65-72 years
- Typical presentation includes locally advanced clinical stage and other medical comorbidities
  - 90% with dyspnea, non-pleuritic chest wall pain, or both
  - 10-20% present with spontaneous pneumothorax
  - Advanced disease: clotting abnormalities, respiratory failure, pneumonia, small bowel obstruction, myocardial involvement (cause of death in ~10%)
- Exam: dullness at the lung base
- Workup: CRX and CT chest imaging
favorable prognostic factors$^{1,2}$

- Epithelial histology
- Young age (<55 years, <75 years)
- Good performance status
- Early-stage disease (stage I)
- Female gender
- Lack of weight loss
- Normal platelet count
- Normal hemoglobin
- Lack of chest pain at diagnosis
- Pleural fluid pH >7.3
- High pleural/serum glucose ratio

• Median survival untreated: 4-8 months
• Trimodality treatment can improve survival to 20-38 months in well selected, early-stage patients
• Median survival for stage III-IV patients treated with multiagent chemotherapy: 12 months
roles of surgery

- **Diagnostic**
  - Percutaneous needle biopsy (40-69%)
  - Needle biopsy combined with cytology (80-90%)
  - Thoracosopic pleural biopsy (80-100%)
- **Palliative**
  - Talc pleurodesis
  - Pleurectomy/decortication
- **Radical**
  - Goal is complete gross cytoreduction of tumor
  - Extended pleurectomy or extrapleural pneumonectomy
  - Conduit for multimodality therapy

![Survival by stage in surgery patients](image)

chemotherapy regimens

- **First-line combination chemotherapy:**
  - Q3 week pemetrexed 500 mg/m2 D1 + cisplatin 75 mg/m2 D1
  - Pemetrexed + cisplatin + bevacizumab

- **Alternative first-line chemotherapy:**
  - Pemetrexed + carboplatin
  - Gemcitabine + cisplatin
  - Pemetrexed alone
  - Vinorelbine

- **Second-line chemotherapy:**
  - Pemetrexed alone (if not given first-line)
  - Gemcitabine (+/- cisplatin)
  - Vinorelbine
  - Under investigation: doxorubicin +/- onconase, vorinostat, bortezomib, antineoplaston, erlotinib + bevacizumab, imatinib, carboplatin + vinorelbin, AZD2171 and PXD2171 (VEGF)
reasons to administer radiation therapy

• Following surgery:
  • After extrapleural pneumonectomy, radiation therapy traditionally administered in all patients with good performance status to treat microscopic residual disease
  • Beginning to be used after radical pleurectomy, ideally on protocol due to increased concern of pulmonary toxicity
  • After extrapleural pneumonectomy or radical pleurectomy: R2 resection, pN2 nodal metastasis
• For prevention of instrument tract recurrence
• As definitive therapy, may provide durable local control for non-surgical candidates or in cases of progression on chemotherapy
• For palliation to decrease pain, stop bleeding and decrease coughing/wheezing
emerging therapeutic approaches

- Systemic therapy:
  - Chemotherapy combined with targeted or immune agents
  - Maintenance chemotherapy or low dose chemotherapy
  - Exploit the immunological effects of gemcitabine
  - Gene therapy
  - PD-1/PD-L1 inhibitors and other immunotherapies
- Intrapleural photodynamic therapy
- Radiation therapy with radio-immunomodulation, with radiosensitizing chemotherapy
- Intensity-modulated radiation therapy (IMRT)
- Intensity-modulated proton therapy (IMPT)
conclusions

- Chemotherapy is the only standard modality, with pemetrexed and cisplatin combination being first line
- Long term survival is uncommon, typically only seen in patients undergoing surgery
- Surgical technique is evolving with a trend towards more lung-sparing procedures
- Radiation therapy has an important role in local control, but the technique and its use are evolving as the surgical standard evolves; Innovative techniques like IMRT and IMPT on an intact lung will become more widely utilized
- Second-line treatment and combining immunotherapeutic agents with chemotherapy, RT, and surgery are promising avenues currently being explored
the path forward

Eilon Kirson, MD, PhD
humanitarian use device (HUD) designation allows for FDA approval via HDE pathway

<table>
<thead>
<tr>
<th></th>
<th>HDE application</th>
<th>PMA application</th>
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</thead>
<tbody>
<tr>
<td><strong>Indication for use</strong></td>
<td>Based on HUD designation</td>
<td>Proposed by applicant</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>Will not expose patients to an unreasonable or significant risk of illness or injury</td>
<td>Reasonable assurance of safety</td>
</tr>
<tr>
<td><strong>Effectiveness</strong></td>
<td>Demonstration of probable benefit; exempt from demonstrating effectiveness</td>
<td>Reasonable assurance of effectiveness</td>
</tr>
<tr>
<td><strong>FDA review days</strong></td>
<td>75 days to determine a decision</td>
<td>180 days – if no panel 320 days – if panel</td>
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current status of HDE application and anticipated preparation for commercial launch

Today
- Pre-submission meeting held with FDA in Q3 2018
- HDE application package in final stages of preparation

Q4 2018
- Anticipate Q4 2018 filing
- 75 day review clock to FDA decision letter

2019
- Organization ready at FDA approval:
  - Promotion initially targeted to centers of excellence, largely leveraging existing sales force
  - Initiate process towards payer coverage and contracting
  - Engagement with advocacy groups
- US regulatory submission for second generation torso system
- EU regulatory package prepared

2020 and beyond
- Full commercial launch with:
  - Approval of second generation torso system
  - Established commercial reimbursement
question and answer session