**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: October 11, 2021

**ClinicalTrials.gov ID: NCT02387216**

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | MM-121-01-02-09 |
| Brief Title: | A Study of MM-121 in Combination With Chemotherapy Versus Chemotherapy Alone in Heregulin Positive NSCLC ( SHERLOC ) |
| Official Title: | SHERLOC: A Phase 2 Study of MM-121 in Combination With Docetaxel Versus Docetaxel Alone in Patients With Heregulin Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer (Merrimack Pharmaceuticals Inc.) |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | October 2021 |
| Overall Status: | Terminated [Based on the preliminary results seen during interim analysis, which were confirmed in the final analysis, the Sponsor terminated the study] |
| Study Start: | February 1, 2015 [Actual] |
| Primary Completion: | January 2, 2019 [Actual] |
| Study Completion: | January 2, 2019 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Elevation Oncology |
| Responsible Party: | Sponsor |
| Collaborators: | Merrimack Pharmaceuticals |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | |

| | |
|---|---|
| U.S. FDA-regulated Device: | |
| Unapproved/Uncleared Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: 30044<br>Board Name: Quorum Review Inc.<br>Board Affiliation: Quorum Review Inc.<br>Phone: 206-448-4082<br>Email:<br>Address: |
| Data Monitoring: | Yes |
| FDA Regulated Intervention: | Yes |
| Section 801 Clinical Trial: | Yes |

## Study Description

| | |
|---|---|
| Brief Summary: | The purpose of this study is to determine whether the combination of MM-121 plus docetaxel is more effective than docetaxel alone in regards to PFS in patients with heregulin-positive NSCLC. |
| Detailed Description: | This study is a randomized, open-label, international, multi-center, phase 2 study in patients with Heregulin-positive NSCLC histologically classified as adenocarcinoma that have progressed following no more than two systemic therapies for locally advanced or metastatic disease, one of which must have been a platinum containing regimen. All patients will initially be screened for heregulin status. Eligible patients will be randomized to receive MM-121 in combination with docetaxel versus docetaxel alone. |

## Conditions

| | |
|---|---|
| Conditions: | Non-Small Cell Lung Cancer<br>NSCLC<br>Adenocarcinoma<br>Heregulin |
| Keywords: | NSCLC<br>Non-Small Cell Lung Cancer<br>heregulin<br>ErbB3<br>docetaxel |

## Study Design

| | |
|---|---|
| Study Type: | Interventional |
| Primary Purpose: | Treatment |
| Study Phase: | Phase 2 |
| Interventional Study Model: | Single Group Assignment<br>Randomized, open-label, international, multi-center, Phase 2 study in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) |
| Number of Arms: | 2 |
| Masking: | None (Open Label) |
| Allocation: | Randomized |
| Enrollment: | 153 [Actual] |

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Arm A: Experimental Arm<br>MM-121 in combination with Docetaxel | Drug: MM-121<br>Investigational, fully human antibody targeting and inhibiting ErbB3<br>Other Names:<br>• seribantumab<br>Drug: Docetaxel<br>approved chemotherapy treatment for NSCLC<br>Other Names:<br>• Taxotere |
| Active Comparator: Arm B: Comparator Arm<br>Docetaxel alone | Drug: Docetaxel<br>approved chemotherapy treatment for NSCLC<br>Other Names:<br>• Taxotere |

## Outcome Measures

[See Results Section.]

## Eligibility

| | |
|---|---|
| Minimum Age: | 18 Years |

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with a diagnosis of cytologically or histologically documented adenocarcinoma of the lung with either metastatic disease (stage IV), Stage IIIB or Stage IIIC disease not amenable to surgery with curative intent
- Not received more than 2 prior systemic therapies- one of which must have been a platinum based regimen- for primary or recurrent disease
- Tissue submitted for HRG-biomarker testing
- ECOG performance status (PS) of 0 or 1

Exclusion Criteria:

- Known ALK mutation
- Presence of exon 19 deletion or exon 21 (L858R) substitution of the EGFR gene
- Received >2 prior systemic anti-cancer drug regimen for locally advanced disease
- Prior treatment with an anti-ErbB3 antibody
- CTCAE grade 3 or higher peripheral neuropathy
- Symptomatic CNS metastases or CNS metastases requiring steroids
- Any other active malignancy requiring systemic therapy
- Clinically significant cardiac disease

## Contacts/Locations

Central Contact Person:

Central Contact Backup:

Study Officials: MM-121 Program Medical Director, MD
Study Director
Merrimack Pharmaceuticals

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## IPDSharing

Plan to Share IPD:

## References

Citations:

Links:

Available IPD/Information:

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# Documents

Study Protocol
Document Date: March 2, 2017
Uploaded: 09/21/2020 14:29

# Study Results

## Participant Flow

| | |
|---|---|
| Recruitment Details | 87 multi-national sites |
| Pre-assignment Details | One patient was inappropriately enrolled into the sherloc study hence why 152 and not 153 |

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Overall Study

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Started [1] | 103 | 49 |
| Completed [2] | 3 | 2 |
| Not Completed | 100 | 47 |
| Progressive disease | 2 | 0 |
| Withdrawal by Subject | 3 | 5 |
| Physician Decision | 2 | 0 |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Sponsor Decision | 28 | 12 |
| Death | 60 | 23 |
| unspecified | 5 | 4 |
| Lost to Follow-up | 0 | 3 |

[1] One patient was inappropriately enrolled into the Sherloc study hence why 152 participants started and not 153

[2] Safety population: includes patients receiving at least one dose of study medication

## Baseline Characteristics

Baseline Analysis Population Description

Patients that have signed informed consent, identified as HRG positive based on centralized tissue analysis,& have successfully completed study entry criteria (Safety Population- patients receiving at least one dose of study medication. All safety analyses were performed on either the Modified Intent-to-Treat (mITT) Population or this population).

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br><br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br><br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Baseline Measures

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone | Total |
|---|---|---|---|
| Overall Number of Participants | 103 | 49 | 152 |

| | | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone | Total |
|---|---|---|---|---|
| **Age, Categorical**<br>Measure Type: Count of Participants<br>Unit of measure: participants | Number Analyzed | 103 participants | 49 participants | 152 participants |
| | <=18 years | 0 0% | 0 0% | 0 0% |
| | Between 18 and 65 years | 58 56.31% | 31 63.27% | 89 58.55% |
| | >=65 years | 45 43.69% | 18 36.73% | 63 41.45% |
| **Age, Continuous**<br>Mean (Standard Deviation)<br>Unit of measure: years | Number Analyzed | 103 participants | 49 participants | 152 participants |
| | | 62.6 (10.07) | 62.8 (7.28) | 62.8 (8.68) |
| **Sex: Female, Male**<br>Measure Type: Count of Participants<br>Unit of measure: participants | Number Analyzed | 103 participants | 49 participants | 152 participants |
| | Female | 32 31.07% | 19 38.78% | 51 33.55% |
| | Male | 71 68.93% | 30 61.22% | 101 66.45% |
| **Ethnicity (NIH/OMB)**<br>Measure Type: Count of Participants<br>Unit of measure: participants | Number Analyzed | 103 participants | 49 participants | 152 participants |
| | Hispanic or Latino | 6 5.83% | 4 8.16% | 10 6.58% |
| | Not Hispanic or Latino | 90 87.38% | 41 83.67% | 131 86.18% |
| | Unknown or Not Reported | 7 6.8% | 4 8.16% | 11 7.24% |
| **Race (NIH/OMB)**<br>Measure Type: Count of Participants<br>Unit of measure: participants | Number Analyzed | 103 participants | 49 participants | 152 participants |
| | American Indian or Alaska Native | 0 0% | 0 0% | 0 0% |

| | | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone | Total |
|---|---|---|---|---|
| | Asian | 10 9.71% | 2 4.08% | 12 7.89% |
| | Native Hawaiian or Other Pacific Islander | 0 0% | 0 0% | 0 0% |
| | Black or African American | 2 1.94% | 2 4.08% | 4 2.63% |
| | White | 83 80.58% | 38 77.55% | 121 79.61% |
| | More than one race | 0 0% | 0 0% | 0 0% |
| | Unknown or Not Reported | 8 7.77% | 7 14.29% | 15 9.87% |
| **Region of Enrollment** Measure Type: Number Unit of measure: participants | Number Analyzed | 103 participants | 49 participants | 152 participants |
| Australia | | 9 | 3 | 12 |
| Canada | | 2 | 6 | 8 |
| France | | 11 | 6 | 17 |
| Germany | | 7 | 4 | 11 |
| Hungary | | 1 | 1 | 2 |
| Poland | | 2 | 2 | 4 |
| South Korea | | 0 | 1 | 1 |
| Spain | | 28 | 10 | 38 |
| Taiwan | | 2 | 1 | 3 |
| Thailand | | 3 | 0 | 3 |

| | | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone | Total |
|---|---|---|---|---|
| United States | | 38 | 15 | 54 |
| **Metastatic burden (TNM Stage at Initial Diagnosis)** [1]<br>Measure Type: Count of Participants<br>Unit of measure: participants | Number Analyzed | 103 participants | 49 participants | 152 participants |
| Stage IIA | | 5 4.85% | 3 6.12% | 8 5.26% |
| Stage IIB | | 1 0.97% | 1 2.04% | 2 1.32% |
| Stage IIIA | | 7 6.8% | 4 8.16% | 11 7.24% |
| Stage IIIB | | 13 12.62% | 8 16.33% | 21 13.82% |
| Stage IV | | 77 74.76% | 33 67.35% | 110 72.37% |
| | | [1] Measure Description: Based upon the population treated, the most important baseline measure was CT scans to determine metastatic burden, as the primary endpoint was investigator assessed PFS.<br>TNM Staging (Tumor size):<br>T1 (T1a,T1b & T1c): <3 cm across. T2 (T2a/T2b): > 3 cm but not larger than 5 cm across. T3: > 5 cm but not larger than 7 cm across. T4: Tumor larger than 7cm across. As a rule, the lower the number, the less the cancer has spread. A higher number, such as stage IV, means cancer has spread more. And within a stage, an earlier letter means a lower stage. | | |
| **Heregulin positive status and staining in archival tissue** [1]<br>Measure Type: Count of Participants<br>Unit of measure: participants | Number Analyzed | 103 participants | 49 participants | 152 participants |
| | | 103 100% | 49 100% | 152 100% |
| | | [1] Measure Description: Measure Description: Patients had to be ≥ HRG 1 positive in their submitted tumor sample to qualify for the study | | |

# Outcome Measures

**1. Primary Outcome Measure:**

| | |
|---|---|
| Measure Title | Progression Free Survival |
| Measure Description | Progression Free Survival is defined as the time from randomization to the first documented radiographical progression of disease using RECIST v.1.1, or death from any cause, whichever came first based on investigator assessment.<br><br>Patients that do not experience progression or death at the time of analysis were to be progression censored at the date of last valid tumor assessment. Progression-free survival time distribution and median survival for each treatment group were analyzed using the Kaplan-Meier method. Tumor response was evaluated by the local radiologist according to RECIST version 1.1 to establish disease progression by CT or MRI. |
| Time Frame | Randomization until progression of disease or death due to any cause within 3 years,11 months (the study terminated prematurely) |

Analysis Population Description

The Modified Intent-to-Treat (mITT) Population consisted of all randomized patients who received at least 1 dose of assigned therapy

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br><br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br><br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Measured Values

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Overall Number of Participants Analyzed | 71 | 38 |
| Progression Free Survival<br>Median (Inter-Quartile Range)<br>Unit of measure: months | 3.4 (1.9 to 5.7) | 4.1 (2.7 to 6.3) |

Statistical Analysis 1 for Progression Free Survival

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Group Selection | Arm A (Experimental): MM-121 in Combination With Docetaxel, Arm B (Comparator): Docetaxel Alone |
| | Comments | [Not specified] |
| | Type of Statistical Test | Superiority |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.2302 |
| | Comments | [Not specified] |
| | Method | Log Rank |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Hazard Ratio (HR) |
| | Estimated Value | 1.382 |
| | Confidence Interval | (2-Sided) 95%<br>0.813 to 2.350 |
| | Estimation Comments | [Not specified] |

**2. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Overall Survival |
| Measure Description | Overall Survival (OS) is defined as the time from the date of randomization to the date of death from any cause |
| Time Frame | From date of randomization until the date of death from any cause assessed upto 3 years,11 months (the study terminated prematurely) |

Analysis Population Description

Modified Intent-to-Treat (ITT) population

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br><br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br><br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Measured Values

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Overall Number of Participants Analyzed | 71 | 38 |
| Overall Survival<br>Median (Inter-Quartile Range)<br>Unit of measure: months | 7.7 (3.6 to 10.4) | 8.4 (5.8 to 14.7) |

Statistical Analysis 1 for Overall Survival

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Group Selection | Arm A (Experimental): MM-121 in Combination With Docetaxel, Arm B (Comparator): Docetaxel Alone |
| | Comments | [Not specified] |
| | Type of Statistical Test | Superiority |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.5436 |
| | Comments | [Not specified] |
| | Method | Log Rank |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Hazard Ratio (HR) |

| | | |
|---|---|---|
| | Estimated Value | 1.195 |
| | Confidence Interval | (2-Sided) 95%<br>0.673 to 2.122 |
| | Estimation Comments | [Not specified] |

**3. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Objective Response Rate |
| Measure Description | Objective Response Rate (ORR) is defined as the proportion of patients a best overall response characterised as either a Complete Response (CR) or Partial Response (PR), as defined according to RECIST v1.1 guidelines, relative to the total number of evaluable patients.<br>Complete Response (CR) is defined as disappearance of all lesions and pathologic lymph nodes.<br>Partial Response (PR) is defined as >=30% decrease in the sum of the longest diameter of target lesions |
| Time Frame | Randomization through end of study up to 3 years, 11 months (the study terminated prematurely) |

Analysis Population Description

Modified Intent-to-Treat (ITT) population

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Measured Values

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Overall Number of Participants Analyzed | 71 | 38 |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Objective Response Rate<br>Measure Type: Count of Participants<br>Unit of measure: participants | | |
| Objective Response | 14 19.72% | 2 5.26% |
| Partial Response (PR) | 14 19.72% | 2 5.26% |
| Stable Disease (SD) | 39 54.93% | 26 68.42% |
| Progressive Disease | 12 16.9% | 5 13.16% |
| Not Evaluable | 1 1.41% | 1 2.63% |
| No Evaluation | 5 7.04% | 4 10.53% |

Statistical Analysis 1 for Objective Response Rate

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Group Selection | Arm A (Experimental): MM-121 in Combination With Docetaxel, Arm B (Comparator): Docetaxel Alone |
| | Comments | [Not specified] |
| | Type of Statistical Test | Superiority |
| | Comments | [Not specified] |
| Statistical Test of Hypothesis | P-Value | 0.0455 |
| | Comments | [Not specified] |
| | Method | Cochran-Mantel-Haenszel |
| | Comments | [Not specified] |
| Method of Estimation | Estimation Parameter | Odds Ratio (OR) |
| | Estimated Value | 4.3 |
| | Estimation Comments | [Not specified] |

**4. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Time to Progression |
| Measure Description | Time to Progression (TTP) is defined as the time from the date of randomization to the date of objective tumor progression. In the actual analysis, duration of response (DOR) was analysed. |

| | |
|---|---|
| Time Frame | Randomization to date of objective tumor progression up to 3 years, 11 months (the study terminated prematurely) |

Analysis Population Description

Modified Intent-to-Treat Population

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br><br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br><br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Measured Values

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Overall Number of Participants Analyzed | 71 | 38 |
| Time to Progression<br>Median (Inter-Quartile Range)<br>Unit of measure: months | 3.0 (2.8 to 5.2) | NA (NA to NA) [1] |

[1] Due to an insufficient number of participants with event

Statistical Analysis 1 for Time to Progression

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Group Selection | Arm A (Experimental): MM-121 in Combination With Docetaxel, Arm B (Comparator): Docetaxel Alone |
| | Comments | [Not specified] |
| | Type of Statistical Test | Superiority |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | 0.2726 |
| | Comments | [Not specified] |
| | Method | Log Rank |
| | Comments | [Not specified] |

**5. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Number of Participants With Treatment-emergent Adverse Events Reported With the Combination of MM-121 With Docetaxel Versus Docetaxel Alone |
| Measure Description | Treatment-emergent adverse events (TEAEs) are defined as any event that occurred after the first dose of study drug and was not present prior to study drug administration or worsened in severity after study drug administration |
| Time Frame | TEAEs were collected through the study completion (02 Jan 2019), up to 3 years, 11 months |

Analysis Population Description
Safety Population

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br><br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br><br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Measured Values

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Overall Number of Participants Analyzed | 103 | 49 |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Number of Participants With Treatment-emergent Adverse Events Reported With the Combination of MM-121 With Docetaxel Versus Docetaxel Alone<br>Measure Type: Number<br>Unit of measure: participants | | |
| Patients with any TEAE-Related | 99 | 45 |
| Patients with any TEAE-Serious Adverse event | 40 | 15 |
| Patients with any NCI-CTCAE Grade 3 or Higher | 76 | 31 |

**6. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Pharmacokinetic (PK) Parameters of MM-121 in Combination With Docetaxel and Docetaxel When Given in Combination With MM-121. |
| Measure Description | Pharmacokinetic (PK) profile of MM-121 when given in combination with docetaxel, and of docetaxel when given in combination with MM-121. The maximum observed concentration (Cmax) were to be presented and calculated using non-compartmental analysis. Serum levels of MM-121 were to be measured at a central lab using an enzyme-linked immunosorbent assay. |
| Time Frame | The study terminated prematurely after 3 years, 11 months (02 Jan 2019). PK evaluation were to be performed on samples obtained at Week 1 pre-dose and post-dose and at pre-dose at Cycle 2 and beyond to assess pre-treatment through concentrations of MM-121 |

Analysis Population Description

The PK data were not collected for this abbreviated report. There was no pharmacokinetic data feasible for the analysis, and as such, no related analyses were performed. Hence, data could not be reported in the data table.

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br><br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |

| | Description |
|---|---|
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Measured Values

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Overall Number of Participants Analyzed | 0 | 0 |

No data displayed because Outcome Measure has zero total participants analyzed.

**7. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Percentage of Participants With Treatment-emergent Adverse Events Reported With the Combination of MM-121 With Docetaxel Versus Docetaxel Alone |
| Measure Description | Treatment-emergent adverse events (TEAEs) are defined as any event that occurred after the first dose of study drug and was not present prior to study drug administration or worsened in severity after study drug administration |
| Time Frame | TEAEs were collected through the study completion (02 Jan 2019), up to 3 years, 11 months |

Analysis Population Description
Safety Population

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

Measured Values

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| Overall Number of Participants Analyzed | 103 | 49 |
| Percentage of Participants With Treatment-emergent Adverse Events Reported With the Combination of MM-121 With Docetaxel Versus Docetaxel Alone<br>Measure Type: Number<br>Unit of measure: percentage of participants | | |
| TEAE-Related | 96.1 | 91.8 |
| TEAE-Serious Adverse event | 38.8 | 30.6 |
| NCI-CTCAE Grade 3 or Higher | 73.8 | 63.3 |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | From Baseline through to premature study completion up to 3 years, 11 months (02 Jan 2019) |
| Adverse Event Reporting Description | The safety population includes patients receiving at least one dose of study medication. All safety analyses were be performed on this population. Safety analyses (adverse events and laboratory analyses) were performed using the safety population. Adverse events were coded using the latest MedDRA dictionary (MedDRA 21.0). Severity of adverse events was graded according to the NCI CTCAE version 4.03. |

Reporting Groups

| | Description |
|---|---|
| Arm A (Experimental): MM-121 in Combination With Docetaxel | MM-121 (Seribantumab, a human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. Heregulin-driven ErbB3 signaling has been implicated as a mechanism of tumor growth and resistance to targeted, cytotoxic and anti-endocrine therapies. When used in the combination setting, seribantumab is designed to block ErbB3 signaling in order to enhance the anti-tumor effect of a combination therapy partner): 3000 mg fixed dose intravenous (IV) on Day 1 of each 21-day cycle<br>Docetaxel (approved chemotherapy treatment for non-small cell lung cancer (NSCLC)): 75 mg/m#2 IV on Day 1 of each 21-day cycle |
| Arm B (Comparator): Docetaxel Alone | Docetaxel (approved chemotherapy treatment for NSCLC):<br>75 mg/m#2 IV on Day 1 of each 21-day cycle |

**All-Cause Mortality**

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total All-Cause Mortality | 64/103 (62.14%) | 25/49 (51.02%) |

**Serious Adverse Events**

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 40/103 (38.83%) | 15/49 (30.61%) |
| Blood and lymphatic system disorders | | |
| Anaemia [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Febrile neutropenia [A] † | 7/103 (6.8%) | 4/49 (8.16%) |
| Neutropenia [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Cardiac disorders | | |
| Atrial fibrillation [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Atrial flutter [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Cardio pulmonary failure [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Tachycardia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Gastrointestinal disorders | | |
| Colitis [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Diarrhoea [A] † | 6/103 (5.83%) | 0/49 (0%) |
| Gastrointestinal haemorrhage [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Neutropenic colitis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Small intestinal obstruction [A] † | 1/103 (0.97%) | 0/49 (0%) |
| General disorders | | |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Chest pain [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Fatigue [A] † | 1/103 (0.97%) | 0/49 (0%) |
| General physical health deterioration [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Mucosal inflammation [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pyrexia [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Hepatobiliary disorders | | |
| Cholecystitis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Cholecystitis acute [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Infections and infestations | | |
| Appendicitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Bronchitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Clostridium difficile infection [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Device related infection [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Diverticulitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Influenza [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Listeriosis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Lower respiratory tract infection [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Lung abscess [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pneumocystis jirovecii pneumonia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pneumonia [A] † | 8/103 (7.77%) | 1/49 (2.04%) |
| Respiratory tract infection [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Sepsis [A] † | 1/103 (0.97%) | 2/49 (4.08%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Septic shock [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Investigations | | |
| Lipase increased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Neutrophil count decreased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Metabolism and nutrition disorders | | |
| Decreased appetite [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Starvation [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Musculoskeletal and connective tissue disorders | | |
| Pathological fracture [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Psychiatric disorders | | |
| Delirium [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Depression [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Respiratory, thoracic and mediastinal disorders | | |
| Acute respiratory failure [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Chronic obstructive pulmonary disease [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Hypoxia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pleural effusion [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Pneumonitis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Respiratory failure [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Vascular disorders | | |
| Deep vein thrombosis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Orthostatic hypotension [A] † | 1/103 (0.97%) | 0/49 (0%) |

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 21.0

**Other Adverse Events**

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 103/103 (100%) | 47/49 (95.92%) |
| Blood and lymphatic system disorders | | |
| Anaemia [A] † | 29/103 (28.16%) | 11/49 (22.45%) |
| Febrile neutropenia [A] † | 8/103 (7.77%) | 6/49 (12.24%) |
| Leukocytosis [A] † | 0/103 (0%) | 2/49 (4.08%) |
| Leukopenia [A] † | 6/103 (5.83%) | 4/49 (8.16%) |
| Lymphopenia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Neutropenia [A] † | 29/103 (28.16%) | 11/49 (22.45%) |
| Thrombocytopenia [A] † | 1/103 (0.97%) | 2/49 (4.08%) |
| Cardiac disorders | | |
| Atrial fibrillation [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Atrial flutter [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Cardiac failure [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Cardio pulmonary failure [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Myocardial infarction [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Sinus tachycardia [A] † | 3/103 (2.91%) | 2/49 (4.08%) |
| Supraventricular tachycardia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Tachycardia [A] † | 4/103 (3.88%) | 0/49 (0%) |
| Ear and labyrinth disorders | | |
| Ear pain [A] † | 2/103 (1.94%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Hypoacusis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Tinnitus [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Vertigo [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Endocrine disorders | | |
| Cushingoid [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Hypothyroidism [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Eye disorders | | |
| Blepharospasm [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Dry eye [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Eye irritation [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Eye pruritus [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Lacrimation increased [A] † | 7/103 (6.8%) | 4/49 (8.16%) |
| Ocular hyperaemia [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Vision blurred [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Gastrointestinal disorders | | |
| Abdominal discomfort [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Abdominal pain [A] † | 4/103 (3.88%) | 2/49 (4.08%) |
| Abdominal pain lower [A] † | 2/103 (1.94%) | 3/49 (6.12%) |
| Abdominal pain upper [A] † | 1/103 (0.97%) | 2/49 (4.08%) |
| Anal fissure [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Anal haemorrhage [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Anal inflammation [A] † | 1/103 (0.97%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Aphthous stomatitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Colitis [A] † | 3/103 (2.91%) | 3/49 (6.12%) |
| Constipation [A] † | 7/103 (6.8%) | 7/49 (14.29%) |
| Diarrhoea [A] † | 52/103 (50.49%) | 11/49 (22.45%) |
| Dry mouth [A] † | 5/103 (4.85%) | 0/49 (0%) |
| Duodenitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Dyspepsia [A] † | 6/103 (5.83%) | 2/49 (4.08%) |
| Dysphagia [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Faeces discoloured [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Flatulence [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Gastritis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Gastrointestinal haemorrhage [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Gastrooesophageal reflux disease [A] † | 3/103 (2.91%) | 3/49 (6.12%) |
| Glossitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Glossodynia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Haemorrhoids [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Mucosal inflammation [A] † | 15/103 (14.56%) | 5/49 (10.2%) |
| Nausea [A] † | 30/103 (29.13%) | 14/49 (28.57%) |
| Neutropenic colitis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Odynophagia [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Oesophagitis [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Oral dysaesthesia [A] † | 1/103 (0.97%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Oral pain [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Pancreatitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Rectal haemorrhage [A] † | 0/103 (0%) | 2/49 (4.08%) |
| Rectal tenesmus [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Small intestinal obstruction [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Stomatitis [A] † | 19/103 (18.45%) | 2/49 (4.08%) |
| Vomiting [A] † | 13/103 (12.62%) | 4/49 (8.16%) |
| General disorders | | |
| Asthenia [A] † | 28/103 (27.18%) | 11/49 (22.45%) |
| Chest pain [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Chills [A] † | 4/103 (3.88%) | 0/49 (0%) |
| Cyst [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Discomfort [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Extravasation [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Fatigue [A] † | 45/103 (43.69%) | 16/49 (32.65%) |
| Gait disturbance [A] † | 1/103 (0.97%) | 0/49 (0%) |
| General physical health deterioration [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Hernia pain [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hyperthermia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Influenza like illness [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Infusion site reaction [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Local swelling [A] † | 0/103 (0%) | 1/49 (2.04%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Non-cardiac chest pain [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Oedema [A] † | 2/103 (1.94%) | 5/49 (10.2%) |
| Oedema peripheral [A] † | 5/103 (4.85%) | 3/49 (6.12%) |
| Pain [A] † | 8/103 (7.77%) | 6/49 (12.24%) |
| Pyrexia [A] † | 13/103 (12.62%) | 9/49 (18.37%) |
| Secretion discharge [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Ulcer [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Xerosis [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Hepatobiliary disorders | | |
| Cholecystitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Cholecystitis acute [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Cholelithiasis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Immune system disorders | | |
| Seasonal allergy [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Infections and infestations | | |
| Appendicitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Bronchitis [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Candida infection [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Clostridium difficile infection [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Conjunctivitis [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Device related infection [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Diverticulitis [A] † | 1/103 (0.97%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Ear infection [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Fungal infection [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Furuncle [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Herpes zoster [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Infection [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Influenza [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Laryngitis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Listeriosis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Lower respiratory tract infection [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Lung abscess [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Lymphangitis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Mucosal infection [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Nasopharyngitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Oral candidiasis [A] † | 3/103 (2.91%) | 3/49 (6.12%) |
| Oral herpes [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Otitis media [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Paronychia [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Pharyngitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pneumocystis jirovecii pneumonia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pneumonia [A] † | 12/103 (11.65%) | 6/49 (12.24%) |
| Respiratory tract infection [A] † | 6/103 (5.83%) | 3/49 (6.12%) |
| Rhinitis [A] † | 1/103 (0.97%) | 1/49 (2.04%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Sepsis [A] † | 2/103 (1.94%) | 2/49 (4.08%) |
| Septic shock [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Sinusitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Streptococcal bacteraemia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Tracheitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Upper respiratory tract infection [A] † | 8/103 (7.77%) | 0/49 (0%) |
| Urinary tract infection [A] † | 4/103 (3.88%) | 0/49 (0%) |
| Vaginal infection [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Wound infection [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Injury, poisoning and procedural complications | | |
| Arthropod bite [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Contusion [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Fall [A] † | 1/103 (0.97%) | 2/49 (4.08%) |
| Incision site erythema [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pelvic fracture [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Radiation pneumonitis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Radiation skin injury [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Skin abrasion [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Spinal fracture [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Thermal burn [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Investigations | | |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Activated partial thromboplastin time prolonged [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Alanine aminotransferase increased [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Aspartate aminotransferase increased [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Blood albumin decreased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Blood alkaline phosphatase increased [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Blood bilirubin increased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Blood creatine increased [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Blood creatinine increased [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Blood glucose increased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Blood iron decreased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Blood lactate dehydrogenase increased [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Blood magnesium decreased [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Blood phosphorus decreased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Blood sodium decreased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Breath sounds abnormal [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Electrocardiogram QT prolonged [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Gamma-glutamyltransferase increased [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Haemoglobin decreased [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| International normalised ratio increased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Lipase increased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Lymphocyte count decreased [A] † | 2/103 (1.94%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Neutrophil count decreased [A] † | 14/103 (13.59%) | 3/49 (6.12%) |
| Platelet count decreased [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Transaminases increased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Urine analysis abnormal [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Weight decreased [A] † | 7/103 (6.8%) | 4/49 (8.16%) |
| Weight increased [A] † | 1/103 (0.97%) | 0/49 (0%) |
| White blood cell count decreased [A] † | 8/103 (7.77%) | 1/49 (2.04%) |
| White blood cell count increased [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Metabolism and nutrition disorders | | |
| Decreased appetite [A] † | 34/103 (33.01%) | 8/49 (16.33%) |
| Dehydration [A] † | 9/103 (8.74%) | 3/49 (6.12%) |
| Gout [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hypercalcaemia [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Hyperglycaemia [A] † | 3/103 (2.91%) | 3/49 (6.12%) |
| Hyperkalaemia [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Hypernatraemia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hypoalbuminaemia [A] † | 4/103 (3.88%) | 2/49 (4.08%) |
| Hypocalcaemia [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Hypoglycaemia [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Hypokalaemia [A] † | 7/103 (6.8%) | 5/49 (10.2%) |
| Hypomagnesaemia [A] † | 4/103 (3.88%) | 0/49 (0%) |
| Hyponatraemia [A] † | 4/103 (3.88%) | 4/49 (8.16%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Hypophosphataemia [A] † | 4/103 (3.88%) | 2/49 (4.08%) |
| Hypovitaminosis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hypovolaemia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Starvation [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Musculoskeletal and connective tissue disorders | | |
| Arthralgia [A] † | 6/103 (5.83%) | 2/49 (4.08%) |
| Arthritis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Back pain [A] † | 9/103 (8.74%) | 1/49 (2.04%) |
| Bone pain [A] † | 6/103 (5.83%) | 2/49 (4.08%) |
| Limb discomfort [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Muscle spasms [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Muscular weakness [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Musculoskeletal chest pain [A] † | 4/103 (3.88%) | 1/49 (2.04%) |
| Musculoskeletal pain [A] † | 3/103 (2.91%) | 2/49 (4.08%) |
| Myalgia [A] † | 8/103 (7.77%) | 3/49 (6.12%) |
| Neck mass [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Neck pain [A] † | 1/103 (0.97%) | 2/49 (4.08%) |
| Pain in extremity [A] † | 2/103 (1.94%) | 4/49 (8.16%) |
| Pathological fracture [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Spinal pain [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | |
| Seborrhoeic keratosis [A] † | 1/103 (0.97%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Tumour haemorrhage [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Tumour pain [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Nervous system disorders | | |
| Amnesia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Ataxia [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Cognitive disorder [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Dizziness [A] † | 12/103 (11.65%) | 1/49 (2.04%) |
| Dysgeusia [A] † | 9/103 (8.74%) | 3/49 (6.12%) |
| Encephalopathy [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Headache [A] † | 7/103 (6.8%) | 2/49 (4.08%) |
| Hemiparesis [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Hypoaesthesia [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Lethargy [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Memory impairment [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Motor dysfunction [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Neuropathy peripheral [A] † | 4/103 (3.88%) | 3/49 (6.12%) |
| Neurotoxicity [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Paraesthesia [A] † | 6/103 (5.83%) | 1/49 (2.04%) |
| Paresis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Peripheral sensory neuropathy [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Polyneuropathy [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Presyncope [A] † | 1/103 (0.97%) | 1/49 (2.04%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Restless legs syndrome [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Sciatica [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Sinus headache [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Somnolence [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Spinal cord compression [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Syncope [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Vocal cord paralysis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Psychiatric disorders | | |
| Agitation [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Anorexia nervosa [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Anxiety [A] † | 2/103 (1.94%) | 2/49 (4.08%) |
| Confusional state [A] † | 5/103 (4.85%) | 0/49 (0%) |
| Delirium [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Depression [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Insomnia [A] † | 5/103 (4.85%) | 5/49 (10.2%) |
| Irritability [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Sleep disorder [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Renal and urinary disorders | | |
| Haematuria [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hypertonic bladder [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Incontinence [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pollakiuria [A] † | 1/103 (0.97%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Renal failure [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Renal failure acute [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Renal venous congestion [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Urinary hesitation [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Urinary retention [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Reproductive system and breast disorders | | |
| Bartholin's cyst [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Breast pain [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Breast tenderness [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Erectile dysfunction [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Vaginal haemorrhage [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Vaginal inflammation [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Vulvovaginal pain [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Respiratory, thoracic and mediastinal disorders | | |
| Acute respiratory failure [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Asthma [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Bronchospasm [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Catarrh [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Chronic obstructive pulmonary disease [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Cough [A] † | 12/103 (11.65%) | 6/49 (12.24%) |
| Dysphonia [A] † | 5/103 (4.85%) | 1/49 (2.04%) |
| Dyspnoea [A] † | 20/103 (19.42%) | 9/49 (18.37%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Dyspnoea exertional [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Epistaxis [A] † | 6/103 (5.83%) | 2/49 (4.08%) |
| Haemoptysis [A] † | 2/103 (1.94%) | 2/49 (4.08%) |
| Hiccups [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Hypoxia [A] † | 4/103 (3.88%) | 0/49 (0%) |
| Increased bronchial secretion [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Nasal congestion [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Nasal dryness [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Obstructive airways disorder [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Oropharyngeal pain [A] † | 4/103 (3.88%) | 0/49 (0%) |
| Paranasal sinus hypersecretion [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pleural effusion [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Pneumonitis [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Pneumothorax [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Productive cough [A] † | 3/103 (2.91%) | 1/49 (2.04%) |
| Pulmonary embolism [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Respiratory failure [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Rhinalgia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Rhinitis allergic [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Rhinorrhoea [A] † | 9/103 (8.74%) | 0/49 (0%) |
| Sinus congestion [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Upper-airway cough syndrome [A] † | 2/103 (1.94%) | 1/49 (2.04%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Wheezing [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Skin and subcutaneous tissue disorders | | |
| Alopecia [A] † | 23/103 (22.33%) | 13/49 (26.53%) |
| Dermatitis acneiform [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Dermatosis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Dry skin [A] † | 6/103 (5.83%) | 3/49 (6.12%) |
| Eczema [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Erythema [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Erythema multiforme [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hair colour changes [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hyperhidrosis [A] † | 0/103 (0%) | 2/49 (4.08%) |
| Hyperkeratosis [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Ingrowing nail [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Nail discolouration [A] † | 2/103 (1.94%) | 2/49 (4.08%) |
| Nail disorder [A] † | 3/103 (2.91%) | 3/49 (6.12%) |
| Nail dystrophy [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Nail ridging [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Nail toxicity [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Night sweats [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Onychalgia [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Onycholysis [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Onychomadesis [A] † | 1/103 (0.97%) | 1/49 (2.04%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Pain of skin [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Palmar-plantar erythrodysaesthesia syndrome [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Plantar erythema [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Pruritus [A] † | 2/103 (1.94%) | 2/49 (4.08%) |
| Psoriasis [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Rash [A] † | 10/103 (9.71%) | 6/49 (12.24%) |
| Rash erythematous [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Rash maculo-papular [A] † | 2/103 (1.94%) | 2/49 (4.08%) |
| Rash papular [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Skin exfoliation [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Skin hyperpigmentation [A] † | 1/103 (0.97%) | 1/49 (2.04%) |
| Skin ulcer [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Surgical and medical procedures | | |
| Pain management [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Vascular disorders | | |
| Deep vein thrombosis [A] † | 1/103 (0.97%) | 2/49 (4.08%) |
| Embolism [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Flushing [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Haematoma [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Haemorrhage [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Hot flush [A] † | 1/103 (0.97%) | 0/49 (0%) |

| | Arm A (Experimental): MM-121 in Combination With Docetaxel | Arm B (Comparator): Docetaxel Alone |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Hypertension [A] † | 2/103 (1.94%) | 1/49 (2.04%) |
| Hypertensive crisis [A] † | 0/103 (0%) | 1/49 (2.04%) |
| Hypotension [A] † | 7/103 (6.8%) | 2/49 (4.08%) |
| Ischaemia [A] † | 1/103 (0.97%) | 0/49 (0%) |
| Orthostatic hypotension [A] † | 3/103 (2.91%) | 0/49 (0%) |
| Phlebitis [A] † | 2/103 (1.94%) | 0/49 (0%) |
| Superior vena cava syndrome [A] † | 1/103 (0.97%) | 0/49 (0%) |

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 21.0

## Limitations and Caveats

[Not specified]

## More Information

**Certain Agreements:**

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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