A clinical study to compare MK-2870 to chemotherapy in people with lung cancer (MK-2870-004)

Protocol Title: A Randomized, Open-label, Phase 3 Study of MK-2870 vs Chemotherapy (Docetaxel or Pemetrexed) in Previously Treated Advanced or Metastatic Nonsquamous Non-small Cell Lung Cancer (NSCLC) with EGFR Mutations or Other Genomic Alterations

Why is this study needed?
Researchers are looking for new ways to treat advanced or metastatic non-small cell lung cancer (NSCLC). NSCLC is a type of lung cancer. Advanced cancers have spread in the body or cannot be removed with surgery. Metastatic means the cancer has spread from where it started to other parts of the body.

Current treatments for NSCLC may not work, or may stop working, for some people. MK-2870 (study treatment) is a targeted therapy. A targeted chemotherapy is a treatment that works to control how specific types of cancer cells grow and spread and may kill some normal cells. This is different from traditional chemotherapy, which is intended to destroy cancer cells or stop them from growing but also kills more normal cells that grow quickly.

This clinical study will compare MK-2870 to chemotherapy. The goal of the study is to learn if people who receive MK-2870 live longer overall and live longer without the cancer growing or spreading than people who receive chemotherapy.

Who will take part in this study?
About 556 people with NSCLC will be in this study. They will be 18 years old and older and have:

- NSCLC that is not squamous cell, such as adenocarcinoma or large cell carcinoma. Squamous cells are flat cells that line the inside of the airways in the lungs.
- NSCLC with an epidermal growth factor receptor (EGFR) gene mutation or certain other gene mutations. A gene mutation is a change in the order of DNA.
- Previously received certain treatment for NSCLC.
- Not had other cancers in past 3 years.

What treatments are being given during the study?
During this study, people will have an equal chance to receive 1 of 2 treatments:

- **MK-2870**: The study treatment will be given every 2 weeks.
- **Chemotherapy**: Either docetaxel or pemetrexed will be given every 3 weeks.

People will receive their treatment through a needle into a vein as an intravenous (IV) infusion. People who receive MK-2870 will also receive certain medications before each MK-2870 treatment: an antihistamine, H2 receptor antagonist, acetaminophen, and a corticosteroid. People will continue their assigned treatment until the cancer gets worse or they or the researcher decide to stop treatment.

How is this study designed?
Each person could be in the study for up to 6 years including treatment period and follow-up period to monitor your disease. Both the people in the study and the researchers will know
which treatment the person receives (called an open-label study). During the study, people will
give blood, urine, and tumor tissue, will have imaging tests and physical examinations, and
answer questions about how they are feeling.

What are the goals of this study and how will they be measured?

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<thead>
<tr>
<th>Main goals</th>
<th>How they will be measured</th>
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<tbody>
<tr>
<td>To learn if the <strong>progression free survival (PFS)</strong> of people with EGFR gene changes who receive MK-2870 is longer than those who receive chemotherapy</td>
<td>PFS is the average length of time people live from the start of treatment until a person’s cancer grows or spreads, or death from any cause.</td>
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<tr>
<td>To learn if the <strong>overall survival (OS)</strong> of people with EGFR gene changes who receive MK-2870 is longer than those who receive chemotherapy</td>
<td>OS is the length of time that people live from the start of treatment until death from any cause.</td>
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<table>
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<th>Other goals</th>
<th>How they will be measured</th>
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<tr>
<td>To learn the <strong>PFS</strong> and <strong>OS</strong> of all people in the study** who receive MK-2870 compared to those who receive chemotherapy</td>
<td>PFS and OS will be measured in all people in the study.</td>
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| To learn the **cancer response** of people who receive MK-2870 compared to those who receive chemotherapy | Researchers will measure how the cancer responds in people with EGFR gene changes and in all people in the study.  
  - **Objective response** is the number of people whose cancer responds to treatment (the cancer gets smaller or goes away) during the study.  
  - **Duration of response** is the length of time from when the cancer first responds to treatment until the cancer grows, spreads, or death from any cause. |
| To learn the **quality of life (QoL)** of people who receive MK-2870 compared to those who receive chemotherapy | People will answer questions to measure their QoL, including questions about how they are feeling and their ability to carry out daily tasks. Researchers will measure this in people with EGFR gene changes and in all people in the study.  
  - The change in the scores during the study  
  - The length of time from the start of the study until people’s QoL gets worse |
| To learn about the **safety** of MK-2870 and how well people **tolerate** it | The number of people who:  
  - Had an **adverse event** (AE) – an AE is a health problem that happens or worsens during a study  
  - Stopped treatment due to an AE |

What are the possible benefits and risks?

People in this study may or may not have their cancer stop growing or go away. This study has
an external group of experts that will oversee the overall risk and benefit. If this group of experts decides that the study treatment is not safe or does not show benefit, the study can be stopped. More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.