

CLINICAL TRIAL FACT SHEET

ClinicalTrials.gov ID: **NCT05651932**

Study Protocol K36-MMSET-001: A phase I clinical trial of KTX-1001 (gintemetostat), an oral, first-in-class, selective MMSET catalytic inhibitor that suppresses H3k36me2 in patients with relapsed and refractory multiple myeloma

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Description:

A clinical trial is a medical research study with people who volunteer to test scientific approaches to a new treatment or a new combination therapy. Each clinical trial is designed to find better ways to prevent, detect, diagnose, or treat cancer and to answer scientific questions. The K36-MMSET-001 study is designed to determine the maximum-tolerated dose (MTD) and safety profile of KTX-1001 (gintemetostat), an oral investigational drug for patients with myeloma who have limited treatment options.

Objectives:

- **The primary objective** of this study is to determine how well the study drug works, the dose and the schedule, and/or the recommended phase II dose (RP2D) and schedule of KTX-1001 in combination with investigational therapy of mezigdomide + dexamethasone (abbreviated as **Mezi-Dex** or **MEZId**) or standard-of-care (SOC) therapy with Kyprolis® (carfilzomib) + dexamethasone or Pomalyst® (pomalidomide) + dexamethasone to further define safety and tolerability, and provide preliminary efficacy information.
- **The secondary objective** of this study is to evaluate how KTX-1001 affects the body of the patient (called pharmacokinetics or PK).
- **The exploratory objective** of this study is to evaluate the relationships between biological markers and PK, safety, and activity of KTX-1001 in combination with investigational therapy **Mezi-Dex** or with SOC therapy of Kyprolis + dexamethasone [**Kd**] or Pomalyst + dexamethasone [**Pd**].

Design:

The K36-MMSET-001 study has 2 two parts. Patients will be enrolled into 1 of the parts.

1. **Dose escalation (Part 1)** – Approximately 30–40 patients will receive KTX-1001 at dose levels based on safety information collected during the study. The dose of KTX-1001 will increase as more is learned about how KTX-1001 affects the body. Part 1 is completed.
2. **Dose expansion (Part 2)** – Approximately 20 patients per combination therapy cohort (group of study patients) will receive **Mezi-Dex**, **Kd**, or **Pd** at the dose determined to be the most tolerable during the (completed) Part 1 of this study.

Inclusion criteria:

- 18 years of age or older.
- Relapsed or refractory multiple myeloma (RRMM) per diagnostic criteria of the International Myeloma Working Group (IMWG).
- At least 2 prior lines of therapy for the **Mezi-Dex** cohort. At least 1 prior line of therapy and no more than 3 prior lines of therapy for **Kd** and **Pd** cohorts, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- Measurable disease, including at least 1 of the following:
 - a. Monoclonal protein (myeloma protein or M-protein) ≥ 0.50 g/dL in the serum (liquid part of blood in which the blood cells are suspended).
 - b. M-protein ≥ 200 mg (by 24-hour collection) in the urine.
 - c. Serum free light chain (sFLC) involved light chain ≥ 10 mg/dL or 100 mg/L if sFLC ratio is abnormal.
 - d. Bone marrow plasma cells $\geq 30\%$ (if this is the only criterion for measurability).

International Myeloma Foundation

4400 Coldwater Canyon Avenue, Suite 300, Studio City, CA 91604 USA
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- **For dose expansion (Part 2):** Must have t(4;14) chromosomal abnormality in which parts of chromosomes 4 and 14 are rearranged (translocated), written with a lowercase “t” followed by the numbers of the chromosomes with translocated genetic material. This must be confirmed by the fluorescence *in situ* hybridization (FISH) test in a centralized Clinical Laboratory Improvement Amendments (CLIA) lab using a fresh tumor sample.

Study schedule:

- Screening period of up to 28 days.
- Treatment cycles will be 28 days. Participants will take KTX-1001 orally, twice daily at home.
- Pharmacokinetic and pharmacodynamic samples will be collected several times during Cycle 1, then at one time during Cycle 2 and beyond.
- Dose expansion (Part 2) patients will receive a dose level already evaluated during the dose escalation (Part 1) phase to further define the safety and tolerability of KTX-1001 with investigational therapy **Mezi-Dex** or with standard-of-care therapy **Kd** or **Pd**, and provide preliminary efficacy information.
- End-of-treatment visit.
- Post-treatment visit 30 days after the last dose of KTX-1001.
- Follow-up visits by phone call every 3 months for up to 2 years.

Clinical trial participants will go to the study site weekly during Cycle 1, then every other week for Cycle 2, followed by visits on Day 1 of each subsequent cycle until the end-of-treatment visit.

Informed consent:

A doctor must give a patient the information about a clinical trial so that the patient can make an informed decision about whether to participate in the study. In addition, the doctor must explain all procedures, and address the issues of risks and benefits, and treatment alternatives.

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