CLINICAL STUDY RESULTS

A Study on the Safety and Effects of IPN60210 in People with Multiple Myeloma and Diffuse Large B Cell Lymphoma That Came Back or Did Not Respond to Treatment

The study was stopped earlier than planned. The researchers did not make any conclusions from the results that were available.

The results shown in this summary represent one clinical study. Other clinical studies either singularly or combined may produce different results.

This lay summary was created by Ipsen with the assistance of a third-party writing service provider

What was the study about?

The purpose of this study was to learn about the safety and effects of IPN60210, also known as EZM0414, in people with blood cancers called relapsed/refractory (R/R) multiple myeloma (MM) and R/R diffuse large B cell lymphoma (DLBCL).

MM is a type of cancer that forms in plasma cells, a type of white blood cell (WBC). The cancerous plasma cells accumulate in the bone marrow and take over the healthy cells and create abnormal proteins that may cause complications. People with MM may have increased calcium levels in blood, kidney issues, low levels of red blood cells, and bone damage.

DLBCL is a type of cancer that develops when the body makes abnormal B lymphocytes, a type of WBC. DLBCL is one of most common types of blood cancer in the United States. People with DLBCL may have painless swellings in lymph nodes, fever, night sweats, weight loss, and extreme tiredness.

MM and DLBCL cancer cells can multiply uncontrollably and may affect other parts of the body.

Refractory refers to disease that doesn't respond to treatment or gets worse during the last treatment. Relapsed refers to disease that was previously treated but has gotten worse after earlier treatment and needs new treatment.

Currently, the treatments available for these cancers include chemotherapy, medicines that help the body to identify and kill cancer cells (immunochemotherapy), modified immunity-providing cells to fight cancer (cell therapy), and transplantation of healthy cells into the body.

IPN60210 is a potential new medicine being developed as a treatment for R/R MM and R/R DLBCL. It works by blocking a protein that affects the growth of cancer cells.

The aims of the study were to:

- find the highest dose of IPN60210 that is safe and well-tolerated.
- assess how safe and well tolerated IPN60210 is and find a dose for use in future studies.
- assess the effects of IPN60210.

None of the above-mentioned aims were achieved as the study was stopped early.

The study took place between May 2022 and April 2024 at 8 study sites in the United States.

The study was stopped early by the Sponsor due to business reasons. It was not due to any safety concerns.

Who took part in this study?

13
PARTICIPANTS

5
MEN

8
WOMEN

53-84 YEARS OLD
PARTICIPANTS

To take part in the study, participants had to:

- be 18 years or older.
- have the ability to at least move around and do light activities.
- be diagnosed with R/R MM or R/R DLBCL.
- have a life expectancy of at least 3 months, based on a doctor's assessment.
- have a specific genetic change in their cancer (in some cases).

Participants could not take part in the study if:

- they had a health condition or had received a treatment that could affect the study results or could pose a risk to the participant.

What treatments were used in this study?

Study Treatment

IPN60210 was given as tablets at a dose of 100 mg, 200 mg, or 300 mg once daily in 28-day cycles.

This study had 3 parts:

Screening: The study doctor checked if participants could take part in this study within 1 month of starting the study treatment.

Treatment: This study treatment was planned in 2 parts.

Part 1, where participants were to receive 1 of the 6 dose levels of IPN60210. The doses were to start from a lower to higher dose to find out the maximum tolerated dose (MTD)—the highest safe dose for Part 2.

Part 2, where the MTD selected from Part 1, was to be tested in participants with MM (with certain genetic changes) or DLBCL.

However, as the study stopped early during Part 1, Part 2 was not conducted.

Only 13 participants in Part 1 received the following 3 doses of IPN60210 once daily in 28-day cycles:

- **4 participants received 100 mg**
- **3 participants received 200 mg**
- **6 participants received 300 mg**

Participants received treatment until they experienced an unacceptable adverse event, their cancer worsened, they discontinued the study, their treatment was discontinued by the study doctor, or the sponsor decided to stop the study.

Follow-up: The researchers monitored the health of the study participants for up to 1 month after the last dose of the treatment.

How did the treatment make participants feel?

During the study, participants were asked to report any 'adverse events', for example, if they felt unwell, experienced any kind of medical event, or noticed anything different about their body. Researchers recorded all adverse events reported by participants, whatever the cause. For example, if some participants caught COVID-19, this was reported as an adverse event, although it was not related to the study treatment.

If the study doctor thinks an adverse event may be related to the study treatment, it is called a 'side effect'. A side effect is considered 'serious' when it is life-threatening, causes lasting problems, or leads to hospitalisation.

- Adverse events that are life-threatening, cause lasting problems or require an individual to go to the hospital are considered serious.
- No participant in this study experienced any serious side effect.
- No participant died during the study.

Overall, 69% (9 out of 13 participants) experienced a side effect:

- **50% (2 out of 4 participants)** who received **IPN60210 100 mg**
- **67% (2 out of 3 participants)** who received **IPN60210 200 mg**
- **83% (5 out of 6 participants)** who received **IPN60210 300 mg**

No participant stopped taking part in the study because of a side effect.

The most commonly reported side effects that happened in at least 2 participants are shown below, both as a percentage (%) followed by the actual number of participants in the group (for example, 25% or 1 out of 4).

Side Effects	100 mg (4 Participants)	200 mg (3 Participants)	300 mg (6 Participants)	Total (13 Participants)
Decrease in cells that help the blood to clot	25% (1 out of 4)	33% (1 out of 3)	17% (1 out of 6)	23% (3 out of 13) 
Decreased level of WBC called neutrophils	25% (1 out of 4)	33% (1 out of 3)	0	15% (2 out of 13) 
Extreme tiredness	25% (1 out of 4)	33% (1 out of 3)	17% (1 out of 6)	23% (3 out of 13) 
Headache	0	33% (1 out of 3)	17% (1 out of 6)	15% (2 out of 13) 
Nose and throat infection	0	0	33% (2 out of 6)	15% (2 out of 13) 

More information

To learn more about this study, please visit ClinicalTrials.gov and search for study NCT05121103

For more information about current treatments available, please speak to your healthcare provider. If you have any questions about this study, please contact the sponsor, Ipsen at:

clinical.trials@ipsen.com

Future research

At the time this summary was written, there was no future research planned on this topic.

Study identification and other information

FULL STUDY TITLE: A Phase 1/1b, Open-label Multi-centre Two-part Study of SETD2 Inhibitor EZM0414 in Participants with Relapsed/refractory Multiple Myeloma and Relapsed/refractory Diffuse Large B Cell Lymphoma

STUDY NUMBERS: United States: NCT05121103

PROTOCOL: SET-101

OTHER INFORMATION: Phase 1 studies can take several months to years to complete. Analysis of the study results will show how safe and/or effective a study treatment was during the study.

We thank all the volunteers who took part in this study. Without their support, advances in treatments for medical conditions would not be possible.

We would also like to thank the people who took the time to review this document to make it easier for a general audience to read.