Clinical Trial of Bomedemstat for the Treatment of Essential Thrombocythemia (ET)

This information was presented at **EHA**2022. For more information:

Essential thrombocythemia (ET) is one of a group of rare bone marrow diseases called myeloproliferative neoplasms (MPNs). In ET, the bone marrow makes too many platelets, which are cells that help blood clot. Too many platelets can cause blood clots or bleeding. Other symptoms of ET include itching, bone pain, and especially fatigue. Current treatments can help but may stop working or cause side effects. There are few options for patients with ET, so Imago is developing a new treatment.

ET is caused by mutations, or changes, in the DNA of bone marrow cells. These mutations are most common in the *CALR* and *JAK2* genes.

What is an investigational drug?

An investigational drug is a medication that is a possible treatment for a disease. It is not approved for use except in clinical trials.

For more information:

Why is the study being done?

This study is investigating if bomedemstat can return platelets to normal levels and improve ET symptoms. The results from this study are being used to help design future studies of bomedemstat in patients with ET.

What drug is being tested?

- Bomedemstat is the only medication in this study. It comes in capsules taken by mouth 1 time each day.
- Bomedemstat regulates the activity of a protein called LSD1. LSD1 is needed to produce platelets.
- Too many platelets can cause blood clots. Very high levels of platelets can sometimes lead to serious bleeding as well. Lowering the number of platelets in the blood has been shown to reduce the risk of clots or bleeding in patients with ET.
- The ability of bomedemstat to lower platelets and improve symptoms are important objectives of this study.

Phase of the clinical trial

There are many phases of clinical trials. The information being shared here is from a Phase 2 study.

Phase 0	Phase 1	**Phase 2**	Phase 3	Phase 4

A Phase 2 clinical trial tests the safety and effectiveness of a drug in people living with a specific condition. **For more information on clinical trials:**

Who is participating in the study?

As of May 2022, the study enrolled 73 women and men between the ages of 42 and 92 with ET. They are from the **US, UK, Germany, Italy, Hong Kong, Australia,** and **New Zealand.**

- **All** had a platelet count of more than 450 X 10^9/L.
- **All** had been treated with at least 1 other treatment for ET that either did not work for them or was intolerable.

What are the results so far?

Participants continue to be treated in this study. The results below are preliminary and include information up to 29 April 2022.

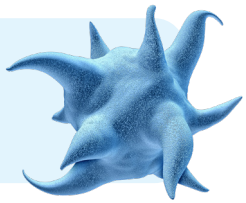
What have clinicians learned about the safety of bomedemstat so far?

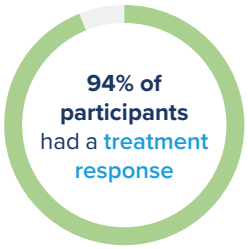
- Bomedemstat has been **generally well tolerated.**
- Most new medical issues reported by patients and related to bomedemstat were **mild.**
- The most common new medical issue was dysgeusia, or *changes in taste*, but was mild for the majority of participants.

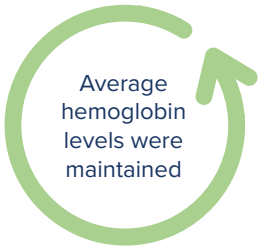
What have clinicians learned about the effectiveness of bomedemstat so far?

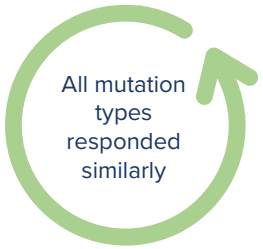
Clinicians wanted to determine if bomedemstat could reduce the number of platelets and the frequency of gene mutations. In this study, 87% of participants were known to have the *CALR* or *JAK2* **gene mutations**. 9% of patients were triple negative. All patients **responded similarly to bomedemstat.** The **results** for participants who took bomedemstat for at least 24 weeks are given below:

A **treatment response** is when a participant has a **platelet** count of 400 X 10^9/L or less without a blood clot event.



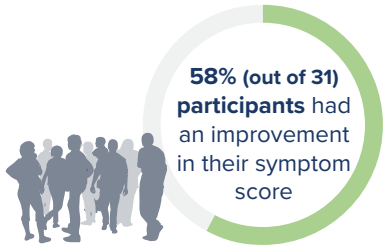


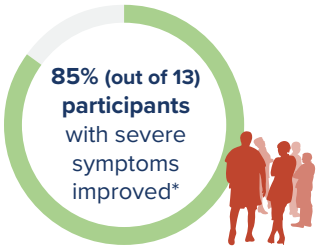




24 participants had their frequency of mutations analysed.

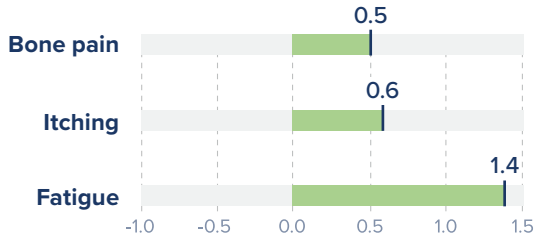
Participants rated their **symptoms** caused by their ET during the study. Key symptoms include fatigue, bone pain, and itching. The results after 24 weeks of treatment are given below.





**Refers to participants with severe symptoms at the start of the study.*

The graphs below show the **average symptom improvement** in bone pain, itching, and fatigue for participants at 48 weeks.



Where can I find more information?

As of May 2022, bomedemstat has been tested in over 200 participants with bone marrow diseases. **This study has finished enrolling new participants.** A larger global study in patients with ET is being planned. There are also new studies of bomedemstat planned for the treatment of other MPNs including polycythemia vera (PV) and myelofibrosis (MF). **If you are interested in learning about these studies or becoming a participant,** please visit **www.imagobio.com**

ETClinicalStudy.com

Full title: IMG-7289 in Patients With Essential Thrombocythemia **Clinical Trial Number:** NCT04254978

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