A Clinical Trial of Bomedemstat (IMG-7289) for the Treatment of Myelofibrosis (MF)

This information was presented at the **2022 European Hematology Association Conference** in Vienna. For more information:

What is Myelofibrosis (MF)?

Myelofibrosis (MF) is a bone marrow (BM) disease that progressively clogs the BM with scar tissue. MF is caused by a genetic change in DNA. This change usually happens in adults who are age 45 or older and is not inherited or passed on to children.

MF is one of a group of rare BM diseases called myeloproliferative neoplasms (MPN). MPN affect cells in the first step of blood cell formation. Each type of MPN affects blood cell production in different ways:

- MF causes too many megakaryocytes, which make platelets, and over time, too many white blood cells (WBC), and too few platelets and red blood cells (RBC).
- Essential thrombocythemia (ET) causes too many megakaryocytes.
- Polycythemia vera (PV) causes too many RBC and often too many platelets and WBC.

When MF occurs in people that have never had problems with their BM before, this is called primary MF. ET and PV can also turn into MF. In rare cases, any of the MPN can turn into acute myeloid leukemia (AML).

What **happens** to the body in MF?

Bone marrow scarring

- Reduces production of all blood cells
- Causes bone pain

Low levels of red blood cells

- Anemia or too few red blood cells, which causes fatigue
- Blood transfusions are often needed in later stages of the disease

Enlarged spleen

- Occurs when the BM is not making enough blood cells
- Pushes on the organs around it, like the stomach, and may cause abdominal pain or a feeling of being full

What **drug** is being tested and how does it work?

- Bomedemstat was the medication tested in this study.
- It is a capsule that is taken by mouth 1 time each day.
- Bomedemstat controls the activity of an enzyme called LSD1.
- LSD1 is needed for the BM to make the correct amount of WBC, RBC, and platelets.

Phase of the clinical trial

There are several phases of clinical trials testing the safety and effectiveness of drugs. Bomedemstat was studied in a Phase 1/2 study in MF.

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

A Phase 1/2 clinical trial tests the safety and effectiveness of a drug in participants with a specific condition. **For more information on clinical trials:**

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 outside of clinical trials.

For more information:

Why is this study being done?

There is no cure for MF. Current MF treatments can help but may stop working or cause side effects. Imago is developing a new treatment due to MF patient needs.

Important objectives of this study included improving or stabilizing: • Symptoms • BM scarring • The ability of BM to produce the normal amount of RBC

The results from this study will be used to help design future studies of bomedemstat in patients with MPN.

Who is **participating** in this study?

This study included 89 men and women with MF between the ages of 35 and 88. The participants were from 6 countries.

Most participants had tried at least 2 other MF treatments. Participants included those with *JAK2, CALR,* and *MPL* mutations. It also included **triple negative** participants. This means they did not have a mutation in one of the usual 3 genes related to MF and other MPN.

In the study: • **46%** had primary MF • **33%** previously had ET • **21%** previously had PV

Is bomedemstat **safe**?

It was found that bomedemstat is generally safe for people with MF. The 2 most common medical issues were:

• Thrombocytopenia (low platelets), which was managed by reduced doses. • Dysgeusia (changes in taste). For most participants this was considered mild.

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

Results are summarized below.

What effect did bomedemstat have on MF?

Bone marrow scarring

85%
had **improved or stable** bone marrow scarring

Spleen volume

In participants who took bomedemstat for at least 24 weeks. The study included participants of all spleen sizes.

64%
had a **decrease** in spleen volume

28%
had a **decrease** in spleen volume of **20% or more**

Changes in MF mutations

52%
had a **decrease** in blood cells with MF mutations

Progression to AML

0%
no participants progressed to AML

How did bomedemstat impact the lives of participants?

Blood transfusions

In participants who regularly needed blood transfusions.

52%
had a **reduced** or stable need for transfusions

3 participants **no longer** needed transfusions

MF symptoms

Participants rated their symptoms weekly, including fatigue, bone pain, and itching.

55%
of **all participants** had an improvement

65%
with **the worst symptoms** at the start of the study had an improvement

Where can I find more information?

As of May 2022, bomedemstat has been tested in over 200 participants with BM diseases. **This study for MF is no longer enrolling new participants.** New studies of bomedemstat are planned for MF, PV, and ET. **If you are interested in becoming a participant,** please visit **www.imagobio.com**

Full title: IMG-7289 in Patients With Myelofibrosis **Clinical Trial Number:** NCT03136185

myelofibrosisclinicalstudy.com

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