

FEASIBILITY STUDY

of

ZETA FUSE® BONE GRAFT

in the Repair of Bone Defects from Metastatic Breast Cancer in the Spinal Vertebral Body

ABOUT THE TRIAL

Zetagen Therapeutics is on a mission to bring forward life-changing therapies to patients suffering from metastatic breast cancer.

This clinical trial is designed for patients like you who have destructive, lytic lesions due to metastatic breast cancer to bone, with or without involvement of other sites. The objective of the trial is to capture early data on the safety and benefit of the ZetaFuse® product.

Your doctor has determined you may be a candidate for this study and may benefit from the treatment of metastatic breast cancer lesions to your spine.

ZetaFuse® is placed into the vertebral body defect created by metastatic breast cancer, via a well-established outpatient procedure called a vertebroplasty.

The doctor performing the outpatient procedure is Dr. Manraj Heran, the principal investigator for this study. He has extensive experience in performing vertebroplasties and has published several clinical papers on the topic.



Is a private, clinical-stage, biopharmaceutical company focused on developing breakthrough therapies for metastatic and primary cancers to bone and soft tissue.

Zetagen has received multiple **Breakthrough Designations** from the US Food and Drug Administration (FDA) and ZetaFuse® has been reviewed and approved for **Compassionate Use** in the United States and for clinical studies in Canada and Australia.



FREQUENTLY ASKED QUESTIONS

How safe is the outpatient procedure?

All procedures have inherent risks as cited in the Participant Information and Consent form.

The vertebroplasty procedure has been performed since 1984 and tens of thousands are performed annually across North America. Dr. Manraj Heran has published several articles for almost two (2) decades on this procedure in peer-reviewed medical journals, e.g., : *Heran MK, Legiehn GM, Munk PL. Current concepts and techniques in percutaneous vertebroplasty. Orthop Clin North Am. 2006 Jul;37(3):409-34, vii.*

What is a clinical trial?

Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat a disease.

Who can join this study?

Female patients with metastatic breast cancer to bone, with or without involvement of other sites and with at least one lytic metastatic lesion located in a vertebral body of the spine.

Why am I being asked to consider this study?

There is no cure for metastatic breast cancer lesions to the spine. Your doctor has assessed that you may be a candidate and that you may benefit from this therapy.

Am I required to be in this study?

No. Taking part in this study is voluntary. Even if you choose to participate in this study, you can leave the study at any time.

Has the ZetaFuse® Bone Graft been used in other patients?

Yes. In the United States, seven (7) patients have already received the product via the FDA's "Expanded Access/Compassionate Use" program.

Have any patient results been published?

Yes. The first and second Compassionate Use patient's results have been published in a peer-reviewed medical journal. You may read the publication by visiting <https://www.futuremedicine.com/doi/10.2217/pmt-2023-0069>

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