

A Study to Evaluate the Investigational Drug LB1148 for Return of Gastrointestinal Function and Adhesions in Subjects Undergoing Bowel Resection (LBS-POI-201 PROFILE)

Are you scheduled to undergo an abdominal or bowel (intestine) surgery where part(s) of the damaged pieces or tissue will be removed?

Are you also having a stoma placed? (A stoma is an opening in your abdominal wall that a surgeon makes in order for waste to leave your body if you can't have a bowel movement through your rectum)



LB1148 is being tested for reducing adhesions (fibrous bands of scar tissue) and post-operative ileus (inability of the bowel to move waste out of your system) after planned abdominal or bowel surgery

The purpose of this study is to find out if LB1148:

- Is safe (previous studies have shown that LB1148 is safe and well tolerated)
- Stops adhesions from forming after surgery
- Helps people quickly recover from symptoms of post-operative ileus

What are the requirements to participate in this research study?

- To qualify, you must:
 - o Be 18 years of age or older
 - o Be scheduled to undergo an elective (non-emergent) bowel resection with a planned stoma via laparotomy or minimally invasive technique
 - o Have a planned stoma takedown or other planned abdominal surgery within 8 months of the initial surgery

Are there any risks to me if I decide to participate?

• All medications and medical procedures carry a risk of side effects; therefore, it is possible that you may experience some discomfort or other side effects associated with the use of either of the study medications.

Does it cost anything to participate?

• If you are qualified and decide to participate in the research study, you will receive study medication at no cost. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

What are the potential benefits of participating?

 Aside from any personal benefit you may receive by using the study medication you are assigned, this research study may also help answer important questions about the safety and efficacy of the investigational medication. This could provide new information about the treatment of intra-abdominal adhesions, which may help other patients in the future.

What should I do now?

- If you think you may qualify to participate in this research study, please discuss it with your care provider. You can also refer to the contact information below.
- For more information about this clinical trial, please contact ______ at ______

A complete listing of sites and additional information can be found at <u>www.clinicaltrials.gov/ct2/show/NCT02836470</u>.

www.palisadebio.com