Eligibility checklist

To be eligible to participate in this trial, you need to meet several eligibility criteria (inclusion criteria) and none of the exclusion criteria. To help make this easier to understand, here is a checklist. If you answer yes to all of the following, you may be eligible to participate in this study. If you answer no to one or more of these questions you should discuss your suitability with your doctor.

Some of these will require you to discuss with or obtain results from your doctor. Some of the blood tests may be in different units to what is documented below and will need converting in such cases.

Inclusion Criteria[1-3]	YES	NO
✓ Do I have a confirmed diagnosis of adenocarcinoma of the pancreas?		
✓ Has my disease spread outside of the pancreas (metastatic disease)?		
✓ Have I received gemcitabine chemotherapy and my disease has gone on to progress?		
✓ Do I have a Karnofsky Performance Status ≥ 70?*		
✓ I have discussed with my doctor the results of my blood tests and I meet the criteria below: ☐ platelet counts > 100,000 cells/µl ☐ haemoglobin > 9 g/dL ☐ ANC > 1,500 cells/µl without the use of haematopoietic growth factors ☐ bilirubin levels within reference ranges ☐ albumin ≥ 3.0 g/dL ☐ AST and ALT levels < 2.5x ULN ☐ Creatinine < 1.5x ULN		
✓ Is my ECG (electrical recoding of the heart) normal or without clinical significance?		
✓ Have I recovered from the effects of any previous surgery, radiotherapy or other anti-cancer treatment?		
✓ Am I aged 18 years or older?		

* Karnofsky Performance Status is a measure of your functional ability
ULN= Upper limit of Normal

If you meet all of the above, answer the checklist below. If you answer yes to any of the below you may not be eligible to participate in the study and you should discuss this with your doctor.

Exclusion Criteria[1,2,4]	YES	NO
✓ Has my cancer spread to my brain?		
✓ Do I have any significant disorders including liver disease, bleeding, inflammation, gastrointestinal occlusion or diarrhoea?		
✓ In the last 5 years have I been diagnosed with a second cancer – other than in-situ cancer or basal or squamous cell skin cancer?		
✓ Have I had any arterial thromboembolic events such as heart attack, unstable angina or stroke in the preceding 6 months?		
✓ Do I have congestive heart failure, abnormal heart rhythms or uncontrolled blood pressure?		
✓ Do I have an active infection or an unexplained fever > 38.5°C?		
✓ Do I have a known hypersensitivity to any of the agents being used in the study including components of liposomal products, MM-398, fluoropyrimidines or leucovorin?		
✓ Have I had any investigational therapy in the 4 weeks prior to commencing the study?		
✓ Do I have any medical or social conditions that are likely to interfere with my ability to sign informed consent, cooperate and participate in the study or interfere with the interpretation of results?		
✓ Am I pregnant or breastfeeding? (Both male and female patients of reproductive potential must agree to use a reliable method of birth control, during the study and for 3 months following the last dose of study drug)		

References

1. European Medicines Agency. EU Clinical Trials Registry. Available from URL
2. US National Institutes of Health. (6th June 2013). Study of **MM-398** With or Without 5-Fluorouracil and Leucovorin, Versus 5-Fluorouracil and Leucovorin in Patients With Metastatic Pancreatic Cancer (NAPOLI 1). Available from URL
3. Merrimack Pharmaceuticals Inc. (2013). *Inclusion Criteria*. Available from URL
4. Merrimack Pharmaceuticals Inc. (2013). *Exclusion Criteria*. Available from URL