SUMMARY PATIENT INFORMATION SHEET

ASTFOX: A Phase I study of the IAP antagonist, ASTX660 (tolinapant), in combination with standard of care FOLFOX chemotherapy in metastatic colorectal cancer

Please take the time to read this short study summary sheet carefully. If you would like to take part, we will give you more detailed information.

Why have I been invited to take part? You may be suitable for this study if you have advanced bowel cancer and your doctors are considering FOLFOX chemotherapy for your treatment. If you and your doctor would like you to take part, we will ask you to have some tests carried out (such as blood tests, CT scans (these take detailed images of the inside of the body), tests of your heart function and potentially biopsies of your tumour tissue). This is to find out if taking part in the study is an option for you.

What is the study treatment? In this study, we will combine two treatments called FOLFOX and ASTX660. FOLFOX intravenous chemotherapy is routinely given for the treatment of bowel cancer. Chemotherapy drugs work by stopping cancer cells from growing and dividing.

ASTX660 is a new drug, not yet licensed for the treatment of cancer. It is a type of drug called an 'IAP antagonist'. IAP stands for 'Inhibitors of Apoptosis Proteins'. IAPs stop cells dying, including some cancer cells which, despite chemotherapy, can still survive. By stopping IAPs, ASTX660 could make chemotherapy more effective. This study is the first stage in testing the treatment combination of ASTX660 and FOLFOX.

ASTX660 is taken by mouth as capsules once a day for 7 days, every 2 weeks. You would also be given FOLFOX chemotherapy intravenously, once every 2 weeks for up to 12 'cycles' of treatment, in other words, about 6 months treatment in total.

What is the purpose of the study? The aim of this study is to test how we can safely combine ASTX660 with FOLFOX chemotherapy. We will also look at how your body processes ASTX660 when given alongside FOLFOX chemotherapy and how this drug changes cells and proteins in your tumour and blood. Up to 30 patients will take part in the study.

What will happen to me if I take part? You will be asked to give blood samples during the study. This will be done once a week initially, and then move to being every 2 weeks. In addition, we will also ask you to give extra blood samples before and after treatment on two days during treatment. You will also be asked to have CT scans and other tests, such as tests to check how your heart is working. Some patients will be asked to give two biopsies (small tissue samples) of their cancer, one before their treatment and one during their treatment. Some of these blood tests, clinic visits and scans would take place as part of your ordinary chemotherapy treatment, even if you weren't taking part in the study. You will also be asked to complete questionnaires about any side effects you might experience during the trial.

What side effects might I have? The main side effects of FOLFOX chemotherapy include low blood cells, tiredness and tingling/ numbness in the hands and feet. The side effects of ASTX660 may include diarrhoea, itching/ rashes and high levels of liver enzymes. A detailed list of potential side effects is given in the main Patient Information Sheet.

If you would like more information, please speak to [nurse's or doctor's contact details]

A diagram to show you the different stages of the study: