Lay language summary – PRIMED at ESMO Breast 2023

A phase 2 trial of loperamide and granulocyte colony-stimulating factors to improve sacituzumab govitecan tolerance in patients with unresectable locally advanced or metastatic triple-negative breast cancer: PRIMED

Sacituzumab govitecan is a drug therapy that targets a protein, Trop2, on cancer cells to deliver irinotecan – a drug that stops the growth of cancer cells. Previous clinical trials in patients with triple negative breast cancer and hormone receptor positive/HER2-negative breast cancer have found that patients treated with sactiuzumab govitecan experienced a longer duration of time during which they can live without their cancer getting worse compared to patients that were treated with chemotherapy alone.

While effective at prolonging survival, cancer therapies can be associated with side effects. For sacituzumab govitecan, the most common side effects are severe diarrhea and low white blood cell counts (neutropenia), with the latter putting patients at risk for developing a fever or infection. In some cases, these side effects can be severe enough to lead to treatment delays and breaks, and in some cases, it can result in patients having to stop treatment all together.

The PRIMED study is evaluating whether giving drugs that are known to treat these side effects in cancer patients (loperamide for diarrhea and granulocyte-colony stimulating factors for neutropenia) at the beginning of the treatment and before they occur, could ultimately result in less incidences of these side effects.

The study will have two phases. Initially, the trial will enroll 25 patients and after two cycles of treatment (21 days, each) the rate of side effects (specifically diarrhea and neutropenia) will be evaluated. If less than 6 patients have experienced an increase of 4-6 stools a day (grade ≥2 diarrhea) and if less than 9 patients have a drop to 1,000 or below in their white blood cell count (grade ≥3 neutropenia), then the trial will continue and enroll another 25 patients. The study will be declared a success if when evaluating all 50 patients there are 7 or less patients with grade ≥2 diarrhea and there are 14 or less patients with grade ≥3 neutropenia.