MedicalXpress

Molecule that 'lights up' cancer accelerating toward FDA approval

October 27 2016, by Brian Wallheimer

The U.S. Food and Drug Administration has granted fast-track status to a Purdue University scientist's optical imaging technology that may one day significantly improve outcomes for pancreatic cancer patients.

Philip Low, Purdue's Ralph C. Corley Distinguished Professor of Chemistry and director of the Purdue Institute for Drug Discovery, developed the OTL 38 molecule that will move quickly to phase 3 clinical trials in human cancer patients. The molecule, given to patients intravenously, attaches to receptors on cancer cells and glows, identifying the cells that should be surgically removed.

Low said up to 40 percent of cancers recur in the original site of the surgery because surgeons might miss a microscopic cluster of 10 or 20 cells that cannot be seen during a normal procedure. OTL 38 illuminates even those tiny clusters.

"This has the potential to save lives because the surgeons will tell you that the only sure way to cure cancer is to cut it all out," Low said. "This technology gives them a significantly better chance to find and remove all the cancer from a patient."

Fast-track status speeds the process of designing and implementing clinical trials and removes waiting times for review of results. The OTL 38 molecule was also granted "orphan drug" status, which can be given to the maker of a drug that treats rare conditions or diseases and offers protection from competition for a period of time.

"When there are fewer than 200,000 patients diagnosed with a disease, there aren't a lot of incentives for a company to develop treatment," Low said. "This orphan drug status provides that incentive to move your drug quickly into an area where an important need is not met."

Low said the positive results of a phase 2 clinical study of the OTL 38 molecule were important to gaining fast-track status. In that trial, 96 percent of the tissue that was illuminated in patients was confirmed by pathology to be cancerous, and 98 percent of the malignant lesions identified by the surgeons fluoresced brightly due to their uptake of the fluorescent dye.

"Those are remarkable numbers," Low said. "That high specificity was likely a key to the FDA's decision."

OTL 38's phase 3 clinical trial for ovarian cancer should begin by the end of the year. Low and his company, On Target Laboratories, are working on earlier-stage trials for OTL 38 in cancers of the lungs, kidneys, brain and other organs.

The company is also developing a molecule that would minimize the amount of brain tissue that would need to be taken to remove cancer cells and a dye that can reveal cancer cells buried beneath tissue that would otherwise likely be missed during surgeries.

Provided by Purdue University