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Results from a new study show improved survival for patients with pleural mesothelioma.

The international study evaluated an immunotherapy drug in combination with chemotherapy as a new first-line treatment.

KINGSTON, Ontario, June 3, 2023 – Late-breaking results for the IND.227 trial were presented today during an oral abstract at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. The Phase III international study evaluated the use of the immunotherapy drug pembrolizumab combined with platinum-pemetrexed chemotherapy as a first-line treatment for patients with unresectable advanced or metastatic pleural mesothelioma.

"The data presented today demonstrate that the use of pembrolizumab and platinum-pemetrexed chemotherapy extends the lives of patients with unresectable advanced or metastatic pleural mesothelioma," said Dr Quincy Chu, Medical Oncologist at the Cross Cancer Institute, and the Canadian Cancer Trials Group (CCTG) study chair for IND.227. "The addition of pembrolizumab to platinum-pemetrexed chemotherapy resulted in significantly improved overall survival, progression-free survival and objective response rates compared to platinum-pemetrexed chemotherapy alone, regardless of PD-L1 expression and represents a new treatment option for patients with advanced pleural mesothelioma."

Pembrolizumab is an anti-programmed death receptor-1 (PD-1) therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. Pembrolizumab is already approved for use in a number of other cancers, including in combination with pemetrexed and platinum chemotherapy in non-small cell lung cancer, as well for cancers such as melanoma, and head and neck cancer and others.

Dr Chu concludes, "Unfortunately, most patients with pleural mesothelioma are not diagnosed until an advanced stage, when the survival rate is lower, and surgery is not an option. Standard treatments with platinum-pemetrexed chemotherapy have been used for nearly 20 years and more effective treatments are needed; only recently have studies shown that new drugs such as immunotherapy drugs improve outcomes."

Joan Davis Prevost is a patient who participated in IND.227 under the care of Dr Marie Florescu from Centre hospitalier de l'Université de Montréal (CHUM) in Montreal. Ms Prevost comments "I was enrolled in the IND.227 trial. I received chemotherapy and immunotherapy and my cancer disappeared. I am off any treatment since September 2020 and I am still in remission today, enjoying life and playing golf whenever I can. I was sentenced to death and this combination treatment has completely changed my fate. I hope all patients with mesothelioma could have access to this combination to get a real chance to crush this cancer."

"Only in the last few years have there been any changes in the standard of care for patients with pleural mesothelioma. Illustrating improvements in both progression free survival and overall survival, the results of this study are poised to have a tangible and meaningful impact on patients' lives," says Emi Bossio, a lung cancer survivor and CCTG Lung Cancer Patient Representative.

"IND.227 was an academic cooperative group trial led by the Canadian Cancer Trials Group with our partners in Italy (NCI-Naples) and France (IFCT) and has defined a new treatment option for patients with pleural mesothelioma. International academic collaborations such as these are an important mechanism to explore new treatments that will improve outcomes for our patients especially in diseases such as pleural mesothelioma," commented Dr Penelope Bradbury, Chair of the Lung Disease Site Committee at CCTG and Medical Oncologist at the Princess Margaret Cancer Centre in Toronto and one of the highest accruing investigators on the study.

“Asbestos exposure is the main risk factor for pleural mesothelioma. Despite its use being banned 30 years ago in Italy, the incidence of mesothelioma is still increasing due to lag between exposure and disease. Until recently, chemotherapy was the only available treatment for 20 years, with sobering results. Participation in this trial was a great option for Italian patients, as demonstrated by the large enrolment numbers. The addition of pembrolizumab to chemotherapy in IND.227 showed prolonged survival, improved progression-free survival, and higher objective response rates, with no unexpected safety findings. Pembrolizumab plus platinum-pemetrexed chemotherapy represents a new treatment option for patients with advanced, unresectable mesothelioma," says Dr Francesco Perrone, Director, Clinical Trials Unit, National Cancer Institute of Naples IRCCS G. Pascale Foundation, President-Elect Italian Association of Medical Oncology (AIOM).

“While pleural mesothelioma was considered as a fatal orphan disease only few decades ago, significant advances have recently been achieved thanks to clinical research efforts and international collaborations. The results of the IND.227 trial are one of these advances, which bring today an additional valuable treatment option for mesothelioma patients,” says French Cooperative Thoracic Intergroup (IFCT) study chair, Dr Laurent Greillier, Department Head, Multidisciplinary Oncology & Therapeutic Innovations, Assistance Publique – Hôpitaux de Marseille, Aix Marseille University.

“We are proud to support CCTG and thrilled that the positive results of this study have the potential to improve patient outcomes,” says Dr Stuart Edmonds, Executive Vice President of Mission, Research and Advocacy at CCS. “With help from our generous donors, we look forward to funding more international clinical trials like this to benefit more people affected by cancer at home and around the world.”

IND.227 study results

At the final analysis of the study, pembrolizumab plus chemotherapy significantly improved overall survival, reducing the risk of death by 21% (hazard ratio 0.79 (95% confidence intervals 0.64-0.98; stratified log rank two-sides p = .0324). Survival at 3 years was higher for pembrolizumab and platinum-pemetrexed chemotherapy compared to platinum-pemetrexed chemotherapy (25% of patients alive vs 17% of patients respectively). Progression-free survival was also significantly improved (hazard ratio for progression or death 0.80, 95% CI 0.65-0.99, stratified log rank two-sided p=0.0372). Objective response rates were significantly higher (62% for the pembrolizumab and platinum-pemetrexed chemotherapy arm and 38% for platinum-pemetrexed chemotherapy alone (p<0.0001). Grade 3 or 4 adverse events occurred in 27% of patients on pembrolizumab and platinum-pemetrexed chemotherapy and in 15% on platinum-pemetrexed chemotherapy and were as expected for this regimen. Quality of life data are still being analyzed.

The trial was supported by a grant from the Canadian Cancer Society (CCS) (707213); Merck supported the trial providing the immunotherapy drug pembrolizumab (KEYTRUDA®) and some funding for the study.

About pleural mesothelioma

Mesothelioma is a type of cancer that starts in the linings of certain parts of the body, and pleural mesothelioma develops in the lining of the lungs. Worldwide, it is estimated there were more than 30,000 new cases of malignant mesothelioma diagnosed and more than 26,000 deaths from the disease in 2020. Pleural mesothelioma is usually advanced and incurable when diagnosed and is related to exposure to asbestos. Because it develops after a long latent period, and because asbestos is still used in developing nations, it is believed that the worldwide incidence of pleural mesothelioma will continue to increase.

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About Canadian Cancer Trials Group

The Canadian Cancer Trials Group (CCTG) is a cancer clinical trials research cooperative that develops, conducts, and analyzes phase I-III trials to test anti-cancer and supportive therapies to improve survival and quality of life for people with cancer. The group includes more than 85 member institutions, comprising over 2,100 investigators working with 4,400 clinical trial staff from across Canada. CCTG is a national program of the Canadian Cancer Society (CCS) and from their operations centre at Queen's University, collaborates with a global network of 20,000 investigators and clinical trial staff in more than 40 countries. CCTG's network of researchers, physicians, scientists, statisticians, and patients are internationally recognized for finding the treatments that give people with cancer longer, better quality lives.

About the Canadian Cancer Society

The Canadian Cancer Society works tirelessly to save and improve lives. We fund the brightest minds in cancer research. We provide a compassionate support system for all those affected by cancer, from coast to coast and for all types of cancer. As the voice for Canadians who care about cancer, we work with governments to establish health policies to prevent cancer and better support those living with the disease. No other organization does all that we do to improve lives today and to change the future of cancer forever. Call 1-888 939-3333 or visit cancer.ca today.

About the National Cancer Institute of Naples

The National Cancer Institute of Naples (NCI-N) coordinates several Italian oncological collaborative groups, including one dedicated to thoracic malignancies, with more than 70 Italian centres, since 1996. NCIN Clinical Trial Unit has led, overall, more than 90 national and international phase 2, 3 and 4 trials, with special interest in the effect of cancer treatment on survival, quality of life and patient-reported outcomes in general. NCI-N is also one among the most active Italian centres for participation in phase 1 trials. For further information, please visit the Institutional website: https://newportal.istitutotumori.na.it.

About the French Cooperative Thoracic Intergroup

The French Cooperative Thoracic Intergroup (IFCT), is an independent, non-profit academic research organization in the field of thoracic oncology. Created in 1999, IFCT is a multidisciplinary group of experts sponsoring clinical research to improve the survival and quality of life of patients with lung cancer. IFCT has its own operational infrastructure and is equipped to design, promote, and carry out clinical studies in France and internationally, and to communicate the findings in the most highly recognized medical journals. The IFCT's activity regularly results in the introduction of new drugs or strategies that improve the efficacy, safety, and/or economic impact of cancer therapies. Since its creation, IFCT has led and participated in 46 clinical trials and 16 real-word evidence (RWE) studies, through a network of 333 centres. Further information: www.ifct.fr