

## Cholangiocarcinoma Patients with a Specific Genetic Biomarker Now have a New Treatment Option

FDA grants approval to Merk & Co. for Keytruda (pembrolizumab)

SALT LAKE CITY, UTAH, USA, June 14, 2017 /EINPresswire.com/ -- The U.S. Food and Drug Administration has granted approval to Merck & Co. for the first cancer drug based on a patients'



The hope is that advanced genetic information will one day be able to identify which patients are most likely to benefit from a specific treatment."

Marion Schwartz

individual genetic characteristics, regardless of where in the body the disease started. Keytruda (pembrolizumab) is for patients with solid tumors identified as having a biomarker called microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). This genetic defect activates cells to search out and destroy the cancer.

"This is an important first for the cancer community," Richard Pazdur, MD, Director of the FDA's Oncology Center of Excellence, said in a statement. "Until now, the FDA has approved cancer treatments based on where in the body the

cancer started—for example, lung or breast cancers. We have now approved a drug based on a tumor's biomarker without regard to the tumor's original location."

Keytruda has been shown to have certain effects that are likely to benefit cholangiocarcinoma patients especially in cases where their tumors continued to grow and spread after past treatment. Of the 149 patients who received Keytruda in clinical trials, 39.6% had a complete or partial response. The response lasted for six months or more for 78% of those patients. Merck is currently conducting further studies in patients with MSI-H or dMMR tumors to verify the treatment benefits of Keytruda.

According to the <u>Cholangiocarcinoma Foundation</u> (CCF) Chief Advocacy Officer, Marion Schwartz, "Molecular profiling provides detailed information about the genetic changes that are present in each patient's tumor." It is strongly recommended that all cholangiocarcinoma patients ask to be tested to determine if they have (MSI-H) or other biomarkers that may offer more treatment options.

Due to these exciting developments, CCF is gathering information from ALL cholangiocarcinoma patients about genetic testing. Help us make progress in cancer research by participating in this <u>Brief Survey</u>.

About the Cholangiocarcinoma Foundation (CCF)

Founded in 2006, the Cholangiocarcinoma Foundation is a global 501(c) (3) non-profit organization whose mission is to find a cure and improve the quality of life for those affected by bile duct cancer.

As a rare and lethal disease, cholangiocarcinoma lacks attention and sufficient resources. There is a vast, unmet need for education about cholangiocarcinoma across the entire disease spectrum - from

bench to bedside. For that reason, the Cholangiocarcinoma Foundation continues its efforts to raise awareness of all stakeholders in the cholangiocarcinoma community through advocacy, education, collaboration and research. More information is available at <a href="https://www.cholangiocarcinoma.org">www.cholangiocarcinoma.org</a>.

## About Cholangiocarcinoma

Cholangiocarcinoma is a "silent" form of cancer that originates from the cells lining the bile ducts. It is classified as a group of three anatomically distinct cancers grouped according to the location from which they arise: within the bile ducts (intrahepatic), outside the bile ducts (extrahepatic), and in between where the bile ducts exit the liver (perihilar).

The incidence and mortality of cholangiocarcinoma in North America and Europe has increased dramatically in the past few decades. In the U.S., there are now approximately 6,000 new cases diagnosed each year. Rates are highest among Hispanics and Asians, and men appear to have a slightly greater mortality from the disease than women. The highest incidence rates are observed in Eastern and South-Eastern Asia, with a peak registered in Thailand (33.4 per 100,000 in men).

Because patients commonly present with symptoms that mimic those of other ailments, and there is no validated method of early detection, the majority of patients are diagnosed when the cancer is far too advanced to be removed by surgery. In these cases, chemotherapy and radiation therapy are the mainstay of treatment. The dismal 5-year survival rate for cholangiocarcinoma is estimated at 2-15%.

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