

Rafael Pharmaceuticals to Present Pancreatic & Biliary Tract Cancer Data on CPI-613® (devimistat) from its Multicenter, Randomized Phase 1b/2 Trials at the 2021 European Society of Medical Oncology World Gastrointestinal (GI) Congress

CRANBURY, N.J., June 30, 2021 (GLOBE NEWSWIRE) -- [Rafael Pharmaceuticals, Inc.](#) ("Rafael" or the "Company"), a leader in the growing field of cancer metabolism-based therapeutics, today announced that data on its lead compound, devimistat, has been selected for an oral presentation at the 2021 [European Society of Medical Oncology World Gastrointestinal Congress](#) (ESMO), taking place June 30 through July 3, 2021.

"We are proud to have our primary clinical investigators present at ESMO to share updates from our ongoing trials for devimistat in pancreatic and biliary tract cancer, two hard-to-treat diseases with few treatment options," said Sanjeev Luther, President and CEO of Rafael Pharmaceuticals. "Dr. Philip A. Philip and Dr. Vaibhav Sahai will share important perspectives on new treatment options from their frontline experience treating cancer and evaluating devimistat in clinical trials."

Presentation Details:

Session Title: Gastrointestinal Cancer: Cancer of the Pancreas and Biliary Tract

Poster Title: A multicenter, randomized phase 1b/2 study of gemcitabine and cisplatin with or without CPI-613 as first-line therapy for patients with advanced unresectable biliary tract cancer (BIT-04)

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Session Title: Session I: Cancer of the Pancreas and Biliary Tract, Q&A

Date: July 1, 2021

Time: 4:34 PM (CEST)

Speaker: Philip A. Philip

Devimistat's mechanism of action aims to stunt the growth of cancer cells, creating an opportunity to increase survival rates for cancers like pancreatic and biliary tract, which have historically produced grim outlooks for patients. According to the Surveillance, Epidemiology, and End Results (SEER) database, [biliary tract cancer has a 5-year relative survival rate of just 9%](#) across all combined SEER stages (localized, regional and distant). Pancreatic cancer has a similar profile, with a [5-year relative survival rate of 10.8%](#). Patients battling both cancers urgently need therapeutic options that can improve survival rates.

"Our team is thrilled to have the opportunity to share updates from our clinical study currently in-progress for the treatment of biliary cancer, especially at the ESMO GI Congress," said Vaibhav Sahai, MBBS, M.S., primary investigator and medical oncologist at the University of Michigan Rogel Cancer Center in Ann Arbor, Michigan.

"I'm pleased to share updates on the treatment of pancreatic cancer. I believe that with each milestone met, we're a step closer to discovering potential new treatment options," said Dr. Philip, M.D., Ph.D., F.R.C.P, primary investigator and medical oncologist at the [Karmanos Cancer Center](#) in Detroit, Michigan.

About CPI-613® (devimistat)

CPI-613® (devimistat) is a first-in-class clinical lead compound of Rafael, which targets enzymes that are involved in cancer cell energy metabolism and are located in the mitochondria of cancer cells. Devimistat is designed to target the mitochondrial tricarboxylic acid (TCA) cycle, a process essential to tumor cell multiplication and survival, selectively in cancer cells. Devimistat substantially increases the sensitivity of cancer cells to a diverse range of chemotherapeutic agents. This synergy allows for potential combinations of devimistat with lower doses of these generally toxic drugs to be more effective with lower patient's side effects. Combination with devimistat represent a diverse range of opportunities to substantially improve patient's benefit in many different cancers. The U.S. Food and Drug Administration (FDA) has given Rafael approval to initiate pivotal Phase 3 clinical trials in pancreatic cancer (AVENGER 500) and acute myeloid leukemia (ARMADA 2000) and has designated devimistat as an orphan drug for the treatment of pancreatic cancer, acute myeloid leukemia, myelodysplastic syndrome, peripheral T-cell lymphoma, Soft Tissue Sarcoma, Burkitt's lymphoma and biliary cancer. The EMA has granted orphan drug designation to devimistat for pancreatic cancer and acute myeloid leukemia.

About Rafael Pharmaceuticals, Inc.

Rafael Pharmaceuticals is a leader in the growing field of cancer metabolism. The company is developing a new, first-in-class category of metabolic oncology therapeutics that attack hard-to-treat cancers by targeting the metabolic processes the disease needs to survive, grow and proliferate. Rafael Pharmaceuticals' lead compound, CPI-613® (devimistat), is a highly selective, well-tolerated and effective anti-cancer agent that is being evaluated in ongoing and completed Phase 1, 2 and 3 clinical trials. Devimistat has been granted orphan drug status by the FDA for the treatment of pancreatic cancer, acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) and Burkitt's, peripheral T-cell lymphomas and soft tissue sarcoma and biliary tract cancer. The Company's investors include Rafael Holdings, Inc. (NYSE: RFL). On June 21, 2021, we announced that we have entered into a merger agreement with Rafael Holdings, Inc., to create a publicly traded late-stage clinical oncology company focused on cancer metabolism-based therapeutics. For more information, please visit [www.rafaelpharma.com](#).

Safe Harbor Statement

This press release contains forward-looking statements. These statements relate to future events or the company's future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "estimate", "predict", "potential" or "continue", the negative of such terms, or other comparable terminology. These statements are only predictions. Actual events or results may differ materially from those in the forward-looking statements as a result of various important factors. Although we believe that the expectations reflected in the forward-looking statements are reasonable, such statements should not be regarded as a representation by the company, or any other person, that such forward-looking statements will be achieved. The business and operations of the company are subject to substantial risks which increase the uncertainty inherent in forward-looking statements. We undertake no duty to update any of the forward-looking statements, whether as a result of new information, future events or otherwise.

In light of the foregoing, readers are cautioned not to place undue reliance on such forward-looking statements.

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