



Lilly Announces Phase 3 Study in Patients with Metastatic Pancreatic Cancer Did Not Meet Primary Endpoint of Overall Survival

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INDIANAPOLIS, Oct. 16, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced top-line results from its Phase 3 SEQUOIA trial evaluating pegilodecakin plus FOLFOX (folinic acid, 5-FU, oxaliplatin) compared to FOLFOX alone in patients with metastatic pancreatic cancer whose disease had progressed during or following a first-line gemcitabine-containing regimen. The SEQUOIA trial did not meet its primary endpoint of overall survival.

The most common Grade 3/4 adverse events occurring at a higher rate ($\geq 5\%$ difference) on the pegilodecakin-plus-FOLFOX arm compared to the FOLFOX arm were neutropenia, thrombocytopenia, fatigue and anemia. Detailed efficacy and safety results will be submitted for presentation at a future medical meeting.

Metastatic pancreatic cancer is one of the deadliest major cancers, with just three percent of patients in the U.S. living five years after the cancer is diagnosed. In the U.S., pancreatic cancer is the third leading cause of cancer death and is expected to become the second leading cause of cancer-related death in the next decade.¹ Globally, pancreatic cancer is the seventh leading cause of cancer-related death.²

"More than 56,700 Americans – mothers, daughters, fathers, sons, colleagues and friends – will be diagnosed with pancreatic cancer this year alone," said Julie Fleshman, JD, MBA, president and CEO of the Pancreatic Cancer Action Network (PanCAN). "Because this is an aggressive disease and the current scope of treatment options is limited, there remains an urgent need for meaningful solutions to improve outcomes for pancreatic cancer patients."

"Pancreatic cancer has proven to be one of the most difficult tumor types to treat and there have been very few recent treatment advancements in the later-line metastatic setting. We are grateful to the patients, investigators and researchers who participated in the study," said Maura Dickler, M.D., vice president, late phase development, Lilly Oncology. "While we are disappointed by the outcome of the SEQUOIA study, we look forward to the upcoming results in lung cancer, learning from those results and increasing our understanding of pegilodecakin's novel mechanism of action in cancer immunotherapy."

Lilly gained pegilodecakin with the acquisition of ARMO BioSciences in June 2018. SEQUOIA was initiated by ARMO in March 2017 based on results of the [Phase 1/1b IVY study](#), which evaluated pegilodecakin – used as a single agent and in combination with chemotherapy and with checkpoint inhibitor therapy – across multiple tumor types including pancreatic, non-small cell lung and renal cell cancers. Results from the IVY trial were also the basis for the ongoing Phase 2 [CYPRESS 1](#) and [CYPRESS 2](#) studies of pegilodecakin in combination with checkpoint inhibitors in non-small cell lung cancer (NSCLC). The CYPRESS studies were initiated by ARMO in March 2018 and results, expected in early 2020, will inform future studies of pegilodecakin in NSCLC. For the next stage of pegilodecakin's clinical development, Lilly is focused on assessing biomarkers and conducting studies in NSCLC and other tumor types including renal cell carcinoma, where the molecule has shown promising activity.

Notes to Editors

About SEQUOIA

SEQUOIA is a global, multi-center, randomized Phase 3 study designed to compare the efficacy and safety of pegilodecakin in combination with FOLFOX (folinic acid, 5-FU, oxaliplatin) compared to FOLFOX alone in participants with metastatic adenocarcinoma of the pancreas whose disease had progressed on one prior gemcitabine-containing regimen. The primary endpoint of the study is overall survival and key secondary endpoints are progression-free survival and objective response rate. SEQUOIA was initiated by ARMO BioSciences in March 2017 and enrolled 567 patients.

About Pancreatic Cancer

Metastatic pancreatic cancer is one of the deadliest major cancers, with just three percent of patients in the U.S. living five years after the cancer is diagnosed. In the U.S., pancreatic cancer is the third leading cause of cancer death and is expected to become the second leading cause of cancer-related death in the next decade.¹ Globally, pancreatic cancer is the seventh leading cause of cancer-related death.²

About Pegilodecakin

Pegilodecakin is an immunotherapy which stimulates the body's natural defenses against cancer and expands tumor-attacking T cells. This class of T cells can infiltrate and destroy cancer cells. Pegilodecakin, a pegylated IL-10, has shown clinical activity as a single agent in renal cancer and promising results in combination with both chemotherapy and checkpoint inhibitor therapy across several tumor types including non-small cell lung cancer and renal cell carcinoma.

About Lilly Oncology

For more than 50 years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world. To learn more about Lilly's commitment to people with cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>. P-LLY

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Lilly Forward-Looking Statement

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the SEQUOIA trial and pegilodecakin as a potential treatment for patients with cancer and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that pegilodecakin will receive regulatory approval or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

¹ American Cancer Society. Cancer Facts & Figures 2019. Available at: <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html>. Accessed October 15, 2019.

² Bray F, Ferlay J, Soerjomataram I, et al. A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6):394–424. doi: 10.3322/caac.21492

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The Lilly logo is rendered in a vibrant red, cursive script font. The letters are fluid and interconnected, with a classic, elegant feel. The 'L' is particularly large and prominent, leading into the 'i', 'l', 'l', 'e', 'y' which follow in a similar flowing style. The logo is centered horizontally in the lower half of the page.

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