Lilly's sofetabart mipitecan receives U.S. FDA's Breakthrough Therapy designation for the treatment of certain patients with platinum-resistant ovarian cancer

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INDIANAPOLIS, Jan. 20, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to sofetabart mipitecan (LY4170156) for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received prior bevacizumab and mirvetuximab soravtansine, if eligible. Sofetabart mipitecan is a novel folate receptor alpha (FRα) antibody-drug conjugate (ADC) that uses proprietary linker technology and an exatecan payload.

Breakthrough Therapy designation aims to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

"Platinum-resistant ovarian cancer remains one of the most challenging settings in gynecologic oncology, with limited treatment options and poor outcomes for patients," said Bhavana Pothuri, M.D., professor of Obstetrics/Gynecology and Medicine at NYU Grossman School of Medicine, NYU Langone Health and director of Clinical Trials Office at the Perlmutter Cancer Center. "The Breakthrough Therapy designation and preliminary clinical data for sofetabart mipitecan across all levels of FRα expression are encouraging and point to its potential as a meaningful treatment option for patients."

"We are pleased the FDA has granted Breakthrough Therapy designation for sofetabart mipitecan, reflecting the significant unmet need in platinum-resistant ovarian cancer and the promising initial results shown in our Phase 1 study," said Jacob Van Naarden, executive vice president, and president of Lilly Oncology and head of corporate business development. "Building on compelling results generated to date, we've initiated our Phase 3 FRAmework-01 trial with the goal of bringing a potential therapeutic option to patients with advanced ovarian cancer, across all levels of folate receptor expression."

The FDA Breakthrough Therapy designation is based on encouraging preliminary results from the Phase 1a/b study. Lilly presented initial Phase 1 results at the 2025 ASCO Annual Meeting in June and updated data at the 2025 ESMO Congress in October, showing responses at all dose levels and across all FRα expression levels, including in patients who progressed on prior mirvetuximab soravtansine. These initial data also indicate a promising tolerability profile with low rates of interstitial lung disease, peripheral neuropathy, and alopecia, and no significant ocular toxicity.

Sofetabart mipitecan recently advanced into the Phase 3 FRAmework-01 study (NCT07213804), a global trial investigating the treatment as a monotherapy in patients with platinum resistant ovarian cancer (PROC), and in combination with bevacizumab in patients with platinum-sensitive ovarian cancer (PSOC). Lilly is conducting the FRAmework-01 study in partnership with the European Network for Gynaecological Oncological Trial groups (ENGOT - lead groups GINECO/NOGGO e.V.), the GOG Foundation (GOG), and the Asia-Pacific Gynecologic Oncology Trials Group (APGOT)

About Ovarian Cancer
Ovarian cancer is the fifth leading cause of cancer death among women in the United States. While most patients initially respond to platinum-based chemotherapy, approximately 70% will experience recurrence, leading to progressively shorter remission periods with each subsequent treatment. When cancer recurs during or within six months of platinum therapy, known as platinum-resistant disease, patients face limited treatment options.

About Sofetabart Mipitecan
Sofetabart mipitecan (LY4170156) is composed of an Fc-silent, folate receptor alpha (FRα) specific humanized monoclonal antibody linked to exatecan, a topoisomerase I inhibitor, via a proprietary cleavable polysarcosine linker (PSARlink™). Sofetabart mipitecan was designed to target FRα across all expression levels with improved therapeutic index. FRα is a cell-surface glycoprotein encoded by the gene FOLR1 that binds to the essential nutrients folic acid and reduced folates, bringing them into cells to facilitate cell division and growth.[1,2] FRα is overexpressed in many solid tumors such as ovarian, non-small cell lung, and colorectal cancers.[1,3,4] Sofetabart mipitecan is currently being studied in patients with ovarian cancer as well as other FRα-expressing solid tumors, NCT06400472 and NCT07213804.

About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram, and LinkedIn. P-LLY

sponsorship of us by, any other companies.

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about sofetabart mipitecan as a potential treatment for people with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received prior bevacizumab and mirvetuximab soravtansine, if eligible, and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that any of these therapies will prove to be a safe and effective treatment or receive regulatory approval, or that Lilly will execute its strategy as expected. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's 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.

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