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# **Ligand to Receive Milestone and Royalties as Result of FDA Approval of Sage Therapeutics' ZULRESSO™ (brexanolone) Injection**

**ZULRESSO is the first and only treatment specifically indicated for postpartum depression**

SAN DIEGO--(BUSINESS WIRE)-- **Ligand Pharmaceuticals Incorporated (NASDAQ: LGND)** announced that it will receive a \$3 million milestone payment as a result of the U.S. Food and Drug Administration's (FDA) approval of Sage Therapeutics' (NASDAQ: SAGE) ZULRESSO™ (brexanolone) injection for the treatment of postpartum depression (PPD). ZULRESSO uses Ligand's Captisol® in its formulation. Ligand is also eligible to receive a royalty on sales of ZULRESSO in the U.S.

ZULRESSO is the first and only medicine specifically approved to treat PPD, the most common medical complication of childbirth. ZULRESSO is expected to be available in late June following scheduling by the U.S. Drug Enforcement Administration, which is expected to occur within 90 days.

PPD can affect women during pregnancy or after childbirth. It is estimated PPD affects approximately one in nine women who have given birth in the U.S. Symptoms may include sadness, anxiety, irritability, withdrawing from friends or family, having trouble bonding with her baby and thinking about harming herself or more rarely, her baby. Without proper screening, up to half of PPD cases may go undiagnosed.

## **About Postpartum Depression**

Postpartum depression (PPD) is the most common medical complication of childbirth. PPD is a distinct and readily identified major depressive disorder that can occur during pregnancy or after giving birth. Expert opinions vary as to the timing of the onset of PPD, ranging from onset during pregnancy up to 4-weeks postpartum and onset during pregnancy up to 12-months postpartum. PPD may have devastating consequences for a woman and for her family, which may include significant functional impairment, depressed mood and/or loss of interest in her newborn, and associated symptoms of depression such as loss of appetite, difficulty sleeping, motor challenges, lack of concentration, loss of energy and poor self-esteem. Suicide is the leading cause of maternal death following childbirth. PPD affects approximately one in nine women who have given birth in the U.S. and 400,000 women annually. More than half of these cases may go undiagnosed without proper screening.

## **About Captisol®**

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella, University Distinguished Professor at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled several FDA-approved products, including Amgen's Kyprolis<sup>®</sup>, Baxter International's Nexterone<sup>®</sup>, Spectrum's EVOMELA<sup>®</sup> and Melinta Therapeutics' Baxdela<sup>™</sup>. There are many Captisol-enabled products currently in various stages of development.

## **About Ligand Pharmaceuticals**

Ligand is a biopharmaceutical company focused on developing or acquiring technologies that help pharmaceutical companies discover and develop medicines. Our business model creates value for stockholders by providing a diversified portfolio of biotech and pharmaceutical product revenue streams that are supported by an efficient and low corporate cost structure. Our goal is to offer investors an opportunity to participate in the promise of the biotech industry in a profitable, diversified and lower-risk business than a typical biotech company. Our business model is based on doing what we do best: drug discovery, early-stage drug development, product reformulation and partnering. We partner with other pharmaceutical companies to leverage what they do best (late-stage development, regulatory management and commercialization) to ultimately generate our revenue. Ligand's Captisol<sup>®</sup> platform technology is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. OmniAb<sup>®</sup> is a patent-protected transgenic animal platform used in the discovery of fully human mono-and bispecific therapeutic antibodies. Ligand has established multiple alliances, licenses and other business relationships with the world's leading pharmaceutical companies including Novartis, Amgen, Merck, Pfizer, Celgene, Gilead, Janssen, Baxter International and Eli Lilly.

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## **Forward-Looking Statements**

This news release contains forward-looking statements by Ligand that involve risks and uncertainties and reflect Ligand's judgment as of the date of this release. These include statements regarding: the expectations regarding scheduling and future availability of ZULRESSO in the treatment of PPD; the statements regarding the potential for ZULRESSO to rapidly resolve PPD symptoms; estimates as to the number of women with PPD in the U.S. and rates of diagnosis; and the amount and timing of the milestone payment or royalty payments to be received by Ligand. All statements regarding ZULRESSO and PPD in this press release come from public statements made by Sage Therapeutics and Ligand has not independently verified such information. Actual events or results may differ from our expectations. For example, the Drug Enforcement Administration scheduling and launch of ZULRESSO may not occur on the timelines reported by Sage; Sage may encounter issues, delays or other challenges in launching or commercializing ZULRESSO, including issues related to market acceptance and reimbursement, challenges related to limiting the site of administration of the product to a certified healthcare facility monitored by a qualified healthcare provider, and the necessity for a Risk Evaluation and Mitigation Strategies plan; challenges associated with execution of Sage's sales and patient support activities, which in

each case could limit the potential of Sage's product; results achieved with ZULRESSO in the treatment of PPD once Sage has launched the product may be different than observed in clinical trials, and may vary among patients; Sage may encounter unexpected safety or tolerability issues with ZULRESSO; the number of patients with PPD or the unmet need for additional treatment options may be significantly smaller than Sage has reported; success in early stage clinical trials may not be repeated or observed in ongoing or future clinical trials; and Sage may encounter technical and other unexpected hurdles in the commercialization of ZULRESSO. The failure to meet expectations with respect to any of the foregoing matters may reduce Ligand's stock price. Additional information concerning these and other important risk factors affecting Ligand can be found in Ligand's prior press releases available at [www.ligand.com](http://www.ligand.com) as well as in Ligand's public periodic filings with the Securities and Exchange Commission, available at [www.sec.gov](http://www.sec.gov). Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this press release, except as required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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Ligand Pharmaceuticals Incorporated

Todd Pettingill

[investors@ligand.com](mailto:investors@ligand.com)

(858) 550-7893

@Ligand\_LGND

LHA

Bruce Voss

[bvoss@lhai.com](mailto:bvoss@lhai.com)

(310) 691-7100

Source: Ligand Pharmaceuticals Incorporated