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Ligand's Partner Melinta Therapeutics Announces U.S. FDA Approval of Baxdela™ (Delafloxacin) for Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

SAN DIEGO--(BUSINESS WIRE)-- **Ligand Pharmaceuticals Incorporated (NASDAQ: LGND)** announces that partner Melinta Therapeutics, a privately held company focused on discovering, developing, and commercializing novel antibiotics to treat serious bacterial infections, announced yesterday that the U.S. Food and Drug Administration (FDA) has approved Baxdela™ (delafloxacin), indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible bacteria. Baxdela is a fluoroquinolone that exhibits activity against both gram-positive and gram-negative pathogens, including MRSA (methicillin-resistant Staphylococcus aureus), and is available in both intravenous (IV) and oral formulations. Baxdela IV utilizes Ligand's Captisol® technology. As a result of the approval, Ligand has earned a $1.5 million milestone payment and will earn a 2.5% royalty on Baxdela IV sales.

"We congratulate Melinta for this first regulatory approval for Baxdela," said John Higgins, Chief Executive Officer of Ligand. "Melinta has been an excellent partner, efficiently managing their clinical development work and collaboratively interfacing with Ligand's technical team in successfully leveraging our Captisol technology for the IV formulation of Baxdela. We have identified this program as one of Ligand's Big Six partnered pipeline assets given its medical importance and stage of development. This approval and Melinta's recently-announced commercial and co-development agreement with Menarini Group position Baxdela for global commercial success."

"The approximately 3 million patients hospitalized each year in the U.S. with ABSSSI often present treatment challenges owing to their underlying medical conditions, making optimal antibiotic selection difficult. Baxdela provides a treatment option for adult patients with ABSSSI based on its coverage spectrum, IV and oral dosing flexibility, efficacy and safety profile," said Eugene Sun, M.D., CEO of Melinta. "The approval of Baxdela demonstrates FDA's commitment to making new and effective antibiotics available to address unmet needs for hospitalized ABSSSI patients."

"Antibiotic resistance is a growing concern, and physicians need more tools in the fight against this threat to modern medicine. Approval of new therapies like Baxdela, which is effective against MRSA and other serious pathogens, provides physicians another option in addressing the challenges of ABSSSI patients," said Dr. David Hooper, professor of medicine, Harvard University, and chief of Infection Control, associate chief, Division of

Infectious Diseases, Massachusetts General Hospital.

The Baxdela New Drug Application (NDA) approvals were supported by two Phase 3 studies in patients with ABSSSI, demonstrating that IV and oral Baxdela monotherapy was statistically non-inferior to the combination of vancomycin plus aztreonam at the FDA primary endpoint of early clinical response at 48-72 hours. Baxdela was well tolerated with a 0.9% discontinuation rate in the Phase 3 studies due to adverse events. In addition, Baxdela has not shown any potential for QT prolongation or phototoxicity in definitive clinical studies. There have been no signals of adverse effects on liver function, kidney function, or glucose regulation in controlled clinical studies. The 450 mg tablet is bioequivalent (area under the curve) to, and interchangeable with the 300 mg IV dose, and can be dosed without regard to food. There are no anticipated drug-drug interactions with delafloxacin other than co-administration with chelating agents, such as antacids.

Full prescribing information and medication guide for Baxdela will be made available at www.baxdelarx.com. For questions or comments, call 1-844-MELINTA (1-844-635-4682).

About Baxdela

Baxdela (delafloxacin) tablets and intravenous injection are approved for the treatment of ABSSSI (Acute Bacterial Skin and Skin Structure Infections). Baxdela was given priority review by the FDA due to its designation as a Qualified Infectious Disease Product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) Act of 2012. The QIDP designation qualifies Baxdela for certain incentives related to the development of new antibiotics, including a five-year extension of any non-patent exclusivity period awarded to the drug.

Indication & Usage

Baxdela is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following:

Gram-positive organisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis;

Gram-negative organisms: Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.

IMPORTANT SAFETY INFORMATION:
WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS, AND EXACERBATION OF MYASTHENIA GRAVIS

Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:

- **Tendinitis and tendon rupture**
- **Peripheral neuropathy**

- **Central nervous system effects**

Discontinue Baxdela immediately and avoid the use of fluoroquinolones, including Baxdela, in patients who experience any of these serious adverse reactions.

Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Baxdela in patients with known history of myasthenia gravis.

Contraindications

Baxdela is contraindicated in patients with known hypersensitivity to Baxdela or other fluoroquinolones.

Warnings and Precautions

Risk of tendinitis, tendon rupture, peripheral neuropathy and central nervous system effects is increased with use of fluoroquinolones. Discontinue Baxdela immediately at the first signs or symptoms of any of these serious adverse reactions.

Avoid Baxdela in patients with known history of myasthenia gravis.

Hypersensitivity Reactions may occur after first or subsequent doses of Baxdela. Discontinue Baxdela at the first sign of hypersensitivity.

Clostridium difficile-associated diarrhea has been reported in users of nearly all systemic antibacterial drugs, including Baxdela. Evaluate if diarrhea occurs.

Prescribing Baxdela in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions in patients treated with Baxdela were nausea (8%), diarrhea (8%), headache (3%), transaminase elevations (3%), and vomiting (2%).

Use in Specific Populations

In patients with severe renal impairment (eGFR of 15-29 mL/min/1.73 m2) dosing of Baxdela should be dosed at 200 mg IV every 12 hours or 450 mg orally every 12 hours. Baxdela is not recommended in patients with End Stage Renal Disease [ESRD] (eGFR of <15 mL/min/1.73 m2) due to insufficient information to provide dosing recommendations.

About Melinta Therapeutics

Melinta Therapeutics, Inc. is dedicated to saving lives threatened by the global public health crisis of bacterial infections, through the development and commercialization of novel antibiotics that provide new and better therapeutic solutions. Melinta's lead product is Baxdela, an antibiotic approved for use in the treatment of acute bacterial skin and skin structure infections (ABSSSI). Melinta is also committed to developing, through the application of Nobel Prize-winning science, a new class of antibiotics designed to overcome

the multi- and extremely-drug-resistant pathogens for which there are few to no options, known collectively as ESKAPE pathogens (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter species and Escherichia coli), which cause the majority of life-threatening hospital infections.

Melinta Therapeutics is privately held and backed by Vatera Healthcare Partners (www.vaterahealthcare.com) and Malin Corporation plc (www.malinplc.com), among other private investors. The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit www.melinta.com for more information.

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® platform technology is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. OmniAb® 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 Melinta will successfully launch Baxdela or that Baxdela will be successful following launch. Further, the size of the patient population may be smaller than anticipated or the medical field may identify greater concerns which may negatively impact the success of Baxdela. Actual events or results may differ from our expectations. For example, there can be no assurances that Melinta will successfully launch Baxdela or that Baxdela will be successful following launch. Further, the size of the patient population may be smaller than anticipated or the medical field may identify greater concerns which may negatively impact the success of Baxdela. 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 as well as in Ligand's public periodic filings with the Securities and Exchange Commission, available at 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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