



Innoviva Announces FDA Acceptance and Priority Review of New Drug Application for Sulbactam-Durlobactam (SUL-DUR)

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- *SUL-DUR is a targeted antibiotic that was specifically designed to treat serious infections caused by *Acinetobacter baumannii*, including multidrug-resistant and carbapenem-resistant strains, which have been identified by the CDC as an urgent global public health threat.*

BURLINGAME, Calif.--(BUSINESS WIRE)--Nov. 30, 2022-- Innoviva, Inc. (Nasdaq: INVA) ("Innoviva"), a diversified holding company with a portfolio of royalties and other healthcare assets, today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the new drug application (NDA) for SUL-DUR, an investigational drug for the treatment of infections caused by *Acinetobacter baumannii-calcoaceticus* complex (ABC), including multi-drug resistant and carbapenem-resistant strains. The Agency is currently planning to hold an advisory committee meeting to discuss this application. The target PDUFA date (or action date) is May 29, 2023.

The NDA submission is based on results from the landmark Phase 3 ATTACK trial evaluating the safety and efficacy of SUL-DUR versus colistin in patients with infections caused by ABC. In the trial, SUL-DUR demonstrated statistical non-inferiority versus colistin for the primary end point of 28-day all-cause mortality in patients with carbapenem-resistant ABC infections and a significant difference in clinical cure rates. SUL-DUR also exhibited a favorable safety profile with statistically significant reduction in nephrotoxicity.

"Carbapenem-resistant and multidrug-resistant *Acinetobacter* infections are an urgent and emergent threat due to increasing rates of resistance and few viable treatment options. The acceptance of our NDA brings us one step closer to potentially delivering SUL-DUR to patients in this area of high unmet medical need," said David Altarac, MD, Chief Medical Officer of Entasis Therapeutics, a wholly-owned subsidiary of Innoviva. "Our focused and dedicated team looks forward to continuing to work with the FDA throughout the priority review process."

About the Phase 3 ATTACK Trial

The ATTACK trial was conducted to evaluate the efficacy and safety of SUL-DUR versus colistin, both in combination with imipenem/cilastatin as background therapy, for patients with *Acinetobacter baumannii-calcoaceticus* complex (ABC) infections, including carbapenem-resistant and multidrug-resistant strains. The trial consisted of two parts: Part A was a randomized, blinded arm (SUL-DUR versus colistin; non-inferiority margin 20%) in ABC hospital-acquired pneumonia, ventilator-associated bacterial pneumonia, ventilated pneumonia, or bacteremia; Part B was an open label arm (SUL-DUR only) that enrolled patients with ABC infections who did not tolerate colistin/polymyxin B or whose pathogens were resistant to colistin/polymyxin B. The primary efficacy endpoint for the trial was 28-day all-cause mortality. The primary safety objective of the trial was incidence of nephrotoxicity (as measured by the modified RIFLE Criteria).

About *Acinetobacter*

Members of the *Acinetobacter baumannii-calcoaceticus* complex (ABC) are Gram-negative, opportunistic human pathogens that predominantly infect critically ill patients often resulting in severe pneumonia and bloodstream infections. They can also infect other body sites, such as the urinary tract and the skin. ABC is considered a global threat in the healthcare setting due in part to its ability to acquire multidrug resistance. Based on current carbapenem resistance rates, we estimate there are more than 300,000 hospital-treated carbapenem-resistant ABC infections each year globally for which significant morbidity and mortality exists due to limited treatment options.

About sulbactam-durlobactam (SUL-DUR)

SUL-DUR is an intravenous, or IV, investigational drug that is a combination of sulbactam, an IV β -lactam antibiotic, and durlobactam, a rationally designed broad-spectrum IV β -lactamase inhibitor, or BLI, being developed for the treatment of infections caused by ABC, including multi-drug and carbapenem-resistant strains. SUL-DUR has been designated a Qualified Infectious Disease Product by the FDA, a designation that aims to spur development of new antibiotics for difficult-to-treat infections.

About Innoviva

Innoviva is a diversified holding company with a portfolio of royalties and other healthcare assets. Innoviva's royalty portfolio includes respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR[®]/BREO[®] ELLIPTA[®] (fluticasone furoate/ vilanterol, "FF/VI") and ANORO[®] ELLIPTA[®] (umeclidinium bromide/ vilanterol, "UMEC/VI"). Under the Long-Acting Beta2 Agonist ("LABA") Collaboration Agreement, Innoviva is entitled to receive royalties from GSK on sales of RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®]. Innoviva's other healthcare assets include infectious disease and hospital assets stemming from acquisitions of Entasis Therapeutics, including its lead asset sulbactam-durlobactam, and La Jolla Pharmaceutical, including GIAPREZA[®] (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock and XERAVAL[®] (eravacycline) for the treatment of complicated intra-abdominal infections in adults.

ANORO[®], RELVAR[®] and BREO[®] are trademarks of the GSK group of companies.

Forward Looking Statements

This press release contains certain “forward-looking” statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, and future events. Innoviva intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. The words “anticipate”, “expect”, “goal”, “intend”, “objective”, “opportunity”, “plan”, “potential”, “target” and similar expressions are intended to identify such forward-looking statements. Such forward-looking statements involve substantial risks, uncertainties, and assumptions. These statements are based on the current estimates and assumptions of the management of Innoviva as of the date of this press release and are subject to known and unknown risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Innoviva to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: expected cost savings; lower than expected future royalty revenue from respiratory products partnered with GSK; the commercialization of RELVAR[®]/BREO[®] ELLIPTA[®], ANORO[®] ELLIPTA[®] and, formerly, TRELEGY[®] ELLIPTA[®] in the jurisdictions in which these products have been approved; the strategies, plans and objectives of Innoviva (including Innoviva’s growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner, and amount of potential capital returns to shareholders; the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; and projections of revenue, expenses and other financial items; the impact of the novel coronavirus (“COVID-19”). Other risks affecting Innoviva are described under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in Innoviva’s Annual Report on Form 10-K for the year ended December 31, 2021 and Quarterly Reports on Form 10-Q, which are on file with the Securities and Exchange Commission (“SEC”) and available on the SEC’s website at www.sec.gov. Past performance is not necessarily indicative of future results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The information in this press release is provided only as of the date hereof, and Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

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