Innoviva Stock Trading Halted Today

April 17, 2023

- *FDA Advisory Committee to review sulbactam-durlobactam for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia caused by susceptible strains of Acinetobacter*

BURLINGAME, Calif.--(BUSINESS WIRE)--Apr. 17, 2023-- Innoviva, Inc. (Nasdaq: INVA) (Innoviva), a diversified holding company with a portfolio of royalties and other healthcare assets, today announced that Nasdaq has halted trading of Innoviva's common stock.

The U.S. Food and Drug Administration's (FDA's) Antimicrobial Drugs Advisory Committee is meeting today to review and discuss the New Drug Application (NDA) for sulbactam-durlobactam, an investigational antibiotic being studied for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*).

The FDA Advisory Committee meeting is scheduled for 9:00 a.m. – 4:30 p.m. ET today. The briefing materials and webcast information for the meeting can be accessed here. Innoviva is not responsible for the content of, nor the statements made in, the briefing materials prepared by the FDA.

The sulbactam-durlobactam NDA, filed by Entasis Therapeutics Inc., a wholly owned subsidiary of Innoviva, is currently under Priority Review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of May 29, 2023.

About sulbactam-durlobactam
Sulbactam-durlobactam is an intravenous, or IV, investigational drug that is a combination of sulbactam, a beta-lactam antibacterial, and durlobactam, a beta-lactamase inhibitor, being developed for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex *(Acinetobacter)*. Sulbactam-durlobactam has been designated a Qualified Infectious Disease Product by the FDA, a designation that aims to spur development of new antibiotics for serious and life-threatening infections. In November 2022, the FDA accepted the New Drug Application (NDA) for sulbactam-durlobactam for Priority Review and set a Prescription Drug User Fee Act (PDUFA) target date of May 29, 2023.

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 critical-care assets stemming from acquisitions of Entasis Therapeutics Inc., including its lead asset sulbactam-durlobactam, and La Jolla Pharmaceutical Company, including GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock, and XERAVA® (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, 2022 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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Investors

Argot Partners
(212) 600-1902
innoviva@argotpartners.com

Media
Green Room Communications
(412) 327-9499
ISTMedia@grcomms.com

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