# Innoviva Specialty Therapeutics Announces Distribution and Licensing Agreement with Dr. Reddy's for XACDURO® in Select International Markets

June 16, 2026

- *Agreement expands access to XACDURO® for patients with serious Acinetobacter baumannii-calcoaceticus complex (Acinetobacter) infections across South and Central America, the Caribbean, Russia and CIS countries (following applicable regional regulatory approvals)*
- *The rate of carbapenem resistant -Acinetobacter in these geographies exceeds 70%[1,2] representing substantial unmet need*

WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 16, 2026-- Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (Nasdaq: INVA), today announced that it has entered into an exclusive distribution and licensing agreement with Dr. Reddy's Laboratories Ltd., a global pharmaceutical company, for the development and commercialization of XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use, in South and Central America, the Caribbean, Russia and Commonwealth of Independent States (CIS) countries. In the United States, XACDURO® is approved and indicated for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex (Acinetobacter).

*Acinetobacter* is a significant public health concern and is classified as a "critical threat" pathogen in World Health Organization global bacterial priority pathogens list[3].

Under the terms of the agreement, Dr. Reddy's will be responsible for development, regulatory and commercialization activities in the licensed territory. Innoviva Specialty Therapeutics will retain rights to XACDURO in all unlicensed territories and is eligible to receive an upfront payment, regulatory and commercial milestone payments, and tiered royalties on net sales in the licensed territory.

"This agreement reflects our ongoing commitment to addressing antimicrobial resistance by expanding access to important therapeutics for patients and healthcare systems facing serious, difficult-to-treat infections," said Patricia Drake, Chief Commercial Officer of Innoviva Specialty Therapeutics. "Dr. Reddy's brings strong regional capabilities and experience in infectious disease treatments, and we believe this partnership provides a practical path to broaden XACDURO's global reach while maintaining our focus on disciplined execution."

XACDURO is the first and only antibiotic approved in the United States in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*). *Acinetobacter* infections remain a significant global health challenge, particularly in hospital settings where resistant pathogens can limit available treatment options. The FDA approved XACDURO in May 2023.

**About XACDURO®**

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use, is a combination of sulbactam, a beta-lactam antibacterial, and durlobactam, a beta-lactamase inhibitor, approved in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*). XACDURO is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter*.

**Current US FDA approved XACDURO® INDICATION & USAGE**

**Indication**

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use is indicated in adults for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

Limitations of Use

XACDURO is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

**Usage**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of XACDURO and other antibacterial drugs, XACDURO should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**: XACDURO is contraindicated in patients with a history of known severe hypersensitivity to the components of XACDURO or other beta-lactam antibacterial drugs.

**Warnings and Precautions:**

- Hypersensitivity was observed in patients treated with XACDURO in clinical trials. Serious and occasionally fatal

hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before initiating therapy with XACDURO, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta lactams, and other allergens. If an allergic reaction occurs, discontinue XACDURO.

- *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs. If CDAD is suspected or confirmed, the risk/benefit of continuing treatment with XACDURO should be assessed.
- Prescribing XACDURO in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication 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 reported in >10% of patients treated with XACDURO were liver test abnormalities (19%), diarrhea (17%), anemia (13%), and hypokalemia (12%).

To report SUSPECTED ADVERSE REACTIONS, contact Innoviva Specialty Therapeutics, Inc. at 1-800-651-3861 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**Before administering, please see the Full Prescribing Information for XACDURO.**

**About Innoviva Specialty Therapeutics**

Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc., is focused on delivering innovative therapies in critical care and infectious disease. Innoviva Specialty Therapeutics' products, through its affiliates, include GIAPREZA ® (angiotensin II), XERAVA® (eravacycline), XACDURO® (sulbactam for injection; durlobactam for injection), and NUZOLVENCE® (zoliflodacin). Innoviva Specialty Therapeutics also markets ZEVTERA (ceftobiprole), an advanced-generation cephalosporin antibiotic, in the U.S. through an exclusive license from Basilea Pharmaceutica International Ltd, Allschwil. For more information about Innoviva Specialty Therapeutics, please visit www.innovivaspecialtytherapeutics.com.

**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®, GIAPREZA®, XERAVA®, XACDURO®, ZEVTERA® and NUZOLVENCE® 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); the timing, manner, and amount of potential capital returns to shareholders; the development of the LYNX® platform; 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 timing, manner and amount of capital deployment, including potential capital returns to stockholders; and risks related to the Company's growth strategy. 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, 2025 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.

ANORO®, RELVAR® and BREO® are trademarks of the GSK group of companies. ZEVTERA is a trademark of Basilea Pharmaceutica International AG, Allschwil.

[1] Lavrinenko (2021) *Antibiotics*
[2] Rojas (2026) *Antibiotics*
[3] WHO Bacterial Priority Pathogens List (2024)

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**Investor and media contact**
Irwin Tendler
Head of Investor Relations
Executive Director, Corporate Development
investors.relations@inva.com

Source: Innoviva Specialty Therapeutics