



## Entasis Therapeutics, a Wholly Owned Subsidiary of Innoviva, Presents Efficacy and Safety Data from Landmark Phase 3 ATTACK Trial at IDWEEK 2022

October 19, 2022

### ***Presentations Reinforce Topline Safety and Efficacy Findings and Highlight Consistency between Clinical and Microbiological Endpoints***

**WALTHAM, Mass. — October 19, 2022 (Globe Newswire)**—[Entasis Therapeutics Holdings Inc.](#), a late-stage clinical biopharmaceutical company focused on the discovery and development of novel antibacterial products, and wholly owned subsidiary of Innoviva, Inc. (Nasdaq: INVA), today announced the presentation of additional safety and efficacy data from the Company's pivotal Phase 3 ATTACK trial. The study results will be presented at [IDWeek 2022](#), the annual meeting of the *Infectious Disease Society of America* held October 19-23, 2022 in Washington, D.C.

"The data we are presenting at *IDWeek 2022* reinforce the positive safety and efficacy findings we previously described from our topline data analysis," said David Altarac, MD, Chief Medical Officer of Entasis. "These data underscore the potential impact of SUL-DUR, if approved, as a treatment option for patients with drug-resistant *Acinetobacter* infections, where no current standard of care exists."

On Thursday, October 20 there will be two oral presentations and three poster presentations followed by an oral presentation Saturday, October 22<sup>nd</sup>.

### **Oral Presentations**

An oral presentation entitled *Microbiologic and clinical outcome concordance in the global phase 3 ATTACK trial: sulbactam-durlobactam (SUL-DUR) versus colistin therapy in patients with Acinetobacter baumannii-calcoaceticus complex (ABC) infections* will be presented October 20 1:45-3pm ET by David Altarac, MD Chief Medical Officer of Entasis. Results of the study showed non-inferiority in 28-day all-cause mortality and overall trends favoring SUL-DUR, such as higher clinical cure rate at Test of Cure and greater microbiologic favorable response at Test of Cure. The study showed that treatment with SUL-DUR demonstrated lower mortality, higher clinical cure rates, and greater microbiologically favorable outcomes than colistin in patients with carbapenem-resistant ABC infections. Concordance between clinical and microbiological outcomes was observed.

The second oral presentation entitled *Efficacy of sulbactam-durlobactam (SUL-DUR) versus colistin in patients with extensively drug-resistant (XDR) and pan-drug resistant (PDR) Acinetobacter baumannii-calcoaceticus complex (ABC) infections*, will be presented October 20 1:45-3pm ET by Alita Miller, PhD, interim Chief Scientific Officer for Entasis. Results showed that ABC isolates from patients in ATTACK were highly antibiotic-resistant, but >95% susceptible to SUL-DUR. Treatment with SUL-DUR demonstrated lower mortality, higher clinical cure rates, and greater microbiologically favorable outcomes than colistin in patients with XDR or PDR ABC infections. In global surveillance studies, 100% of PDR ABC isolates were susceptible to SUL-DUR.

The third oral presentation titled *Population pharmacokinetic (PPK), pharmacokinetic/pharmacodynamic attainment (PTA), and clinical pharmacokinetic/pharmacodynamic (PK/PD) analyses for sulbactam-durlobactam (SUL-DUR) to support dose selection for the treatment of Acinetobacter baumannii calcoaceticus complex (ABC) infections* will be presented October 22 1:45-3pm ET in the late breaking session by Sujata Bhavnani, PharmD, M.S., FIDSA of the Institute for Clinical Pharmacodynamics. This study evaluated PPK in 373 subjects, including 110 patients who received SUL-DUR and underwent PK sampling in the pivotal Phase 3 ATTACK trial. Investigators concluded that simulated plasma and ELF exposures yielded >90% probability of target attainment, which when combined with the favorable efficacy and safety findings from ATTACK, support a dose of 1.0 g sulbactam/1.0 g durlobactam via a 3-hour infusion, every 6 hours in patients with normal renal function and renal function-based dose adjustments.

### **Poster Presentations:**

In addition to the oral presentations, three poster presentations highlighted additional SUL-DUR and ATTACK trial details and results.

**Title:** Sulbactam-durlobactam (SUL-DUR) versus colistin therapy in patients with *Acinetobacter baumannii-calcoaceticus* complex (ABC) infections: A detailed safety review from the pivotal phase 3, global, randomized, active-controlled trial (ATTACK)

**Summary:** In the ATTACK trial, SUL-DUR achieved the primary safety objective of significantly reduced incidence of nephrotoxicity compared with colistin, was generally well tolerated in severely ill patients, and demonstrated a favorable safety profile with no new safety signals identified.

**Presenter:** Drew Lewis, MD, MTM&H, FACP

**Poster #: 675**

**Date and time:** Thursday, October 20, 2022, 12:15pm-1:30pm ET

**Title:** Efficacy and safety of sulbactam-durlobactam (SUL-DUR) are consistent across regions in the global ATTACK phase 3 trial in the treatment of carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex (CRABC) infections

**Summary:** Results were consistently favorable for SUL-DUR vs colistin across regions for 28-day and 14-day all-cause mortality, clinical cure, microbiological favorable outcome, and nephrotoxicity based on RIFLE criteria.

**Presenter:** Khurram Rana, PharmD

**Poster #: 225**

**Date and time:** Thursday, October 20, 2022, 12:15pm-1:30pm ET

**Title:** Characterization of colistin-resistant (COL-R) *Acinetobacter baumannii-calcoaceticus* complex (ABC) isolates from a recent global phase 3 trial (ATTACK)

**Summary:** A large number of ABC infections in ATTACK were colistin-resistant (COL-R); most of which were in Europe. SUL-DUR maintained *in vitro* activity against colistin-resistant, XDR and PDR subsets of ABC isolates from ATTACK. Patients with COL-R infections treated with SUL-DUR had favorable clinical and microbiological outcomes.

**Presenter:** Sarah McLeod, PhD

**Poster #: 518**

**Date and time:** Thursday, October 20, 2022, 12:15pm-1:30pm ET

All Entasis *IDWeek 2022* presentations will be made available on the Entasis website <https://www.entasistx.com/our-science/presentations-by-event>.

### **About Sulbactam-Durlobactam (SUL-DUR)**

SUL-DUR is an intravenous, or IV, investigational drug that is a combination of sulbactam, an IV  $\beta$ -lactam antibiotic, and durlobactam, a novel broad-spectrum IV  $\beta$ -lactamase inhibitor, or BLI, being developed for the treatment of infections caused by *Acinetobacter baumannii calcoaceticus* complex (ABC), including carbapenem-resistant strains. Top-line results were [announced](#) in October 2021.

### **SUL-DUR Expanded Access Program**

Entasis Therapeutics will consider providing a requesting physician with pre-approval access to SUL-DUR, for the treatment of an individual patient outside of a clinical trial, when certain conditions are met. More information about its [Expanded Access Program](#) and policies is available [here](#).

### **About Entasis Therapeutics Holdings Inc.**

Entasis is a late-stage clinical biopharmaceutical company, and wholly owned subsidiary of Innoviva, Inc., is focused on the discovery, development, and commercialization of novel antibacterial products to treat serious infections caused by multidrug-resistant Gram-negative bacteria. Entasis' pathogen-targeted design platform has produced a pipeline of product candidates, including SUL-DUR (targeting *Acinetobacter baumannii* infections), zoliflodacin (targeting *Neisseria gonorrhoeae* infections), ETX0282CPDP (targeting Enterobacterales infections) and ETX0462 (targeting Gram-negative infections including *Pseudomonas*). For more information, visit [www.entasistx.com](http://www.entasistx.com).

### **About Innoviva**

Innoviva is a diversified holding company with a portfolio of royalties and innovative healthcare investments and assets. Its royalty portfolio includes respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, "FF/VI"), ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, "UMEC/VI") and, formerly, TRELEGY® ELLIPTA® (the combination FF/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®. ANORO®, RELVAR®, BREO®, TRELEGY® and ELLIPTA® are trademarks of the GSK group of companies.

Innoviva strengthened its portfolio in the hospital and infectious disease space through the acquisition of Entasis Therapeutics Holdings Inc. and La Jolla Pharmaceutical Co. Its development pipeline includes potentially first- and best-in-class medicines for the treatment of multidrug-resistant bacteria, including lead asset SUL-DUR. The Company's commercial and marketed products include 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 (cIAIs).

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### **Cautionary Statement Regarding Forward Looking Statements**

*To the extent that statements contained in this press release are not descriptions of historical facts, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements include any statements regarding Innoviva's completion of the offering, the anticipated principal amount of securities sold, the final terms of the offering, Innoviva's anticipated use of proceeds, Innoviva's ability to repurchase the 2023 Notes and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. The Company undertakes no obligation to update or revise any forward-looking statements. Forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Company's business in general, see the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 28, 2022, which is on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov). In addition to the risks described above and in Innoviva's other filings with the SEC, other unknown or unpredictable factors also could affect Innoviva's results. 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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