

## **Cipla USA furthers AMR stewardship with acquisition of key anti-infective ZEMDRI™ (IV Plazomicin)**

- **Cipla USA to hold worldwide rights (excluding Greater China) of ZEMDRI™ (IV Plazomicin)**
- **Plazomicin is an IV aminoglycoside with once-daily dosing for cUTI in adults, with proven activity against certain drug-resistant bacteria**
- **Acquisition consistent with Cipla's legacy of pioneering contribution to global healthcare challenges, industry leadership in anti-microbial resistance (AMR) stewardship practices and expertise in manufacturing, marketing and educational programs in the anti-infective segment**
- **Product to add depth and synergy to pipeline of specialty products in the U.S.**

**Warren, New Jersey & Mumbai, India; July 24, 2019:** Cipla USA Inc. ("Cipla USA"), a wholly-owned subsidiary of the leading global pharmaceutical company Cipla Limited (BSE: 500087; NSE: CIPLA EQ; hereafter referred to as "Cipla"), announced the acquisition of the prescription drug ZEMDRI™ (Plazomicin) from Achaogen Inc. ("Achaogen") in a Chapter 11, U.S. Bankruptcy Code auction of Achaogen's assets. Cipla USA has acquired worldwide rights of ZEMDRI™ (excluding Greater China) with its allied assets and limited liabilities.

ZEMDRI™ is a once-daily novel intravenous (IV) aminoglycoside for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, in adults who are unresponsive to currently available treatment options. ZEMDRI™ was approved by the United States Food & Drug Administration (USFDA) in June 2018, and was launched in the same year, with patent protection expected to continue until 2031 or 2032. It has been granted a new technology add-on payment (NTAP) by the Centers for Medicare & Medicaid Services (CMS), for its administration in a hospital in-patient setting. The product has also been filed for approval in the European Union (EU).

ZEMDRI™ is the latest milestone in Cipla's history of proactive and humanitarian leadership in enabling access to life-saving drugs. In 2001, at the height of the global HIV movement, Cipla changed the treatment paradigm with its offer of a triple combination anti-retroviral therapy at less than a dollar a day in Africa against the prevailing price of around USD 12,000 a year for one patient. With anti-microbial resistance (AMR) today being an urgent global healthcare challenge, Cipla has been at the forefront of AMR stewardship. Plazomicin is a novel antibiotic effective against some of the cUTI-causing gram-negative bacteria that are resistant to beta-lactam



antibiotics including carbapenems. Clinical studies have shown sustained microbiological eradication of the bacteria with Plazomicin.

Cipla is a signatory to the Industry Declaration on AMR at the World Economic Forum in Davos in 2016 that laid out a roadmap to combat AMR. An independent analysis released by the Access to Medicine Foundation in January 2018 identified Cipla as one of the drug-makers leading the effort to curb overuse of antibiotics, and implement production and source systems that help prevent environmental release of antibiotics<sup>1</sup>. Its Antibiotic Benchmark Report recognised Cipla for its work in educating healthcare practitioners (HCPs), illustrating AMR trends in marketing material, adapting packaging to support rational use, and engaging in AMR surveillance<sup>2</sup>. In India, Cipla has a long history of antibiotic development from ampicillin in the 1970s to quinolones in the 1990s. More recently, Cipla introduced the extremely effective antibiotic colistin in India.

**Umang Vohra, Managing Director and Global Chief Executive Officer, Cipla, said:** "The acquisition of ZEMDRI™ deepens our pipeline of specialty products in the U.S. in our identified focus areas of central nervous system, lung delivery of medicines, and institutionally administered products. With a robust front-end commercial infrastructure for U.S. hospital sales in place, we expect to extract strong synergy from our IV Plazomicin and IV Tramadol assets. Cipla has been a leading industry voice in the fight against AMR and our expertise in manufacturing, marketing and conducting educational programs in the antibiotic segment makes us well-placed to take ZEMDRI™ globally to expand our leadership position."

#### **About ZEMDRI™:**

ZEMDRI™ is an aminoglycoside with once-daily intravenous dosing that has activity against certain Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (CRE) and extended-spectrum beta-lactamases (ESBL) producing Enterobacteriaceae. Achaogen's EPIC (Evaluating Plazomicin In cUTI) clinical trial successfully evaluated the safety and efficacy of ZEMDRI in adult patients with cUTI, including pyelonephritis. ZEMDRI™ is engineered to overcome aminoglycoside-modifying enzymes, the most common aminoglycoside-resistance mechanism in Enterobacteriaceae, and has *in vitro* activity against ESBL- producing, aminoglycoside-resistant, and carbapenem-resistant isolates. The Centers for Disease Control and Prevention (CDC) has characterized ESBL- producing Enterobacteriaceae as a "serious threat" and CRE as "nightmare

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<sup>1</sup> For more: <https://accesstomedicinefoundation.org/newsroom/superbugs-first-independent-comparison-of-pharma-companies-efforts-to-address-drug-resistant-infections> (last accessed July 21, 2019)

<sup>2</sup> For more: <https://accesstomedicinefoundation.org/amr-benchmark/case-studies/case-3-broad-generic-antimicrobial-portfolio-cipla> (last accessed July 21, 2019)



bacteria", which is an immediate public health threat that requires urgent and aggressive action. The safety profile of Plazomicin is consistent with that of the traditional aminoglycosides. For more information on the product, indication and safety including boxed warning, please visit <https://zemdri.com/>.

#### **About Cipla USA:**

Cipla USA is a wholly-owned subsidiary of Cipla representing its direct market presence in the U.S., and focused on marketing the highest quality pharmaceutical products in the retail and institutional spaces in the country. The addition of InvaGen Pharmaceuticals, Inc. and Exelan Pharmaceuticals, Inc in 2016, including the manufacturing facilities in New York, strengthened Cipla USA's presence in the U.S. By leveraging Cipla's strong R&D and manufacturing capabilities, Cipla USA has been able to build a strong organic pipeline of limited competition complex generic products, and explore an inorganic portfolio of specialty products, all with a view to offering meaningful healthcare solutions to patients in the country. Cipla USA is headquartered in Warren, New Jersey, and is today among the most dispensed generic players by prescription. For more information, please visit [www.ciplausa.com](http://www.ciplausa.com).

#### **About Cipla:**

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well known. Our 46 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Mar'19), 3rd largest in the pharma private market in South Africa (IQVIA MAT Mar'19), and is among the most dispensed generic players in the U.S. For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility and affordability to the centre of the movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit [www.cipla.com](http://www.cipla.com), or click on [Twitter](#), [Facebook](#), [LinkedIn](#).



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