



Arpida Comments on FDA's Anti-infective Drugs Advisory Committee Outcome

Reinach, Switzerland, November 20, 2008 – Arpida (SWX: ARPN) announced today that the Anti-infective Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has voted 17 to 2 against the approval of intravenous iclaprim, an antibiotic currently in development for the treatment of patients with complicated skin and skin structure infections (cSSSIs), including those caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

Arpida remains confident in the efficacy and safety of intravenous iclaprim and its potential in combating serious resistant infections. Iclaprim has been tested against both vancomycin and linezolid, and in combined Phase III studies that included nearly 1,000 patients with cSSSI, iclaprim has been shown to have high cure rates, exceeding 90 percent in the Per-Protocol population. Iclaprim has demonstrated potent bactericidal (killing) activity against MRSA and an extended range of resistant pathogens, with a well tolerated side-effect profile. Arpida is fully committed to iclaprim's development and will continue to work with the FDA to address any questions related to iclaprim in anticipation of the drug's Prescription Drug User Fee Act (PDUFA) goal date of January 16, 2009.

In addition to the FDA regulatory application, the European Medicines Agency (EMA) accepted intravenous iclaprim for review August 2008. In September 2008, Arpida filed a New Drug Submission for intravenous iclaprim in Canada.

Arpida continues to study the potential of iclaprim, including investigation of an oral formulation. In early 2008, Arpida received FDA approval to conduct a Phase II iclaprim 'intravenous-to-oral' switch trial in patients with cSSSI. Patient enrolment was completed in September 2008 and results are expected in December 2008.

Additional studies are ongoing worldwide to investigate the use of intravenous iclaprim in hospital-acquired pneumonia, ventilator-associated pneumonia and healthcare-associated pneumonia.

Committed to the future development and commercialization of iclaprim, Arpida has anticipated potential scenarios and instituted judicious business plans that allow for

continued development of its portfolio of products. Arpida continues to work in close collaboration with regulatory authorities to obtain intravenous iclaprim market authorization in the United States and Europe.

About MRSA

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a type of bacteria that is resistant to most commonly available antibiotics.ⁱ MRSA infections occur most frequently among persons who have weakened immune systems in hospitals and healthcare facilities; however community-associated MRSA infections, such as abscesses, boils, and other pus-filled lesions, are increasingly being diagnosed in healthy people who have not been recently hospitalized or have undergone medical procedure.^{iii, ii} The most common antibiotic used to treat MRSA infections is vancomycin, but recent evidence suggests resistance to vancomycin is on the rise.^{iii, iv}

Approximately 2.3 million people in the United States acquire MRSA and 89.4 million people are colonized with *S. aureus* annually, according to the Centers for Disease Control and Prevention (CDC).^{i, v} An estimated 292,000 hospitalizations with a diagnosis of *S. aureus* infection occur annually in U.S. hospitals and, of these, approximately 126,000 hospitalizations are related to MRSA.^{vi} MRSA is responsible for an average of 94,000 life-threatening infections and 18,650 deaths each year in the United States.^{vii}

About Iclaprim

Iclaprim is an antibiotic currently in development for the treatment of serious infections requiring hospitalization caused by Gram-positive bacteria, including those caused by MRSA. Iclaprim was designed to meet a growing medical need for additional treatment options to combat resistant infections and is the first antibiotic in the dihydrofolate reductase (DHFR) selective inhibitor class to demonstrate efficacy against cSSSIs caused by MRSA. The DHFR class has been proven safe and effective in more than four decades of clinical use.

About Arpida

Arpida (SWX: ARPN) is a biopharmaceutical company headquartered in Reinach, Switzerland with operations in Switzerland and the United States. It focuses on the discovery, development and commercialization of novel drugs for the treatment of microbial infections. Arpida has a fully integrated platform for the discovery and development of drug candidates to address the increasing prevalence of resistance of bacteria, such as methicillin-resistant *Staphylococcus aureus* (MRSA), to existing antibiotic therapies. Arpida is currently developing an iclaprim oral formulation as a step-down therapy after intravenous

therapy. Apart from the flagship iclaprim program, Arpida has an innovative antifungal treatment in Phase III clinical development as well as several earlier-stage programs (AR-709 and AR-2474).

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ⁱ Centers for Disease Control and Prevention Web site. Healthcare-Associated Methicillin Resistant Staphylococcus aureus (HA-MRSA) Overview. Available at http://www.cdc.gov/ncidod/dhqp/ar_MRSA.html. Accessed October 22, 2008.

ⁱⁱ Centers for Disease Control and Prevention Web site. Community-Associated Methicillin Resistant Staphylococcus aureus (CA-MRSA) Overview. Available at http://www.cdc.gov/ncidod/dhqp/ar_mrsa_ca.html. Accessed October 22, 2008.

ⁱⁱⁱ Sakoulas, G et al. Clinical Infectious Diseases 2006; 42: S40-S50.

^{iv} Tenover F, Moellering RC Jr. Clinical Infectious Diseases 2007; 44: 1208-15.

^v Centers for Disease Control and Prevention Web site. S. aureus and MRSA Surveillance Summary 2007. Available at http://www.cdc.gov/ncidod/dhqp/ar_mrsa_surveillanceFS.html. Accessed October 22, 2008.

^{vi} Kuehnert MJ et al. Emerging Infectious Diseases 2005; 11: 868-72.

^{vii} Klevens, RM et al. Journal of the American Medical Association. 2007; 298: 1763-71.