



**ARPIDA ANNOUNCES POSITIVE RESULTS IN FIRST PHASE III TRIAL OF ICLAPRIM IN COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS**

- **Iclaprim achieves primary efficacy endpoint in first Phase III trial: statistical non-inferiority to Zyvox®**
- **Excellent safety profile - no serious adverse events related to treatment**

**Muenchenstein / Basel, Switzerland, November 30<sup>th</sup>, 2006.** Arpida Ltd. (SWX: ARPN) today announced positive results from the ASSIST-1 (Arpida's Skin and Skin Structure Infection Studies) clinical trial. In this Phase III trial, iclaprim was compared to linezolid, marketed by Pfizer as Zyvox®. The primary efficacy endpoint of statistical non-inferiority in the clinical cure rate at the Test-Of-Cure (TOC) visit was achieved.

Dennis Stevens, MD, PhD, Professor of Medicine at the University of Washington and Chief of the Infectious Disease Section at the Veterans Administration Medical Center Boise, Idaho (USA), the principal investigator in the ASSIST-1 programme commented: "Arpida designed the ASSIST clinical trials to compare iclaprim to linezolid for efficacy because of emerging problems with vancomycin resistance among Gram positive pathogens and because at least one study demonstrated that linezolid was more effective than vancomycin for complicated skin and skin structure infections. This is a courageous and novel approach, but one in keeping with the FDA's desire to identify antibiotics that offer defined improvements in efficacy and safety. In this Phase III trial, iclaprim has shown good efficacy as well as excellent safety. Overall, the results of ASSIST-1 are a convincing indication of iclaprim's potential to become a valuable weapon in the fight against resistant bacteria – an area of high and increasing unmet medical need."

"I am delighted by the positive results from this study: they constitute a major milestone in our efforts to demonstrate the effectiveness and safety of iclaprim. With these data, iclaprim has now been compared with both vancomycin (Phase II) and linezolid (Phase III). In particular, I am pleased with the excellent safety profile demonstrated by iclaprim, comparing very favourably to that of linezolid. In this study, no serious adverse events occurred as a result of treatment. Moreover, no adverse event exceeded 5% of the Intent-To-Treat population," Dr Khalid Islam, President and CEO of Arpida Ltd, commented.

Dr Islam added: "I would like to take this opportunity to thank all patients, Arpida staff as well those involved at the clinical sites and at third parties, whose efforts have been fundamental to the successful and timely completion of this study. With these results, we remain on track for filing a New Drug application with the FDA in 2007."

**ASSIST-1 Results**

Iclaprim demonstrated a clinical cure rate which was statistically non-inferior to that of linezolid at the Test-Of-Cure visit, thereby achieving the primary endpoint of the trial.

Of the total of 497 patients that were enrolled and treated (250 in the iclaprim arm and 247 in the linezolid arm), the vast majority had extensive cellulitis, abscesses, ulcers, burns or wounds. *Staphylococcus aureus* was the most common baseline pathogen (about 70%) and up to 25% of the isolates were methicillin-resistant strains (MRSA). For the microbiologically evaluable patients, the cure rates were 94.7% and 98.8% for iclaprim and linezolid, respectively.

The overall clinical cure rates for the Intent-To-Treat (ITT) population of 497 patients, were 85.5% and 91.9% for iclaprim and linezolid, respectively. For the clinically evaluable patients, the cure rates were 93.8% and 99.1% for iclaprim and linezolid, respectively.

Iclaprim showed an excellent safety profile which compared very favourably with that of linezolid. In this study there were no serious adverse events resulting from treatment. Overall, the proportion of patients in the iclaprim arm, reporting adverse events that were judged by the investigator to be possibly/probably related to treatment, was lower than in the linezolid arm (18.0% of the ITT population for iclaprim versus 25.1% for linezolid). No adverse event exceeded 5% of the ITT population.

The most frequent adverse events related to treatment were nausea (2.4% for iclaprim versus 4.5% for linezolid), headaches (2.8% for iclaprim versus 0.4% for linezolid), pruritis (1.6% for iclaprim versus 2.4% for linezolid), diarrhoea (2.0% for iclaprim versus 0.4% for linezolid) and pyrexia (1.6% for iclaprim versus 1.2% for linezolid).

Formal ECG Phase I studies suggested a potential for QTc prolongation with iclaprim and consequently ECG monitoring was performed in all patients enrolled. In the ASSIST-1 study, initially patients with a pre-treatment QTc interval exceeding 470ms were excluded. This exclusion criterion was removed in March 2006, following the review of the clinical data on the first 200 patients by the Data and Safety Monitoring Board.

In ASSIST-1, the mean maximal prolongation of the QTc interval from pre-treatment values with iclaprim was approximately 6.3ms versus 1.2ms with linezolid. Three patients showed a QTc interval exceeding 500ms (1 in the iclaprim arm and 2 in the linezolid arm). In five patients, a QTc increase relative to pre-treatment of more than 60ms was observed (2 cases in iclaprim arm and 3 cases in linezolid arm). No cardiac events were attributable to QTc prolongation.

### **ASSIST-1 Study Design**

Both ASSIST-1 and ASSIST-2 are international, multicentre, randomised, investigator-blind, comparative Phase III studies, designed to assess the efficacy and safety of Arpida's lead investigational antibiotic iclaprim in treating hospitalised adult patients with complicated skin and skin structure infections (cSSSI), including those infected with methicillin-resistant *Staphylococcus aureus* (MRSA).

In ASSIST-1, patients were randomly assigned (1:1) to receive intravenous iclaprim (0.8 mg/kg) or intravenous linezolid (600mg) for 10 to 14 days and were evaluated during treatment. The Test-Of-Cure visit was performed 7-14 days after the end of treatment.

The primary endpoint of this study was the clinical cure rate at the Test-Of-Cure visit, based on criteria set forth in the protocol previously reviewed by the US and European regulatory authorities.

ASSIST-1 was conducted in various countries in North America, Europe and the rest of the world. In total, 497 patients were enrolled. A similar number is foreseen for the currently ongoing ASSIST-2 trial.

- ends -

## Conference Call

A conference call to discuss these results will be held on November 2006, 30<sup>th</sup>, at 2 pm CET.  
The dial-in numbers are:

+41 (0) 91 610 56 00 (Europe)  
+44 (0) 207 107 0611 (UK)  
+ 1 (1) 866 291 4166 (USA)

The conference call (Call ID 334, followed by the #) will be available for play-back for 48 hours after the call by dialling:

+41 (0) 91 612 43 30 (Europe)  
+44 (0) 207 108 6233 (UK)  
+ 1 (1) 866 416 2558 (USA)

A Powerpoint presentation related to this press release will be available on [www.arpida.com](http://www.arpida.com) as from 1 pm today.

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## About Arpida Ltd.

Arpida (SWX: ARPN) is a biopharmaceutical company with research facilities near Basel, Switzerland, in Copenhagen, Denmark and in the USA. It focuses on the discovery and development of novel antibiotic drugs that seek to overcome the growing problem of bacterial resistance.

Arpida's leading product candidate is intravenous iclaprim, a broad-spectrum antibiotic that targets severe infections requiring hospital treatment, including those caused by methicillin-resistant *Staphylococcus aureus* (MRSA). Arpida is currently conducting global Phase III trials with intravenous iclaprim for the treatment of cSSSI (complicated skin and skin structure infections). The US Food and Drug Administration has granted fast track status to intravenous iclaprim for the treatment of cSSSI.

An oral formulation of iclaprim has successfully completed three Phase I trials: a radiolabelled ADME study (absorption, distribution, metabolism and excretion), a Phase I bioavailability trial with a solution and one with a capsule formulation. Arpida strongly believes that the availability of an oral formulation will be an important differentiating feature of iclaprim over virtually all of the antibiotics for the treatment of serious bacterial infections, particularly those caused by MRSA. Iclaprim could be offered not only as an intravenous therapy for hospital use in acute situations, but also as an oral formulation, allowing early patient discharge and outpatient treatment. This switch should be a valuable instrument in reducing healthcare costs and enhancing patient comfort.

Arpida's third most advanced programme, AR-709, targets upper and lower respiratory tract infections in the community setting. AR-709 exhibited potent activity against 611 pneumococcal clinical isolates from Europe, the USA and Asia irrespective of the mechanisms of resistance to currently used drugs. Arpida received authorisation to enter first-in-man studies with AR-709 in the UK in the second half of 2006.

In addition, the company has a further 12 antibiotic programmes derived from its own discovery platform, which are at various stages of research and development.

*This press release contains specific forward-looking statements, e.g. statements including terms like believe, assume, expect or similar expressions. Such forward-looking statements are subject to known and unknown risks, uncertainties and other factors which may result in a substantial divergence between the actual results, financial situation, development or performance of the company and those explicitly or implicitly presumed in these statements. Against the background of these uncertainties readers should not place undue reliance on forward-looking statements. The company assumes no responsibility to update forward-looking statements or to adapt them to future events or developments.*