



ARPIDA GRANTED IND FOR ORAL ICLAPRIM FROM US FDA

Oral antibiotic could provide new alternatives to care-givers

Muenchenstein / Basel, Switzerland, 13th July, 2005. Arpida Ltd (SWX: ARPN), a Swiss anti-infectives company, announced today that the US Food and Drug Administration (FDA) has granted an Investigational New Drug Application (IND) for the oral formulation of iclaprim, the company's second development programme for iclaprim as an oral antibiotic. The decision will allow Arpida to initiate a Phase I dose-escalation trial designed to investigate the safety, tolerability and pharmacokinetics of a capsule formulation of iclaprim. The injectable formulation of iclaprim is in a Phase III programme for the treatment of complicated skin and skin structure infections (cSSSI) in hospitals.

The Phase I study with oral iclaprim will be conducted in healthy male and female subjects. The primary objective of the ascending dose study is to determine the safety and tolerability of oral iclaprim for its further clinical development. The study will also provide additional data on the pharmacokinetics of this iclaprim formulation at different doses. Clinical trials (Phase I) with oral iclaprim are currently ongoing under approved protocols from the German Health Authorities. The IND will now allow Arpida to conduct global clinical studies of oral iclaprim under FDA-approved protocols.

Prof. John Bartlett, a leading specialist and Chief of the Division of Infectious Disease at Johns Hopkins University School of Medicine stated: "Resistant pathogens, in particular MRSA (methicillin-resistant *Staphylococcus aureus*), continue to be a social and economic burden. Today, we have limited options for outpatient therapy in this area of high medical need. An oral antibiotic that is active against MRSA and other resistant pathogens could be an important addition to the limited armamentarium currently available to infectious disease physicians."

Dr Khalid Islam, President and CEO of Arpida, said: "The IND for oral iclaprim is an important milestone for our second clinical programme. The development of an oral formulation of iclaprim will be an important contributor to the commercial success of this new antibiotic. Healthcare costs for hospital-acquired infections have been estimated to be \$5-6 billion for the US alone. In-hospital expenditure is the biggest component of this figure and consequently an oral formulation of iclaprim would offer the potential to discharge patients earlier leading to significant cost savings. In addition, early discharge could significantly reduce the probability of patients contracting new infections and enhance patient comfort. The dual possibility of intravenous and oral therapy with iclaprim may constitute an important advantage to the patients and to healthcare providers and clearly differentiates it from most other antibiotics for serious infections currently on the market or in development."

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About Arpida Ltd.

www.arpida.ch

Arpida, a biopharmaceutical company with research centres based near Basel and Copenhagen, is focused on the discovery and development of novel antibiotic drugs that seek to overcome the growing problem of bacterial resistance. Arpida uses an integrated multidisciplinary platform including genomics-assisted selection of novel antibacterial targets to develop its portfolio of potential drug candidates.

Arpida's leading product candidate is injectable iclaprim, a broad-spectrum antibiotic that targets severe infections requiring hospital treatment, including those caused by MRSA (methicillin-resistant *Staphylococcus aureus*). In March 2005, Arpida received clearance from the FDA to conduct Phase III clinical trials for injectable iclaprim in the US as part of a global Phase III programme for the treatment of cSSSI (complicated skin and skin structure infections).

An oral formulation of iclaprim is in Phase I clinical trials. Oral iclaprim could offer an alternative to switch patients from any existing intravenous antibiotic and thus allow earlier hospital discharge.

Arpida's third most advanced programme, AR-709, targets severe respiratory tract and inner ear infections in the community setting. AR-709 is in late pre-clinical development. In addition, the company has a further 12 pre-clinical antibiotic programmes derived from its own discovery platform, which are at various stages of development.

In May 2005, Arpida listed on the SWX Swiss Exchange (ticker: ARPN) raising a total of CHF97.2 million (€63 million). The company has research facilities near Basel, Switzerland and in Copenhagen, Denmark, and it currently employs 75 people.

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