

Ipsat Therapies Announces Positive Top-line Data from Phase IIb Study of Ipsat P1A

Helsinki, Finland, 25 October, 2007 – Ipsat Therapies announced today that the Ipsat P1A phase IIb study met both primary endpoints.

Ipsat P1A is the most advanced of Ipsat's portfolio of beta-lactamases, specifically designed to inactivate residual amounts of antibiotics in the patients' gastrointestinal tract, after parenteral administration of beta-lactam antibiotics for serious infections.

The recently completed Phase IIb study was a randomised, placebo controlled, double blind, multi-center study in hospitalized patients treated with intravenous ampicillin for serious respiratory infections. It was designed to evaluate the preventative effect of oral administration of Ipsat P1A on the changes in intestinal microflora, development of antimicrobial resistance and gastrointestinal side effects induced by ampicillin. Group 1 (n=54) was treated with intravenous ampicillin and oral P1A, and group 2 (n=58) was treated with intravenous ampicillin and placebo.

Ampicillin treatment led to significant changes in intestinal microflora, with a reduction in 'similarity index' and an increase in the number of ampicillin-resistant coliforms compared to baseline. Administration of Ipsat P1A effectively prevented these effects, as demonstrated by a smaller decrease in similarity index in the treated group compared to placebo (-27.2% vs -44.5%, respectively, $p < 0.001$). Treatment with P1A also reduced the emergence of ampicillin-resistant coliforms by more than 3-fold compared to placebo (+ 12.7% vs + 40.2%, respectively, $p < 0.001$). The study therefore met primary end-points, in both intent-to-treat and per protocol populations.

"We are delighted with the outcome of this trial. It clearly shows the efficacy of Ipsat P1A in preserving the intestinal microflora and preventing the emergence of antibiotic-resistant bacteria. By protecting the intestinal microflora, Ipsat P1A preserves colonization resistance during antibiotic treatment", commented Nora Kaarela, CEO of Ipsat Therapies.

P1A was well tolerated. The rate of overall adverse events was comparable between the two treatment groups. Four patients developed diarrhea, three in the placebo group and one in the treated group.

When the normal intestinal microflora is altered during parenteral antibiotic treatment, an overgrowth of pathogenic and resistant bacteria and of *Candida*

species are observed, potentially leading to clinically important secondary infections, such as *C. difficile*. "We believe P1A and its follow-on products have the potential to significantly contribute to safer and more cost-efficient treatment with antibiotics, by reducing secondary infections and minimizing the spread of bacterial resistance in the environment", commented Kaarela.

During 2008 IPSAT will initiate additional clinical studies with the objective of demonstrating reduction in the frequency of secondary infections during antibiotic treatment. These activities will be financed by proceeds from a financing round that will close in early 2008. "In parallel to our clinical development of P1A and further advancement of our preclinical beta-lactamase projects we aim to enter into one or several strategic partnerships in order to maximize the commercial potential of our portfolio", says Nora Kaarela.

About Gut Microflora and the Similarity Index

The human gastrointestinal tract harbors a diverse community of microorganisms, consisting mainly of anaerobic bacteria. Denaturing gradient gel electrophoresis (DGGE) is a culture-independent method giving information about the human intestinal bacterial community including species that are difficult if not impossible to culture. DGGE is an electrophoretic technique to separate the 16S ribosomal-RNA gene sequences of similar size, but with different base-pair compositions, producing a molecular fingerprint profile of the microbial community. These fingerprint profiles are compared to each other by computer analysis resulting in calculation of the Similarity Index (%) between the individual profiles.

The effect of antibiotic therapy on the intestinal microflora is evaluated by comparing the DGGE fingerprint profile (Similarity Index) from fecal samples before antibiotic treatment with samples taken during or after treatment.

About hospital infections

Hospital-acquired infections are a major cause of morbidity in developed countries. It is estimated that 7.5 million patients suffer from hospital-acquired infections a year and nearly 340,000 of them die. The financial costs associated with hospital infections are equally staggering. Dr. John A. Jernigan, Chief of Interventions and Evaluations at the CDC, has said that hospital-acquired infections result in up to \$27.5 billion in additional health care expenses annually in the USA. At the beginning of August 2007, new Medicare rules were issued, under which the government insurance program will no longer pay hospitals for care associated with treating certain hospital-acquired infections. The new rules will go into effect in October 2008. Medicare reportedly pays for more than 60% of the hospital infections in the USA. The Centers for Medicare and Medicaid Services (CMS) have reported to be considering expanding the list of hospital infections for non-payment in future years.

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Notes to editors:

Ipsat Therapies

Ipsat Therapies Ltd is a private company focusing on the development of products in the anti-infective field. Ipsat's focus is primarily on the development of products for the prevention of antibiotic resistance, antibiotic-associated diarrhea and hospital associated infections. The Company became operational early 2000 and has raised €22 million in funding to date. For more information please visit <http://www.ipsat-ther.com>.