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News

**Enanta Pharmaceuticals Presents Safety Data On Novel
Cyclosporin-A Analogs for Asthma**

**Data presented at 2nd Annual Meeting of the
Federation of Clinical Immunologists Societies (FOCIS)**



WATERTOWN, Mass., July 1, 2002 -- Enanta Pharmaceuticals Inc. presented data today from preclinical toxicology and ADME (absorption, distribution, metabolism and excretion) studies of its novel cyclosporin softdrug analogs.

Last month, the company announced that it had discovered a new class of *cyclosporin* 'softdrug' analogs. These compounds can be delivered topically to the target organ (lung, skin, colon), exert a potent local anti-inflammatory effect, and are inactivated upon systemic absorption, thus limiting their toxicity.

This latest study evaluated toxicity in a head-to-head comparison of cyclosporin with the Enanta softdrug metabolite. Both compounds were administered by daily intravenous injection for 14 days, at three dose levels. Blood chemistry analyses and microscopic examination of kidneys by a pathologist were used to assess toxicity. Cyclosporin-treated animals exhibited significant changes in blood chemistry values that are consistent with kidney and liver dysfunction, and mild anemia. Cyclosporin also resulted in dose-dependent adverse changes in kidney pathology, including tubular necrosis. The study concluded that the Enanta softdrug metabolite did not cause toxicity in contrast to cyclosporin.

A second ADME study in rats was designed to assess the pharmacokinetics and clearance of the Enanta softdrug when administered to the lungs (intratracheal), as compared to intravenous (IV) administration. By measuring the amount of compound present in the blood, urine and feces over time, it is possible to assess its systemic exposure and clearance. The study concluded that intratracheal delivery of the Enanta softdrug resulted in a slow distribution from the lungs into the bloodstream and significantly lower systemic exposure compared to IV dosing.

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“We are developing novel cyclosporin A (CsA) analogs that are applied via the inhalation route to the lungs. Based on the ‘*T-cell strategy*’ in asthma, these compounds will be efficacious in reducing airway inflammation and hyper-responsiveness,” said Jens Eckstein, Ph.D., Director, Lead Discovery and Program Manager Novel Cyclosporin Therapeutics, and the study’s presenter. “We believe that this strategy significantly reduces the toxicity of CsA and provides an important therapeutic opportunity for the treatment of severe and steroid-resistant asthma patients.”

According to the Academy of Allergy, Asthma and Immunology (AAAAI), between 12 and 15 million people in the United States, including close to 5 million children, have asthma. Asthma is a chronic disease in which airflow in and out of the lungs may be blocked by muscle squeezing, swelling and excess mucus.

The Federation of Clinical Immunology Societies (FOCIS) meeting provides a scientific forum to foster the cross-disciplinary approach required to understand and treat immune-based diseases as the discipline of clinical immunology evolves. The evolution is a reflection of the shared pathophysiology of many diseases, including autoimmune diseases, cancer, allergy/asthma, infectious diseases, immune deficiency, and transplant rejection.

Headquartered in Watertown, Mass., Enanta Pharmaceuticals is using its breakthrough chemistry technology – *Drug Morphing*[™] and *Peptide Morphing*[®] -- to create new intellectual properties by ‘morphing’ existing drugs, natural products and biologically active peptides into novel small-molecule drugs. The Company is initially focusing on new chemical entities derived from existing drugs that address significant unmet medical needs: (a) new-generation macrolide antibiotics to overcome bacterial resistance; and (b) anti-inflammatory drugs for a variety of indications, including asthma, psoriasis and inflammatory bowel diseases.

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