For Immediate Release For Further Information Contact: Andrew Fisher at (301) 608-9292

Email: Afisher@unither.com

## UNITED THERAPEUTICS ANNOUNCES FILING OF SUPPLEMENTAL NEW DRUG APPLICATION FOR INTRAVENOUS REMODULIN®

Silver Spring, MD and Research Triangle Park, NC, February 2, 2004: United Therapeutics Corporation (NASDAQ:UTHR) announced today that it has filed a supplemental New Drug Application (sNDA) with the United States Food and Drug Administration (FDA) to add the intravenous route of delivery to the Remodulin label for the treatment of pulmonary arterial hypertension.

The sNDA was filed on the basis of a recently completed study in normal volunteers that established the steady state bioequivalence of Remodulin when delivered intravenously as compared to subcutaneous delivery. The Remodulin bioequivalence study compared total exposure during steady state (AUC<sub>ss</sub>) and maximal exposure during steady state (Cmax<sub>ss</sub>), during hours 48-72 of the three-day infusion period. The acceptable 90% confidence interval range to establish bioequivalence is between 80% to 125%. Analysis of the data from the 51 volunteers who completed both routes of administration using subcutaneous Remodulin as the comparator showed the following:

- intravenous AUC<sub>ss</sub> was 93%, with a 90% confidence interval of 90%-96%; and
- intravenous Cmax<sub>ss</sub> was 106%, with a 90% confidence interval of 99%-113%.

Remodulin is currently approved by the FDA as a subcutaneous therapy for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise.

United Therapeutics is a biotechnology company focused on combating chronic and lifethreatening cardiovascular, infectious and oncological diseases with unique therapeutic products.

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