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Sent: 1/3/2003 3:44:30 PM
To: DP-IV PDT TO [dpivedtt@NorthAmerica.msx.merck.com]
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Subject: DRAFT Preliminary Interim Analysis Memo/ RMC Background Slides- L-224715
Attachments: RMC_DRAFT_Background_L-224715_Herman.ppt; L-224715 _ Protocol 005_DRAFT Interim Analysis Memo.doc

Hi,

Attached is the DRAFT preliminary interim analysis memo (provided to Peter Kim today) summarizing the results of the Phase IB study in type 2 diabetics. Also attached are DRAFT background slides (sent to RMC today) for next week's RMC presentation.

Gary

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RMC_DRAFT_B...


L-224715 _ Protocol 005_DR...

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L-000224715
DP-IV Inhibitor
Update on Phase I Data

RMC
Jan 8, 2003

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Key points

- L-224715 generally safe & well tolerated
  - no clear dose limiting toxicity identified
- L-224715 lowers post-OGTT glucose in type 2 diabetics
  - greater reduction of glucose-AUC observed at higher of 2 doses tested
    - optimal effect may require maximal DP-IV inhibition
  - BID regimens may be required to maintain high DP-IV inhibition and optimize chances for best efficacy
  - milder diabetics appear to respond better

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Decisions Requested

- Support for "Go" decision to phase II
- Support for team recommendation to proceed to expanded Phase II program
  - Define dose range
  - Assess QD vs. BID efficacy
  - Determine responder population

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L-224715 generally well tolerated

Exposure: single and multiple dose in healthy volunteers, single dose in obese male, in females, and in healthy elderly, single doses in patients with type 2 diabetes (134 volunteers, 53 patients with type 2 diabetes)

- No dose limiting tolerability issues identified
  - No trends for significant changes in lab, ECG or vital signs parameters

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