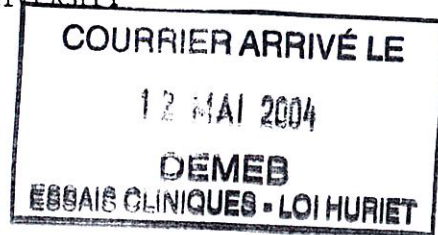




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22<sup>nd</sup> April 2004

Dear Investigator,

Many thanks for your continuing support in the ongoing ODIXa-HIP study 10944. I am pleased to be able to report to you on behalf of the steering committee some new information relevant to this trial. First of all, we enrolled until now 188 patients and most of the countries/centres are active now. On March 30<sup>th</sup>, 2004 and April 19<sup>th</sup>, 2004 the Data Monitoring and Safety Board reviewed the first [REDACTED] patients in this trial and recommended that the trial should proceed without any change of protocol.

Following the lock of clean database of the previous ODIXa-HIP study 10942 on April 1st, 2004, the Steering committee met on April 21st, 2004 to review the final data of this study (10942). We in the Steering Committee can now give you information about the final results and our interpretation of these data.

We are pleased with the observation of dose response, increasing efficacy with increasing dose. The original aim of this study was to demonstrate a dose-trend, and this was achieved ( $P=0.0504$ ). The DVT rates observed are consistent with those observed in other contemporary trials, and even the lower doses were within the accepted ranges of the control drug enoxaparin. For further information see Table 1 – 4.

All bleeding events in the previous ODIXa-HIP study 10942 are now adjudicated by our central independent Bleeding Adjudication Committee, based on the clean and complete data set.

The finding of dose response concerning bleeding events was, however, also documented. We recognise the difficulties and limitations of making meaningful interpretations of bleeding events in open-label clinical trials, but nevertheless, the data suggest to us a dose trend in terms of bleeding events ( $P=0.0008$ ). For further information see Table 5 – 10.

It is important to note that these reported bleedings were treated according the local hospital routine and none of these patients sustained any sequelae. In particular the Steering committee noticed:

1. There were no fatal bleeds or bleeds into critical organ.
2. There were no clinical significant bleeds that could not be treated.
3. All bleedings adjudicated as major were related to the surgical site.
4. There were no wound healing complications reported in these patients.

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ODIXa-HIP study 10942. Appendix, Tables 1 - 10

