



NEWS RELEASE

20th EORTC-NCI-AACR SYMPOSIUM on “Molecular Targets and Cancer Therapeutics” Geneva, Switzerland, 20-24 October 2008

Embargoed: 00.01 hrs CEST, Monday 20 October 2008

Assessing the quality of phase I clinical trial abstracts submitted to the EORTC-NCI-AACR and ASCO meetings

Geneva, Switzerland: Researchers have developed a method of assessing the quality of phase I clinical trial abstracts submitted to two different oncology conferences: EORTC-NCI-AACR (ENA) [1] and American Society of Clinical Oncology (ASCO). The results, presented on Thursday (23 October) at the 20th ENA Symposium on Molecular Targets and Cancer Therapeutics in Geneva, show there is room for improvement and the researchers suggest authors of conference abstracts should adopt guidelines for reporting phase I clinical trials.

Dr Jeremy Ho, an internal medicine resident under the supervision of associate professor Dr Lillian Siu at the Princess Margaret Hospital (Toronto, Canada), had worked with colleagues to develop a quality score for abstracts based on an electronic survey of experts. They had used it to measure the quality of 1,683 phase I abstracts published in the ASCO Annual Proceedings from 1997 to 2006, and then they used the same method to measure the quality of 304 abstracts presented at the ENA symposia from 2003-2007.

When they compared abstracts on phase I trials from the period where there was an overlap between the two conferences (2003-2006), they found that the mean average quality score for the 229 ENA abstracts was 69.6% compared to 64.5% for the 713 ASCO abstracts.

Dr Ho said: “ASCO is a much bigger meeting than ENA, with different objectives, scope and audience. Our study is not meant to be a direct comparison to criticise the quality of abstracts submitted to either meeting. The data enable us to gain insight on areas where improvements in the quality of phase I trial abstract reporting can be made, regardless of the meeting.

“The slightly higher quality score for the ENA abstracts is probably due to a higher figure for the maximum number of characters allowed per abstract (2,500 for ENA and 2,000 for ASCO), an allowance for updating previously presented data, and the more specialised anti-cancer drug development focus of the ENA symposia. There remains room for improvement in both conferences for improving abstract quality and we believe this may be achieved by adopting guidelines for reporting on phase I clinical trials.”

Dr Ho and his colleagues have drawn up a list of what they believe should be included in any guidelines on reporting phase I trials. The following are items that are absolutely essential:

- Description of dose-limiting toxicity encountered on study
- Conclusion explicitly states maximum tolerated doses (MTD) or residual disease (RD) or reason for early trial closure
- Description of grade three toxicity and above that may be related to study drug
- Description of drug delivery schedule or formulation
- Number of patients on study
- Title identifying study as dose finding or phase I
- Pharmacokinetic analysis, if applicable

The following items should also be reported:

- Explicit definition of primary end point or objective
- Rationale for study
- Pharmacodynamic results, if applicable
- Current status of study
- Information related to treatment cycles
- Efficacy outcome of patients
- Number of patients at each dose level
- Tumour types of responders, if applicable

Dr Ho said: “We are not aware of any such guidelines in existence. We are hoping that our suggestions for guidelines can be validated further and then put into clinical use, for instance, as recommendations and reference guide to clinical researchers to help them with abstract writing, and maybe also as guidelines for conferences to evaluate abstracts being submitted.”

Abstracts at both conferences improved in quality the more recently they were presented, possibly indicating that authors were becoming more aware of what information needed to be included.

Dr Ho said he and his colleagues concentrated on phase I clinical trials for a number of reasons. “Phase I trials are unique in that they evaluate new drugs or drug combinations, and provide necessary foundations for the development of safe and more effective anti-cancer therapies. These trials are often initially presented in abstract format at major cancer conferences. Results of phase I trials published in abstract format frequently influence further research endeavours in higher-phase trials before full peer-reviewed publication occurs.

“We hope that this study will help to raise awareness about the importance of improving abstract quality in oncology conferences and in the cancer literature.”

(ends)

Abstract no: 382. Poster session in the poster area, 12.00-15.00 hrs CEST, Thursday 23 October.

Notes:

[1] EORTC [European Organisation for Research and Treatment of Cancer, NCI [National Cancer Institute], AACR [American Association for Cancer Research].

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From 09.00 hrs CEST Tuesday 21 October to 14.30 hrs CEST Friday 24 October

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