Clinical Trial Results: A Clinical Trial Bazaar!

ANTONIO TITO FOJO, SUSAN E. BATES

Center for Cancer Research, National Cancer Institute, National Institutes for Health, Bethesda, Maryland, USA

Disclosures of potential conflicts of interest may be found at the end of this article.

Dr. Antonio Tito Fojo

Dr. Susan E. Bates

At *The Oncologist*, we launched the “Clinical Trial Results” section “motivated by the premise that every trial, regardless of outcome, can have a benefit to the research community.” But we envision a broader audience. One need only work in a tertiary referral center to see how “creative” community oncologists have become—often, trying new and off-label combinations of approved agents in an effort to help patients who have exhausted standard options, nearly all of which fail to benefit patients whose tumors are intractable. These novel combinations have likely also been tried in the context of a clinical trial but, given the negative outcome, the investigator likely felt the time and effort to report it would be wasted. Besides, what journal would publish a negative result in a small group of patients? The answer: *The Oncologist*.

Two excellent submissions by Beverly Moy and her associates reporting combinations of bosutinib with the aromatase inhibitors exemestane and letrozole are exhibit A [1, 2]. Both combinations were deemed to have unfavorable risk-benefit ratios and now join the overwhelming majority of “targeted agent combinations” proven poorly tolerable. Why toxicity has limited the development of such combinations remains something of a mystery. Exhibit B is a combination of temsirolimus and bryostatin-1 [3]. Although bryostatin-1 development has been halted, studies such as this must be published to inform the future development of other protein kinase C inhibitors. Exhibit C is a combination of sorafenib with everolimus selected on the basis of molecular targets [4]; the reader can decide, is this progress or are we running in place?

To be sure, at *The Oncologist*, we also welcome positive results because we aim to “share results, speed discovery, and inform.” Clinical Trial Results submissions have shown us how succinctly the salient features of a submission can be presented, with more in-depth information found

online. The abbreviated format means a quick read—a nontrivial attribute, given the proliferation of medical literature. Garcia-Carbonero and colleagues report positive results with ramucirumab, a fully human monoclonal antibody targeting the vascular endothelial growth factor receptor 2 combined with modified FOLFOX-6 as first-line therapy for metastatic colorectal cancer (mCRC) [5]. Although the gains reported in this phase II trial come as no surprise, the study provides a first glimpse at tolerability, an attribute likely to emerge as important as ramucirumab competes in a crowded field. Eventually, we will want to know how ramucirumab compares with Avastin and aflibercept—and at Sloan-Kettering, they will want to know its price! (See the 2012 *New York Times* op-ed, “In Cancer Care, Cost Matters,” which discusses MSKCC’s decision not to prescribe aflibercept due to its cost [6].) But importantly, this phase II result, likely to be ratified in the ongoing phase III study, reminds us that although we have come far in mCRC, it is not far enough. Progress in mCRC will require targets other than vascular endothelial growth factor and strategies other than angiogenesis. In that spirit, we have the contribution by Stec et al., a prospective phase II trial of mitomycin C and high-dose 5-fluorouracil with folinic acid in heavily pretreated patients with mCRC [7]. Old fashioned? Yes, maybe even antediluvian, but with interesting activity and, as the authors argue, worthy of further investigation.

Finally, on the subject of tolerability, we have a randomized phase II trial from the North Japan Lung Cancer Group on the tolerability of carboplatin plus weekly paclitaxel compared with docetaxel in elderly patients with advanced non-small cell lung cancer [8]. In Japan, as in the U.S., investigators are finding the elderly tolerate chemotherapy much better than previously thought. Is age 60 indeed the new 50?

Correspondence: Antonio Tito Fojo, M.D., Ph.D., Medical Oncology, National Cancer Institute, Center for Cancer Research, National Institutes of Health, Building 10, Room 12N226, 9000 Rockville Pike, Bethesda, Maryland 20892, USA. Telephone: 301-402-1357; E-Mail: fojot@mail.nih.gov Received March 4, 2014; accepted for publication March 4, 2014; first published online in *The Oncologist Express* on March 25, 2014. ©AlphaMed Press 1083-7159/2014/\$20.00/0 <http://dx.doi.org/10.1634/theoncologist.2014-0091>

What can we say? In several pages of Clinical Trial Results, approximately the length of one full-length article, you will be surprised, informed, and encouraged in seven different ways! To us, this qualifies as a win—for all of us—and it is fully indexed in Medline/PubMed. Read the papers, cite them when you write,

think about the implications for treating your patients, and submit your next trial to **The Oncologist's** Clinical Trial Results.

DISCLOSURES

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EDITOR'S NOTE: Find this month's wide-ranging selection of Clinical Trial Results on pages 344–357 of this issue. Consider submitting your own results at <http://ClinicalTrialResults.TheOncologist.com>.