TSOG NEWS



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Chair's Report

David R. Jones, MD

On behalf of the TSOG Executive Committee, we hope you and your families are well during this COVID crisis. TSOG's first Semi-Annual Meeting took place in Chicago. IL



crisis. TSOG's first Semi-Annual Meeting took place in Chicago, IL February 2020 were we discussed new trial concepts to be included in the TSOG portfolio. The original TSOG site roster has grown from 9 to 24 sites stretched across North America. Our 3 clinical trials continue to open across the TSOG network. This has been a slower process than expected, made worse by the pandemic. To facilitate transparency and celebrate sites opening and accruing to TSOG trials, we will be including this information in this quarterly newsletter. We are excited to share that TSOG is poised to open its first collaborative clinical trial (LEADER) and first multi-national cooperative group trial with CTONG (see page 3).

Finally, led by Project Coordinator Maria Singh, TSOG's first subcommittee has been formed. Composed of the TSOG Research Team Members from all 24 sites, the TSOG Site Coordinator Working Group will facilitate TSOG's initial primary focus which is rapid accrual and successful completion of thoracic surgeon-lead oncology trials.

It is an exciting time for TSOG, but we need your help to open the trials and increase accrual!

David R. Jones, Ara Vaporciyan, Raphael Bueno & David Harpole

2020 TSOG Semi-Annual Meeting Chicago, IL

Seven clinical trial proposals were presented during the 2020 TSOG Semi-Annual Meeting held on February 29th, 2020 in Chicago, Illinois. Thoughtful discussions about the proposed trials evolved during the meeting and further comments were collected via a post-meeting online survey. The Executive Committee reviewed responses and made recommendations for each concept presented. Selected TSOG concepts will be further developed into detailed clinical trials while others will be supported for extramural funding in anticipation of future review by TSOG. Chosen trials will become TSOG's second round of trials that will be opened to accrual. We hope to have two of these opened within the next 6 months.

Sai Yendamuri, MD (right) from Roswell Park Comprehensive Cancer Center discussing his concept "Reprogramming obesity-induced tumor biology and immune response in early lung cancer with metformin". TSOG will be writing a strong letter of support for a pending R01 (or equivalent) proposal for funding of such a trial.





Harvey Pass, MD (left) from NYU Langone Medical Center discussing his concept "Validation of fibulin 3 as a biomarker for pleural mesothelioma". The PI is currently identifying interested TSOG sites willing to participate in an EDRN (Early Detection Research Network) grant proposal to support the trial and correlative studies.

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TSOG Executive Board Member David Harpole, MD and TSOG Member Harvey Pass engage in discussion during the Semi-Annual Meeting.



Ghulam Abbas (left) from West Virginia University presented his concept "TSOG registry of anatomic pulmonary segmentectomy for stage I lung cancer". West Virginia University is a new TSOG site in the process of activating TSOG 101 ctDNA



New TSOG Members (left to right) Abby Goerge (Site Coordinator, Rush University), Christopher Seder (PI, Rush University) Sharinett (site Coordinator, University of Michigan), Jules Lin (PI, University of Michigan), Yaron Shargall (PI, McMaster University) and Ghulam Abbas (PI, Ghulam Abbas) all in the process of activating TSOG protocols.



Philip Linden, MD (right) from University Hospitals Cleveland Medical Center presented his concept "Radiomic analysis as a noninvasive method to determine aggressiveness of predominant ground glass lesions". There was enthusiasm for the concept, but also acknowledgement of overlap with the existing TSOG 102 GGO trial. Discussions centered on possibly combining the two projects if possible.





Philip Carrott, MD from Baylor College of Medicine presenting his concept "Gastric ischemic conditioning for neovascularization: A randomized control trial" at the 2020 TSOG Semi-Annual Meeting. Baylor is a new TSOG site in the process of activating all 3 current TSOG trials.

New TSOG Trials

LCMC4 Evaluation of Actionable Drivers in EaRly Stage Lung Cancer (LEADER)

TSOG PI: David R. Jones, MD

Memorial Sloan Kettering Cancer Center



FOUNDATION

Thoracic

screening is а collaborative protocol, developed by the Lung Cancer Mutation Consortium (LCMC) and TSOG leadership which is designed to determine the feasibility of comprehensive molecular profiling to detect actionable oncogenic drivers in patients with suspected early-stage lung cancers scheduled to undergo biopsies to establish the diagnosis of lung cancer. The primary purpose of this trial is to determine the presence of 10 oncogenic drivers (mutations in *EGFR*, *BRAF*^{V600E}, *MET* exon 14, and *HER2*, rearrangements in *ALK*, *RET*, *NTRK*, and *ROS1*, and amplification of *MET* and HER2) that can be targeted for neoadjuvant therapies administered before surgery.

Phase II study of adjuvant chemotherapy +/-Atezolizum ab in ctDNA positive patients with resected NSCLC

TSOG PI: James Isbell, MD and Bob Li, MD

Memorial Sloan Kettering Cancer Center



tumor-derived DNA (ctDNA) is a Circulating promising biomarker with preliminary evidence suggesting that its persistence after presumed "complete" resection for NSCLC is associated with poor survival. Given the micrometastatic nature of disease in these circumstances, it has been postulated that additional systemic therapy (e.g., immunotherapy) in patients who are ctDNA positive following resection may be of benefit. The primary objective of the trial is to determine if the addition of adjuvant checkpoint inhibitor therapy to platinum-doublet therapy results in higher ctDNA clearance rates among patients with Stage IB to IIIB NSCLC who are ctDNA positive following complete resection. Secondary Objectives include overall survival; disease free survival; time to ctDNA clearance; duration of ctDNA clearance; correlation of ctDNA levels to radiographic recurrence; and clinical, histologic and molecular/genomic factors associated with ctDNA.



TSOG Semi-Annual Meeting attendees (left to right)
Bryan Meyers, MD from
Washington University; Washington University; TSOG Executive Board Member Ara Vaporciyan, MD; Stacy Su, MD from Fox Chase Cancer Center, Shannon Nesbit (Clinical Research Coordinator, Stanford University); Brian Whang, MD from Brigham and Women's Hospital.

TSOG Site Coordinator Working Group

TSOG initiated it's first subcommittee - the Site Coordinator Working Group. This idea was proposed by TSOG Executive Board Member Ara Vaporciyan, MD and was unanimously endorsed as a good idea at the Chicago meeting. The primary focus of the group is to provide a platform for TSOG site coordinators to enhance the process of advancing TSOG's mission (protocol activation, patient accrual, and adherence to trial regulations). The working group will meet on a monthly basis concentrating on areas such as identifying and addressing barriers to protocol activation and accrual, as well as ideas to improve communication across the TSOG community.

Update on Current TSOG Trials



| Updates | TSOG 101 ctDNA Trial | TSOG 102 GGO Trial | TSOG 103 Colorectal Mets Trial |
|---|-------------------------|-----------------------|-----------------------------------|
| Numbers Enrolled | 74 (active 37) | 59 (48 active) | 21 (18 active) |
| Sites Open | 2 | 4 | 4 |
| Sites Accruing | 1 | 4 | 1 |
| Sites Anticipated to be Open within 60 days | 5 | 8 | 6 |
| Highest Accruing Sites 2020 | MSKCC | MSKCC | MDACC |

Current TSOG protocols include a trial of circulating tumor DNA analysis in patients undergoing induction therapy for resectable stage IIA-IIIB non-small cell lung cancer (TSOG 101), led by Dr. James Isbell at MSK; a registry trial for the active surveillance of patients with imaging-identified multiple ground glass opacities in the lung (TSOG 102), led by Dr. James Huang at MSK; and a trial evaluating the role of multimodality management in risk-stratified patients with lung-limited metastatic colorectal cancer (TSOG 103), led by Dr. Mara Antonoff at MD Anderson.

| TSOG sites still opening clinical trials | TSOG PI |
|---|--|
| Allegheny General Hospital Cancer Center | Benny Weksler |
| Baylor College of Medicine | Philip W. Carrott, Jr |
| Case Western Reserve University SOM (University Hospitals Cleveland Medical Center) | Philip A. Linden |
| Duke University | David Harpole |
| Fox Chase Cancer Center | Abbas E.Abbas |
| Massachusetts General Hospital | Michael Lanuti |
| Mayo Clinic | Dennis Wigle |
| McMaster University | Yaron Shargall |
| NYU Langone Medical Center | Harvey I. Pass |
| Roswell Park Comprehensive Cancer Center | Sai Yendamuri |
| Rush University Medical Center | Michael Liptay Christopher W. Seder |
| Stanford University | Douglas Liou Joseph Shrager |
| Thomas Jefferson University | Nathaniel R. Evans |
| University of California Los Angeles | Jay M. Lee |
| University of Michigan | Jules Lin |
| University of Pittsburgh | James Luketich Arjun Pennathur |
| University of Southern California | Elizabeth A. David |
| University of Toronto (University Health Network) | Tom Waddell |
| West Virginia University | Ghulam Abbas |

If you are interested in learning more about TSOG, please visit the <u>TSOG page</u> on the AATS website or contact TSOG Project Coordinator Maria Singh, singhm1@mskcc.org.