A Message from the Phase 1 Director

I am very excited to release the Summer 2018 Phase 1 Clinical Trials Program newsletter. Since the last newsletter, the program has grown even more. We have new faces and new leaders to help take our program to the next level.

Over the past three months, our faculty and staff members have been extremely busy promoting and expanding the Phase 1 services. In April, members of the Phase 1 team represented the program at the Alabama Cancer Congress meeting in Point Clear. This included presentations from several of our faculty members and a prominent booth display.

In May, Dr. Luciano Costa, served as the PI for our first multiple myeloma study that requires inpatient observation. This was a first for our program and is a step in the right direction, since a number of first-in-human strategies will require inpatient stays.

Also in May, our manuscript “So You Want To Be a Principle Investigator” was published in the Journal of Oncology Practice.

During the first week of June, many of our faculty members not only attended ASCO 2018 in Chicago, but were also authors on a number of presentations. See page 3 for a complete list of Phase 1 abstracts.

While at ASCO, the Phase 1 group met with many pharmaceutical companies, and I am pleased to report that we received commitments for three new first-in-human trials. We also expanded our repertoire of sponsors, who would like to work with our program.

Drs. Amit Mehta and Francisco (Paco) Robert have taken on the initiative to start a Phase 1 Educational Curriculum, and we look forward to having a cadre of our fellows join the program for a three-month rotation.

Kudos to all who are working hard to underwrite the success of our program.

~Dr. Mansoor Saleh

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OUR MOTTO

The motto of the UAB Phase 1 Clinical Trials Program is “the drug called HOPE”. It is dedicated to provide HOPE to cancer patients and their families during their search for treatment options and compassionate care.

It is our hope that patients with cancer, for whom conventional therapeutic options no longer provide benefits, will come to see the Phase 1 Clinical Trials Program as an option in their continuum of care. We would like our patients and referring colleagues to see the Phase 1 Clinical Trials Program as a close to home destination site for access to novel therapeutic options, thereby keeping patients close to friends and family.
Ashley Anderson, NP, RN has been working with the Phase 1 Program as a Nurse Practitioner since 2016. This March marked the beginning of her new position as the Phase 1 Clinical Operations Manager.

Elizabeth Mills, NP, RN has been working with the Phase 1 Program as a Research Nurse Coordinator since 2017. This June marked the beginning of her exciting new career as a Nurse Practitioner for the Phase 1 Program.

Nikolaos Papadantonakis, M.D. has joined the Phase 1 team and will be overseeing the leukemia patients on clinical trials. His interests are in AML and CML in adult patients. Dr. Papadantonakis joined UAB in 2016, from the Cleveland Clinic Foundation in Cleveland, Ohio and has been a Principal Investigator on Phase 2 and Phase 3 clinical trials in leukemia. Please join us in congratulating Dr. Papadantonakis for enrolling his FIRST patient in the Phase 1 Program. His patient with AML was enrolled on the UAB 1614 LSD-1 clinical trial.

Monica Mason brings with her 26 years of drug development experience including operational management of nonclinical and clinical trial support services programs at Southern Research. Monica joined the CCC as the Administrative Operations Manager for the Phase 1 Clinical Trials Program in March.

Kelsey Antonio comes to the Phase 1 Program from just across the hall in the CCC Director’s office and has been at UAB for four years. Kelsey joined our finance team in February and serves in the role of Program Coordinator II.

Alice Perry comes to the Phase 1 program from the UAB Infusion Therapy Department located on Acton Road. Alice, who has been at UAB since 2008, has 24 years of nursing experience.

Devan Carmichael is a recent graduate from UAB and received her Bachelor of Science in Public Health with a concentration in Environmental Health Sciences. Devan, who has been part of the Phase 1 team as a student assistant for the past six months, was hired to join the team full time in June.

Ratika Dhawan has an MBBS from Government Medical College in Mysore, India; and is a MPH graduate from UAB. She is originally from Delhi, India and moved to United States in 2011. She is very passionate about Oncology and has been working in research for 6 years.
A novel combination of cabazitaxel chemotherapy, paired with the androgen antagonists abiraterone acetate and enzalutamide, is being evaluated in a Phase 1 trial being launched by the UAB Phase 1 Program. This is the only trial that combines three FDA-approved drugs that have already been shown to extend survival when administered by themselves. These drugs have different mechanisms of activity, and this novel combination may be safe and could lead to synergistic improvement in outcomes.

Mansoor Saleh, M.D.  
Principal Investigator

Guru Sonpavde, M.D.  
IIT Lead and Co-Investigator

After a long hiatus, the Phase 1 Program has resumed collaborations with Roche-Genentech conglomerate in the early drug development program. The UAB Phase 1 Program was the first site to be activated in U.S. for their novel CD-40 agonist molecule. This is a co-stimulatory molecule that works with other immunotherapy drugs to enhance T-cell anti-tumor activity. Dr. Mansoor Saleh is the PI at UAB and will enroll patients with colorectal cancers, head and neck cancers, and non-small cell lung cancer.

**ASCO 2018: Phase 1 Abstracts**

- **Phase 1b study of gedatolisib in combination with palbociclib and endocrine therapy (ET) in women with estrogen receptor (ER) positive (+) metastatic breast cancer (MBC) (B2151009).**
- **Activity and tolerability of the first-in-class anti-CD47 antibody Hu5F9-G4 with rituximab tolerated in relapsed/refractory non-Hodgkin lymphoma: Initial phase 1b/2 results.**
- **Veliparib in combination with nivolumab and platinum doublet chemotherapy (CT) in metastatic/advanced NSCLC.**
- **SEA-CD40, a non-fucosylated CD40 agonist: Interim results from a phase 1 study in advanced solid tumors.**
- **Epacadostat plus nivolumab for advanced melanoma: Updated phase 2 results of the ECHO-204 study.**
Education & Community Outreach

The 2018 Alabama Cancer Congress (ACC) Tri-State Meeting was held in Point Clear, Alabama April 13-15, 2018. ACC is committed to the promoting of education, advocacy and community for professional medical cancer organizations and has become the leading representative body of providers for cancer medicine in Alabama. Topics presented at this year’s Tri-State meeting (Alabama, Louisiana and Mississippi) by our Phase 1 physicians included: “Novel Treatment for Lymphoma including CAR-T Treatment,” Dr. Amitkumar Mehta; “Making Treatment Choices in Patients with Relapsed Myeloma,” Dr. Luciano Costa; and “Oncology Care in the New Era- Do We Really Know How to Select the Best Candy from the Candy Jar?,” Dr. Mansoor Saleh. Traci McArdle, RN, Nurse Manager and Jennifer Garcia, RN, CRC for the Phase 1 Clinical Trials program also attended the meeting and hosted at the Phase 1 exhibition booth.
Phase 1 Education—Lecture Series

The inaugural Phase 1 lecture series began on Monday, May 14 in the LoBuglio Conference Room. This series, under the leadership of Drs. Amitkumar Mehta and Francisco Robert, will cover important topics relevant to clinical trials and early drug development. The lecture series is meant as an ongoing educational program for the Phase 1 faculty, staff and fellows in the Division of Hematology & Oncology. At the first lecture in the series, Dr. Saleh spoke about the history of Phase 1 trials at UAB, the strides that have been taken to date, and the growth and development of the Phase 1 Clinical Trials Program over the last three years. Lectures in the series will be held monthly.

2018 Phase 1 Lecture Series Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Speaker</th>
<th>Location</th>
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<tbody>
<tr>
<td>May 14</td>
<td>Clinical Research at UAB CCC Historical Perspective</td>
<td>Mansoor Saleh, M.D.</td>
<td>WTI 231</td>
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<tr>
<td>June 11</td>
<td>Evolution of Tumor Biomarkers in Lung Cancer</td>
<td>Francisco Robert, M.D.</td>
<td>WTI 231</td>
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<td>July 23</td>
<td>Immuno-Oncology</td>
<td>Amitkumar Mehta, M.D.</td>
<td>WTI 231</td>
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<tr>
<td>August 13</td>
<td>Measurable Disease in NHL</td>
<td>TBD</td>
<td>WTI 231</td>
</tr>
<tr>
<td>September 10</td>
<td>Clinical Trial Designs</td>
<td>Francisco Robert, M.D.</td>
<td>WTI 231</td>
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Clinical Trials Education Program — Living with Cancer

On Wednesday, May 30, Dr. Mansoor Saleh spoke at a roundtable discussion with patients, caregivers, nurses, navigators and community members about clinical trials, describing the clinical trials process and the important role trials play in cancer care. Participants left the discussion with a better understanding of terminology, the value of clinical trials and their contribution to the development of new therapies in cancer care, and resources for finding credible and reliable information on clinical trials. The discussion was part of the Living With Cancer Seminar Series, sponsored by the Cancer Center’s Patient and Family Resource Center.
National Nurses Week—May 7-11, 2018

National Nurses Week was celebrated with great fun and excitement in Phase 1. Nurses are vital to our success, and we’re thankful to have an amazing group of nurses on our team!

UAB CCC inaugural Lace Up for a Cure—June 2, 2018

The Phase 1 team never shies away from its responsibility to give back to the community. Our staff members, Freda Lewis (Regulatory Manager) and Monica Mason (Administrative Operations Manager), volunteered at the Cancer Center’s Lace Up for a Cure 2K walk, held at the UAB Campus Green.

Freda and Monica outside WTI during Lace Up for a Cure
PHASE 1 CLINICAL TRIALS PROGRAM

SOLID TUMOR STUDIES

**UAB 1508:** A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects with Advanced Malignancies

- Solid Tumor with FGFR Mutation
  - (FGFR INHIBITOR)
  - FGFR alteration + Fresh Biopsy

**UAB 1614:** A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB059872 in Subjects with Advanced Malignancies

- SCLC, Neuroendocrine Tumor, AML/MDS
  - (LSD-1 INHIBITOR)
  - Archived tissue

**UAB 1695:** A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors

- NSCLC, Breast Cancer, Bladder Cancer, RCC
  - (Anti-Fucose)
  - Archived tissue + Prior I/O therapy allowed

**UAB 1728:** A Phase 1, Open-Label, Dose-Escalation and Expansion, Safety and Tolerability Study of INCB062079 in Subjects with Advanced Hepatocellular Carcinoma and Other Malignancies

- Hepatocellular Carcinoma, HNSCC, Esophageal Cancer, Cholangiocarcinoma, Ovarian Cancer
  - (FGFR4 Inhibitor)
  - Archived tissue + Prior I/O therapy allowed

**UAB 1701:** A Phase 1/2 Study of BMS-986242 Administered in Combination with Nivolumab (BMS-936558, Anti-PD-1) in Advanced Malignant Tumors

- SCCHN, Bladder Carcinoma, Renal Cell Carcinoma, NSCLC, Melanoma, Gastric Cancer
  - (IDO Inhibitor + Nivolumab)
  - Prior I/O therapy allowed

**UAB 1710:** A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01949 in Combination with Immune Therapies in Subjects with Advanced or Metastatic Malignancies

- Any Solid Tumor
  - (OX40 Agonist + Ipilimumab + Nivolumab)
  - Prior I/O therapy allowed

**UAB 17120:** An Open-Label, Multicenter, Dose Escalation Phase 1B Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Therapeutic Activity of R07009789 (CD40 Agonist) in Combination with Atezolizumab (Anti-PD-L1) in Patients with Locally Advanced and/or Metastatic Solid Tumors

- NSCLC, CRC, HNSCC
  - (CD40 Agonist)
  - Screening and on study biopsies

**UAB 17123:** A Phase 1/2, Open-Label, Dose-Escalation, Safety, Tolerability, and Efficacy Study of Epacadostat and Nivolumab in Combination with Immune Therapies in Subjects with Advanced or Metastatic Malignancies (ECHO-208)

- Solid Tumors
  - (Epacadostat + Nivolumab + Anti-KIR Agent)
  - Archived tissue + Prior I/O therapy NOT allowed
PHASE 1 CLINICAL TRIALS PROGRAM

DISEASE SPECIFIC STUDIES

**UAB 1469**: A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects with Advanced Malignancies
- Peripheral T Cell Lymphoma
- (MDM2/MDX INHIBITOR)
- PS3 Wild Type Status + Archived Tissue

**UAB 1709**: A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB059872 in Subjects with Advanced with Advanced Malignancies
- Prostate Cancer
- (AR Agonist)
- Archived tissue + Bone and/or Soft Tissue Mets

**UAB 1766**: A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors
- NSCLC
- (Anti-Endoglin + Nivolumab)
- Prior I/O Treatment Allowed

**UAB 1774**: A Phase 1, Open-Label, Dose-Escalation and Expansion Study of INCB062079 in Subjects with Advanced Hepatocellular Carcinoma and Other Malignancies
- Pancreatic Cancer and Colorectal Cancer
- (CCR2/5 Inhibitor + Chemo/Nivolumab)
- Frontline CRC and Pancreatic Cancer + Metastatic CRC and Pancreatic Cancer with MSS + Fresh Biopsy Pre and On-Study

**UAB 17106**: A Phase 1, Open-Label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies
- Colorectal Cancer
- (Trametinib + Ipilimumab + Nivolumab)
- MS Stable + Only for 2nd or 3rd Line + BRAF V600 not Mutated

**UAB 17107**: A Phase 1/2a Study of BMS-986242 Administered in Combination with Nivolumab (BMS-936558, Anti-PD-1) in Advanced Malignant Tumors
- Prostate Cancer
- (Anti-CD38 + Anti-PD1)
- Biopsy Needed + No Prior I/O Therapy

HEMATOLOGIC MALIGNANCIES STUDIES

**UAB 1666**: A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01949 in Combination with Immune Therapies in Subjects with Advanced or Metastatic Malignancies
- HL
- (AFM13 (CD30 Inhibitor) + Pembrolizumab)
- Archived Tissue

**UAB 1669**: An Open-Label, Multicenter, Dose Escalation Phase 1B Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Therapeutic Activity of R07009789 (CD40 Agonist) in Combination with Atezolizumab (Anti-PD-L1) in Patients with Locally Advanced and/or Metastatic Solid Tumors
- Multiple Myeloma
- (Daratumumab + Atezolizumab + Immunomodulatory Agent)
- No Prior I/O Therapy + No CAR-t cell Therapy + > 2 Lines of Treatment

**UAB 1806**: A Phase 1/2, Open-Label, Dose-Escalation, Safety, Tolerability, and Efficacy Study of Epacadostat and Nivolumab in Combination with Immune Therapies in Subjects with Advanced or Metastatic Malignancies (ECHO-208)
- Multiple Myeloma
- (BCMA x CD3 T Cell Antibody)
- Failed at Least 3 Prior Therapies
PHASE 1 CLINICAL TRIALS PROGRAM

Patient Referrals:
phase1referral@uab.edu
205-996-HOPE (996-4673)
cancercenter.uab.edu/phase1