A Message from the Phase 1 Director

We are completing our 3rd year as a formal program dedicated to the conduct of first-in-human clinical trials. In 2015, we began with six Phase 1 studies and a staff of eight. We will end 2018 with more than 40 Phase 1 clinical trials, a staff of more than 30 and twelve faculty members. It is indeed an incredible accomplishment that attests to the commitment of the Cancer Center, the School of Medicine and the Center for Clinical & Translational Research to establish a program specifically focused on promoting first-in-human drug development at UAB.

Most importantly, this is a testament to the dedication of our staff who have given their best to get us to where we are today. Throughout this process, we have maintained our ethos to be patient centered, and to provide the patients in our state and the surrounding region novel therapeutic options for the treatment of cancer.

In this issue of the Phase 1 Newsletter, we highlight some of our accomplishments, introduce new faces and appreciate our HOPE awardees. You will see that we are expanding our footprint to accommodate our growth and progress.

In celebration of achieving this milestone, I say “Where There is Will, There Will Be Hope.”

Mansoor Saleh, M.D.
Professor of Medicine
Senior Scientist,
UAB Comprehensive Cancer Center
Director, UAB Phase 1 Program
Medical Director, UAB Clinical Trials Administration Office

IN THIS ISSUE
♦ Phase 1 Growth
♦ Promotions and New Faces
♦ Education and Achievement
♦ Announcement of CITP 4.0
♦ New Abstract in ASCO Journal
♦ Phase 1 Education Lecture Series
♦ Phase 1 Hope Award
♦ Join Our Team
♦ From Our Patients
♦ Science of Hope
♦ Contact Information

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.

*HOPE stands for “Hope Offering Pain Ease.”
The Phase 1 Program is Growing!

Renovation Approved for Phase 1 Expansion

Renovations of old lab spaces on the 5th Floor of the Lyons Harrison Building scheduled to begin in September. The space will be renovated to accommodate additional staff offices, meetings, storage, and monitor space for the growing clinical research team.

**Phase 1 Active Clinical Trials**

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Number of Active Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr-15</td>
<td>6</td>
</tr>
<tr>
<td>2015</td>
<td>13</td>
</tr>
<tr>
<td>2016</td>
<td>18</td>
</tr>
<tr>
<td>2017</td>
<td>25</td>
</tr>
<tr>
<td>2018</td>
<td>41</td>
</tr>
</tbody>
</table>

**Phase 1: First-in-Human Clinical Trial Accruals**

<table>
<thead>
<tr>
<th>YEAR</th>
<th># of New Accruals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>60</td>
</tr>
<tr>
<td>2016</td>
<td>96</td>
</tr>
<tr>
<td>2017</td>
<td>90</td>
</tr>
<tr>
<td>2018*</td>
<td>53</td>
</tr>
</tbody>
</table>

*Year to date
Rebecca Arend, M.D. has joined the Phase 1 team and will be overseeing the gynecologic oncology patients. Her clinical interests include translational research, targeted therapy, chemoresistance, immunotherapy and personalized medicine.

Lisa Williams, RN has joined the Phase 1 team as a Research Nurse Coordinator. Lisa has been a registered nurse at UAB for 25 years. 13 years were spent working with hematopoietic stem cell transplant patients as an inpatient nurse and 11 years as a research nurse coordinator and research manager for the Bone Marrow Therapy and Cellular Therapy program.

Pankit Vachhani, M.D. joined our faculty as an Assistant Professor. Dr. Vachhani comes to UAB from Roswell Park Comprehensive Cancer Center, Buffalo, New York. His primary interest is in hematological malignancies (AML/MDS) with specific research interests in the treatment of high-risk, elderly and relapsed AML.

Luis Villalba has a BBA with a concentration in Finance from the University of Puerto Rico. With more than 15 years of experience in finance and accounting, Luis decided to join the Phase 1 team as a Financial Associate. Luis previously handled the Accounts Receivable department for EBSCO International.

Kimo Bachiaevili, M.D. joined our faculty as an Assistant Professor. Dr. Bachiaevili comes to UAB from the New York City Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, New York. His primary interest is in haematological malignancies, with a focus on early drug development and translational research in MDS.

Olumide Gbolahan, M.D. joined our faculty as an Assistant Professor. Dr. Gbolahan comes to UAB from Indiana University. His interests are in gastrointestinal and genitourinary malignancies.
Education and Achievements

CITP 4.0

Phase 1 Director, Dr. Mansoor Saleh, is Principal Investigator for the UAB HSF-GEF funded Clinical Investigator Training Program (CITP). Photographed are participants and faculty of CITP 4.0, the fourth class, which includes aspiring investigators from 4 schools and 10 divisions.

Phase 1 representatives include Drs. Olumide Gbolahan (back row, 3rd from left) and Pankit Vacchani (back row, 2nd from right).

Phase 1 Abstracts Accepted for 20th Annual Research Retreat

“UAB CCC First In Human Phase 1 Clinical Trials – A 2 Year Experience”
Ravi Paluri, Peng Li, Ashley Anderson, Lakshminarayana Nandagopal, Traci Mcardle,
Matthew Young, Gurudatta Naik, Mansoor Saleh

“Racial Diversity in Phase 1 Clinical Trial Participation at UABCCC Phase 1 Program”
Ashley Anderson, Gurudatta Naik, Courtney Estes,
Matthew Young, Traci McArdle, Mansoor Saleh

“Time-To-Trial Activation – Experience of UAB Phase 1 program”
Gurudatta Naik, Ashley Anderson, Courtney Estes, Matthew Young, Traci McArdle, Mansoor Saleh
Education and Achievements

Phase 1 at UAB Post ASCO Highlight Review

The UAB Post ASCO Highlight Review was held at the Renaissance Ross Bridge from August 24-25, 2018. Phase 1 Investigators Drs. Mansoor Saleh, Amitkumar Mehta and Francisco Robert served on the Immunotherapy Discussion Panel. Other Phase 1 Faculty gave talks on various topics including:

- **Breast Cancer: Hormone Positive**, Erica Stringer-Reasor, MD
- **Renal**, Lakshmi Nandagopal, MD
- **GI Colorectal**, Ravi Paluri, MD
- **CART-T: Where It Really Works**, Luciano Costa, MD
- **Lung**, Robert Francisco, MD

Phase 1 Publication Makes Cover Page of ASCO– Journal of Oncology

“**So You Want to be a Principal Investigator**”
Mansoor Saleh and Gurudatta Naik

This article aims to begin an exploration of the role and increasing responsibilities of a PI and the growing need for structured investigator training. We propose options to better equip the PI to achieve compliance with Good Clinical Practice. Click [here](#) to read more in the June 2018 ASCO Journal of Oncology Volume 14, Issue 6.
Education and Achievements

2018 Phase 1 Lecture Series Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Speaker</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 13</td>
<td>PK/PD/Biomarkers</td>
<td>Dr. Edward Acosta, PharmD.</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>
</tr>
<tr>
<td>October 8</td>
<td>Molecular Pathways &amp; Designer Drugs</td>
<td>Eddy Yang, M.D., Ph.D.</td>
<td>WTI 231</td>
</tr>
<tr>
<td>November 12</td>
<td>Measureable Disease in NHL</td>
<td>Andrew Smith, M.D.</td>
<td>WTI 231</td>
</tr>
</tbody>
</table>

Phase 1 Hope Award

The Phase 1 Hope award is given to the recipient who has shown outstanding patient care, teamwork, and dedication to the Phase 1 Program.

The recipient of the Phase I Hope Award for June 2018 was Dwight Adams. Dwight is our Patient Services Coordinator, who is the gate keeper to all referring physicians as well as direct communication with all patients and families. He is continuously dedicated to excellent communication with patients, families, physicians and staff.

The recipient of the Phase I Hope Award for August 2018 was Renarda Lane. Renarda is our Financial Officer, who is the keeper of all of our funds coming in and being spent. Renarda always goes above and beyond to help others. It does not matter what is going on outside of work or how busy she is, she is always willing to help as much as she possibly can.

Dr. Saleh with June’s Hope Award recipient, Dwight Adams.

Monica Mason with August’s Hope Award recipient, Renarda Lane.
NOW HIRING!!

PHASE I RESEARCH PROGRAM
COMPREHENSIVE CANCER CENTER
(2) RESEARCH NURSE COORDINATOR - (T52200)

DESCRIPTION:
To coordinate and organize clinical patient care provided by a unit. To follow the patient from referral through treatment, discharge and follow-up, providing patient and family education and maintaining records and documentation. To maintain a working nursing knowledge of the department's specialty, draft protocols or policies, collect records, and prepare data for publication.

QUALIFICATIONS:
Graduate from an accredited School of Nursing and three (3) years of related experience required. Currently licensed as a Registered Nurse (RN) by the Alabama Board of Nursing required.

WWW.UAB.EDU/CAREERS
From Our Phase 1 Patients

Caroline Brown, RN
Phase I Research Coordinator

Carolyn received a beautiful handmade item as a wedding gift from one of our patients. She recently enjoyed her honeymoon in St. Croix.

Jennifer Garcia, RN
Phase I Research Coordinator

Jennifer received a beautiful thank you card from one of our sweet patients. She is loved by all of her patients.

Roger Wright has been a Phase 1 patient since August 2016 on multiple clinical trials. Mrs. Wright has blessed our staff on many occasions with her homemade goods. In this picture, Mr. and Mrs. Wright delivered loaves of fresh zucchini bread to the clinic.
**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 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 1707**: A Phase 1, Open-Label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

- Melanoma, NSCLS(PDL1+), HNSCC, Urothelial Cancer, RCC, Gastric Cancer, Hodgkin Lymphoma, DLBCL
- (CD40 Inhibitor)
- Archived tissue

**UAB 17102**: 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
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)

P53 Wild Type Status + Archived Tissue

(NEW) **UAB 1663:** A Phase I Trial of Prednisone, Abiraterone, Cabazitaxel and Enzalutamide (PACE) for Metastatic Castration-resistant Prostate Cancer (mCRPC)

Prostate Cancer
(Prednisone, Abiraterone, Cabazitaxel and Enzalutamide (PACE))

**UAB 1709:** A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB059872 in Subjects 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, Safety and Tolerability Study of INCB062079 in Subjects with Advanced Hepatocellular Carcinoma and Other Malignancies

Pancreatic Cancer and Colorectal Cancer
(CCR2/S 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 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

**UAB 1812**: A Phase 1b Study of TAK-659 in Combination With Venetoclax for Adult Patients With Previously Treated Non-Hodgkin Lymphoma

(TAK-659 + Venetoclax)

Failed at least 1 Prior Therapy

**UAB 1825**: A Phase I/II, Open-Label, Dose Escalation and Expansion Study to Evaluate Safety, Tolerability, and Clinical Activity of the Antibody-Drug Conjugate GSK2857916 Administered in Combination with Lenalidomide Plus Dexamethasone (Arm A), or Bortezomib Plus Dexamethasone (Arm B) in Participants with Relapsed / Refractory Multiple Myeloma (dreaMM 6)

(GSK2857916 + Lenalidomide/Bortezomib + Dexamethasone)

Failed at Least 1 Prior Therapy
PHASE 1 CLINICAL TRIALS PROGRAM

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