2019
Happy New Year
from the
O’Neal Comprehensive Cancer at UAB
Phase 1 Clinical Trials Program

New Year,
New Name,
New Opportunities
A Message from the Phase 1 Director

New Year, New Name, New Opportunities

It is indeed a pleasure to write the message for the first newsletter of the year, which I hope will reach all of you when you return in the New Year! By the time you read this newsletter, our Phase 1 Program will be part of the O’Neal Comprehensive Cancer Center at UAB, a new name for our cancer center.

This has been a year of accomplishments, achievements and fulfillments. We have had over 20 active first-in-human trials at any given time during the year and are on target to reach our milestone of 44 trials by early 2019. We enrolled close to 100 patients in Phase 1 studies and look forward to exceeding this mark in 2019. We are making progress with our plans to open an in-patient Phase 1 service and we hope to expand our clinical trial repertoire as a result.

Our work has been published in the NEJM, presented at a number of national meetings and we had significant representation at the Cancer Center Research Retreat. Furthermore, it is gratifying to see our program provide more than “hope” and see a number of our patients “graduate” and complete their Phase 1 treatment with remarkable clinical responses.

In this issue, we welcome our new Phase 1 Team members and look forward to new opportunities that will come to fruition in the new year. The Phase 1 Program has exceeded the objectives we set forth in 2015. Our projections forecast new growth, new clinical trials and new molecules to be studied. Most of all, we look forward to having more opportunities and clinical trial options for our patients.

Thank you all for supporting us through 2018, and we look forward to making major strides and accomplishments in 2019.

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

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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.
New Faces of the Phase 1 Program

Monica Fomby joined the Phase 1 team as a Clinical Lab Assistant. Monica comes to us from UAB OB/GYN Oncology where she was a clinical lab assistant and was involved in processing tissue samples in and out of the operating room. She worked under Dr. Rebecca Arend.

Lauren McWhorter joined the Phase 1 team as the Budget and Finance Manager. Lauren will oversee the financial aspects of the Phase 1 program and work actively on process improvement and overall program planning. Lauren has been at UAB for 5 ½ years and has been involved in clinical research for the last 13 years.

Fran Thorne, BSN, RN, joined the Phase 1 team as a Research Nurse Coordinator. Fran most recently worked as an inpatient nurse in the UAB Bone Marrow Transplant Program. She has a wide range of experience including intensive care, infectious and pulmonary disease, and general medical-surgical nursing capacities.

Shellie Talley recently joined the Phase 1 team as a non-nurse Research Coordinator. Coming from an independent clinical research program, Shellie brings 12 years of clinical research experience. In her free time, she is an ultra runner. She finished her first 50K marathon last June.
**Education and Achievements**

**Dr. Saleh Speaks at Grand Rounds**

Dr. Saleh was invited to present at the UAB Pulmonary and Critical Care Grand Rounds in October. He spoke on the relevance of translational research in oncology and its application in pulmonary research. This talk was meant to inform junior and senior clinical faculty as well as basic researchers involved in translational research in Pulmonary Medicine.

**New England Journal of Medicine Features Our Phase 1 Study**

"CD47 Blockade by Hu5F9-G4 and Rituximab in Non-Hodgkin’s Lymphoma"

Ranjana Advani, M.D., Ian Flinn, M.D., Ph.D., Leslie Popplewell, M.D., **Andres Forero, M.D.**, Nancy L. Bartlett, M.D., Nilanjan Ghosh, M.D., Ph.D., Justin Kline, M.D., Mark Roschewski, M.D., Ann LaCasce, M.D., Graham P. Collins, M.D., Thu Tran, B.S., Judith Lynn, M.B.A., et al.

Dr. Andres Forrero-Torres, M.D. was recently published in the *New England Journal of Medicine (NEJM)*. He was the principal investigator for an important Phase 1 dose escalation trial at UAB in the Phase 1 Program, using an Anti-CD47 molecule in lymphoma patients. The CD47 molecule is unique in that it sends a “Do-Not-Eat-Me” signal to phagocytic molecules that prevents them from destroying tumor cells. The novel study agent, blocks this signal and thus exposes the tumor cells to be destroyed by immune cells. It is exciting to see our research and our PI in this prestigious publication. Click [here](#) to read more in the November 1, 2018 issue of the *New England Journal of Medicine*. 
Dr. Saleh was invited by Aga Khan University in Karachi, Pakistan as an international guest speaker to talk on “Targeted Therapy in Cancer – Does Race/Ethnicity make a difference?” Dr. Saleh spoke on the importance of understanding biological and pharmacodynamics differences in patients of different race and ethnic origins that can impact treatment outcomes. Under his Global Health Initiative in the Phase 1 Program, Dr. Saleh is involved in training new and experienced clinicians across different continents to develop their interest in clinical research.

The UAB Phase 1 Program made their presence at the recent Alabama Cancer Congress Tristate symposium held in Huntsville, Alabama. The Phase 1 team interacted with sponsors and community physicians across Alabama, Florida, and Mississippi to make them aware of the UAB Phase 1 Program. Ravi Paluri, MD, MPH, FACP, a faculty member in the Phase 1 Program also spoke on the recent developments in clinical trials in gastrointestinal cancer patients. His talk was titled, “ASCO 2018 Updates in Colorectal and Non-Colorectal Cancers.”
Education and Achievements

20th Annual Research Retreat a Success

The Phase 1 Director, Dr. Mansoor Saleh along with Dr. Eddy Yang, co-chaired the 20th Annual Research Retreat, which focused on Developmental Therapeutics. The event was held at The Club overlooking the beautiful skyline of Birmingham. The Phase 1 team was well represented at the retreat.

L to R: Eddy Yang M.D., Ph.D. Co-Chair, Professor, Department of Radiation Oncology; Michael J. Birrier, M.D., Ph.D. CCC Professor of Medicine/Hematology & Oncology; Mansoor N. Saleh, M.D. Co-Chair, Professor, Division of Hematology/Oncology, Director of Phase 1 Program.

“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

“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

2019 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>January 14</td>
<td>So You Want To Be a PI—Roles &amp; Responsibilities</td>
<td>Mansoor Saleh, M.D.</td>
<td>WTI 231</td>
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<tr>
<td>February 11</td>
<td>Basic Clinical Trial Statistics</td>
<td>TBD</td>
<td>WTI 231</td>
</tr>
<tr>
<td>March 11</td>
<td>AML</td>
<td>Pankit Vacchani, M.D.</td>
<td>WTI 231</td>
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Phase 1 Hope Award

The Phase 1 Hope Award is given to recipients who have shown outstanding patient care, teamwork, and dedication to the Phase 1 Program.

Gurudatta Naik is our Phase 1 navigator who received the Phase 1 Hope Award in December. Guru has a reputation for knowing all things Phase 1. He is always willing to help and does so in a patient and caring manner. While working abroad, Guru was still available to the staff 24/7 without complaint. His passion, dedication, loyalty and professionalism has been exemplary.

Shereta Wiley is one of our Phase 1 Data Managers who received the Phase 1 Hope Award in December. She was recognized for being an overall team player and her commitment to quality. We have received numerous compliments from her sponsors on her efficiency in resolving queries and the accuracy of her data.

Valecia Bendion is one of our certified medical assistants on JT15 who was awarded the Phase 1 Hope Award in December. Valencia is the first person that comes in contact with our patients in the JT15 Phase 1 clinic. She demonstrates care and compassion to all of them. She has a very calming effect on others and is always so willing to help. We receive a lot of positive comments from our patients on the wonderful care that she provides.
CBS 42 partnered with the O’Neal Comprehensive Cancer Center at UAB, the state’s biggest weapon against breast cancer, to learn about the new technologies and treatments that are now used to fight against this disease. During this news special, the Phase 1 Program was highlighted to showcase the clinical trials that are available for breast cancer patients. Click here to learn more.
Mrs. Donna Johnson is one of our Phase 1 trial participants that was recently featured on the local news channel series, The Local War on Breast Cancer, highlighting her current journey on a Phase 1 study. Donna has been on trial for more than two years and is tolerating therapy well. She is thankful for the treatment, the opportunity, and the care she is receiving on trial.

Mr. Stanley Myers began a Phase 1 study at UAB in October 2016, after being diagnosed with progressive metastatic melanoma and traditional treatments and procedures had failed. He has completed two full years on study with visits to our unit for evaluation and treatment every two weeks. As of his last day with us, his scans showed a complete resolution of all target lesions! It is an amazing feat to be able to “graduate from the Phase 1 program” with complete remission. Our staff was delighted to be able to celebrate the wonderful news with him and his family!

Mr. Troy Brown was diagnosed with malignant melanoma in 2015 and came to see us in the Phase 1 Program for a clinical trial in October 2016. He was seen in the Phase 1 unit every two weeks while on trial and completed two full years on study in October 2018. At that time, he had sustained disease control. At the two year mark, he was able to “graduate from the Phase 1 Program” and enter the standard of care follow up period.
Phase 1 In The Holiday Spirit

Happy Faces For Fall!

Happy Halloween!

Happy Holidays!

LHRB Door Decorating Contest
NOW HIRING!!

PHASE I RESEARCH PROGRAM
COMPREHENSIVE CANCER CENTER

(3) CLINICAL TRIAL ADMINISTRATOR - (T57188)

DESCRIPTION:
Coordinates and organizes activities of multiple components including policies and regulatory procedures for Oncology Phase I clinical trials. Drafts and/or evaluates protocols, policies and procedures regarding research projects and studies. Interacts with appropriate parties to solve protocol problems, obtain updates and renewals; supervises data collection; ensures accuracy of data input; data analysis, generates/prepares reports as required. Maintains pertinent records and documentation. May follow research participants or patients from recruitment through treatment, discharge and follow-up. May be responsible for collecting, recording, and preparing data for publication. Coordinates with the Office of Grants and Contract Administration and Institutional Review Board. May serve as a liaison between Research Nurse Coordinators interacting with physicians, patients, internal and external constituents, and pharmaceutical sponsors. Will act as a pivotal point of contact and support for the clinical trial research nurses for evaluating protocols, regulatory policies, billing compliance, preparation of specific data and responding to queries on behalf of the nurses.

QUALIFICATIONS:
Bachelor's degree in a related field and three (3) years of related experience required. Work experience may substitute for education requirement.

APPLY HERE:
WWW.UAB.EDU/CAREERS
The Science of HOPE

**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

*(NEW) UAB 1861: DCC-2036-01-003: An Open-Label, Multicenter, Phase 1b/2 Study of Rebastinib (DCC-2036) in Combination with Paclitaxel to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced or Metastatic Solid Tumors
(TIE2 inhibitor + Paclitaxel)
Archived tissue

*(NEW) UAB 1876: A Phase 1/2 Study to Evaluate the Safety, Tolerability, and Efficacy of INCB001158 in Combination With Chemotherapy, in Subjects With Advanced or Metastatic Solid Tumors
(Arginase inhibitor + Paclitaxel)
On study biopsy needed

**DISEASE SPECIFIC STUDIES**

**UAB 1469:** A Phase 1/2a Open-Label Study to Determine the Safety and Tolerability of ALRN-6924 Alone or in Combination in Patients with Advanced Solid Tumors or Lymphomas Expressing Wild-Type p53 Protein
(MDM2/MDX INHIBITOR)
PS3 Wild Type Status + Archived Tissue

**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))
DISEASE SPECIFIC STUDIES CONTINUED

**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, Safety and Tolerability 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

**NEW** **UAB 1824**: A Phase 1 Study of SY-1365, a Selective CDK7 Inhibitor, in Adult Patients with Advanced Solid Tumors

- **Ovarian Cancer**
  - (CDK7 inhibitor)

**NEW** **UAB 1830**: A Phase 1, Multi-Center, Open-Label, Dose-Escalation, Safety, Pharmacokinetic, and Pharmacodynamic Study of Minnelide™ Capsules given alone or in combination with Protein-Bound Paclitaxel in patients with Advanced Solid Tumors

- **Pancreatic Cancer**
  - (HSP90 inhibitor + Abraxane)

**NEW** **UAB 1833**: An Open-Label, Phase 1 Study of SC-004 as Monotherapy and in Combination with ABBV-181 in Subjects with Epithelial Ovarian, Including Fallopian Tube and Primary Peritoneal, and Endometrial Cancers

- **Ovarian Cancer**
  - (CLDN6 inhibitor)
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, Open-label, Dose Finding Study of CC-93269, a BCMA X CD3 T Cell Engaging Antibody, in Subjects With Relapsed and Refractory Multiple Myeloma.

- 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

- Non-Hodgkin Lymphoma
  - (SYK/FLT3 inhibitor + 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)

- Multiple Myeloma
  - (Anti-BCMA + Lenalidomide/Bortezomib + Dexamethasone)
- Failed at Least 1 Prior Therapy

**(NEW) UAB 1853:** A Phase 1 Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of AMG 397 in Subjects With Selected Relapsed or Refractory Hematological Malignancies

- Multiple Myeloma and AML
  - (MCL-1 inhibitor)
- 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