Department of Investigational Cancer Therapeutics

Phase I Clinical Trials

VOLUME 13, NO. 1 • 2017

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Making Cancer History®

FROM THE CHAIR

Funda Meric-Bernstam, MD, Chair, Department of Investigational Cancer Therapeutics

The Department of Investigational Cancer Therapeutics — "The Phase I Program" — at MD Anderson has continued to grow and evolve to meet the needs of patients seeking new treatment options. In Fiscal Year 2016 (Sept. 1, 2015 – Aug. 31, 2016), we enrolled 1,104 patients on clinical trials and submitted 72 new trials. We maintain a large portfolio of clinical trials with the intent of meeting the needs of all patients interested in exploring new treatment options. We have opportunities for patients who have had only a few lines of standard therapy and for patients who have exhausted other treatment options. We have first-in-human trials, trials with novel combinations, including novel agents with standard therapies and novel combinations.

This has been a great year for immunotherapy. We currently have a growing number of ongoing immunotherapy trials including approved agents in novel combinations as well as novel new therapeutic options, including intravenous, oral, and intratumoral therapies. We are actively looking to identify predictors of response and toxicity to immunotherapy approaches. Our investigators' experience with detection as well as management of adverse events allows us to thoroughly explore state-of-the-art therapies.

We remain committed to expanding our precision oncology armamentarium to incorporate new therapeutic modalities including immunotherapy and antibody-drug conjugates. We continue to expand our portfolio of genomically driven trials with approximately 70 trials that cover around 100 genomic targets. Our precision oncology efforts are supported by a partnership with the MD Anderson Institute for Personalized Cancer Therapy. The institute's Precision Oncology Decision Support Team provides point-of-care decision support in our clinics, allowing our providers to rapidly identify actionable genes, variants, and optimal therapeutic options.

The Department of Investigational Cancer Therapeutics continues to expand efforts in translational research and develop collaborations for preclinical investigations of novel therapeutics as well as identifying novel combinations that can be brought into clinical trials. These efforts are strengthened by interaction with the Center for Co-Clinical Trials and strong collaborative grants such as the National Cancer Institute patient xenograft model effort. Expected capabilities in this area will continue to grow and allow us to help with both preclinical modeling of novel agents as well as guiding new indications and new combinations for established therapies.

This year we have also been fortunate to recruit two outstanding investigators, Dr. Timothy Yap, previously at Royal Marsden and the Institute of Cancer Research in London, England, and Dr. Jordi Rodón, previously at Vall d'Hebron University Hospital in Barcelona, Spain. These investigators were already superstars, and we expect they will continue our progress toward Making Cancer History. ■

In Fiscal Year 2016, the Department of Investigational Cancer Therapeutics enrolled 1,104 patients on clinical trials and submitted 72 new trials.

ICT carves out robust immunotherapy trial effort through collaboration

The development and testing of novel therapeutic agents are multi-disciplinary efforts that require the combined expertise of many to be successful. Investigational Cancer Therapeutics (ICT) prides itself on its expansive network of collaborations, both across the institution and with industry partners, to identify the most promising new molecules and accelerate their passage through the clinical trial pipeline toward approval. The department is undertaking over 50 immuno-oncology (IO) trials with the aim of developing a thorough understanding of these promising agents and how patients respond to them. A crucial aspect of the IO portfolio is an effort to comprehensively characterize the incidence of immune-related toxicities associated with these innovative agents. This involves cross-institutional collaboration with groups such as Pulmonary Medicine, Dermatology, Cardiology, and Gastroenterology, Hepatology & Nutrition to manage identified off-target effects. Additionally, ICT has partnered with our Strategic Industry Ventures team to usher in novel compounds, deliver investigator-initiated protocols with translational endpoints, and obtain single-institute investigational new drug applications. For example, Dr. Aung Naing is conducting a large study with Pfizer that will evaluate various combinations of IO checkpoint agonists with radiation or standard-of-care treatment. Naing is also leading a single-site Phase II study evaluating the efficacy of pembrolizumab in patients with rare advanced malignancies such as squamous cell carcinoma of the skin and adrenocortical carcinoma. Other IO efforts in the department include Dr. David Hong's Adaptimmune-sponsored first-in-human Phase I trials of Specific Peptide Enhanced Affinity Receptor (SPEAR) T-cell therapies targeted against MAGE-A10c796T, MAGE-A4, and NY-ESO-1c259T. Dr. Sarina Piha-Paul is leading a Novartis-sponsored study of agonist anti-GITR monoclonal antibody alone and in combination with anti-PD-L1 antibody for patients with advanced solid tumors and lymphomas. Dr. Apostolia Tsimberidou is head of a Phase I/II study evaluating a STAT3 inhibitor combined with several checkpoint inhibitors in patients with advanced cancers. She is also involved with an Immatics-sponsored effort providing personalized, multi-target T-cells to patients with relapsed or refractory solid tumors. Dr. Timothy Yap is principal investigator of a Jounce Therapeutics-sponsored first-in-human Phase I/II trial evaluating ICOS agonist JTX-2011 alone and in combination with a PD-1 inhibitor in patients with advanced ICOS-positive cancers, and an Eli Lilly-sponsored basket study of a PD-L1 inhibitor as monotherapy and in combination with different targeted agents. ICT will continue to prioritize and advance novel early-phase IO studies, cultivating and maintaining many successful industry and institutional collaborations along the way. ■

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NEW FACULTY

Yap expands department's expertise in drug and biomarker development

Timothy Yap, MBBS, PhD, an internationally recognized expert in early-phase biomarker-driven clinical trials and drug development, joined Investigational Cancer Therapeutics as an associate professor in late 2016. He previously was the National Institute for Health Research Biomedical Research Center Clinician-Scientist and Consultant Medical Oncologist in the Phase I Drug Development Unit and Lung Cancer Unit at the Royal Marsden Hospital and The Institute of Cancer Research (RMH/ICR) in London, England. Yap also led a laboratory team within the Cancer Biomarkers Laboratory Group at the RMH/ICR, where he undertook translational research into circulating tumor biomarkers. Yap has been involved in the conduct of more than 100 early-phase clinical trials over the course of his career, including compounds that have now obtained FDA and EMA approval such as the pan-HER family tyrosine kinase inhibitor afatinib, PARP inhibitor olaparib, and CYP17 inhibitor abiraterone. He earned his PhD in Molecular Pharmacology at the ICR, where he focused on the preclinical and clinical development of AKT inhibitors. Since then, he has focused on the early clinical development of other classes of compounds, including DNA repair (ATR and PARP) inhibitors and novel immune checkpoint inhibitor combinations, with a special interest in thoracic cancers. His great breadth of translational and clinical research experience has seen the rapid and rational translation of pre-clinical findings into early-phase trials, many of which incorporate predictive biomarker assays.

Timothy Yap, MBBS, PhD

Here at MD Anderson, Yap is jointly appointed with the Department of Thoracic/Head and Neck Medical Oncology. He will also serve as Medical Director of the Institute for Applied Cancer Science (IACS), and Associate Director for Translational Research in the Institute for Personalized Cancer Therapy; in these roles, he will be instrumental in funneling novel compounds from the IACS drug pipeline into first-in-human, molecularly driven Phase I trials. Yap has received numerous international accolades, including the Young Investigator Award from the US Prostate Cancer Foundation, the McElwain Prize from the UK Association of Cancer Physicians, and several awards from AACR, ASCO, and EORTC, as well as grants from the British Lung Foundation and Academy of Medical Sciences. These outstanding achievements have established his reputation as a key opinion leader in early-phase drug development and translational research.

"I was drawn to MD Anderson because of its world-leading reputation for clinical and research excellence, and the wealth of opportunities to undertake transformative cancer research," Yap stated. "The great opportunity to work with renowned colleagues and friends who I have gotten to know over the years through international collaborations was a decisive factor for me. I wanted to be part of this exciting movement to discover and develop novel therapies at a rapid pace, and to be the conduit that brings together the different teams involved in this complex process. Like everyone else here, I want to Make Cancer History!" ■

A winning combination: Targeted therapy, compassion, and family bring uterine cancer survivor back to her life

Maria Lozano

Maria Lozano celebrated what she calls her seventh birthday this past year, marking the seventh anniversary of the first cycle of treatment that saved her life. In early 2009, Lozano was diagnosed with stage III metastatic endometrial carcinoma that proved resilient following surgery, chemotherapy, and radiation. The taxane- and platinum-based chemotherapy regimen was unforgiving on Lozano's body, leaving her physically depleted and with painful fluid retention in her legs. As the holidays approached that year, it was clear that her disease was outpacing treatment, and her doctor sent her home to be with her family.

It was at this time that she received a call from Dr. Aung Naing and his team with a new option— a spot on a Phase I clinical trial led by Dr. Sarina Piha-Paul combining the VEGF inhibitor bevacizumab and the mTOR inhibitor temsirolimus for patients with advanced cancers including endometrial malignancy. "To tell you the truth, I didn't want to come because the [previous] treatment I thought was going to work didn't, and my body was so weak," Lozano confided. But after some coaxing from her family, she decided to at least meet with Naing, a decision that would change the course of her disease entirely. "There was just something about him that gave me a tiny bit of hope to hang onto—that inspired me. He hadn't lost that human touch."

Lozano immediately enrolled on the trial and started treatment the following week; she would eventually receive 38 cycles over the course of two-and-a-half years. After treatments or scans with Naing, her husband would remark on how positive and uplifted she became, and the targeted agents slowly started to chip away at her cancer. Naing took a whole-body approach to Lozano's care, sending her for physical therapy to help manage the fluid retention in her legs and directing her to a nutritionist to help her learn how to eat as healthily as possible as she recovered. She was able to stop chemotherapy entirely in mid-2012 as her CA-125 dropped into a normal range, and a CT scan in late 2014 confirmed no evidence of disease.

As her condition improved, Lozano seized every opportunity to be with her family. She was able to go to California to help her daughter with her new baby, to dance with her husband at both her son's and daughter's weddings, and to attend her son's law school graduation. Now, she enjoys plenty of independence driving herself around town and cooking her family's favorite dishes to share around their big dining table. She also spends many days looking after her grandchildren: "Oh, they are my therapy!" she said brightly.

Her results give credence to the fact that matching patients to the right drug or combination of drugs can bring them back from the brink and return them to a healthy, fruitful life.

Lozano emphasized tearfully that she has Naing and his wonderful team to thank for all the years and memories that she didn't think she would be able to experience. She maintains a deeply positive outlook and appreciation for each moment. "Dr. Naing didn't promise to cure me, but he said he'd try to prolong my life a few more years. In my mind, I said just five or six more years. This past year was a year plus because it was my seventh," she said. For anyone going through cancer, Lozano advised not to lose faith, to remain upbeat as much as possible, and stay away from people who discourage you. "When I think that my life was going to be over, I am so grateful. It has been a long journey for me and my family, but I'm still here." ■ *–by Erica Di Pierro*

NEW FACULTY

Rodón brings extensive industry and early-phase trial experience to ICT team

Jordi Rodón Ahnert, MD, PhD

The Investigational Cancer Therapeutics team welcomes Jordi Rodón Ahnert, MD, PhD, an associate professor who specializes in early drug development, biomarker discovery, personalized cancer medicine, and neuro-oncology. He comes to MD Anderson from the Research Unit for Molecular Therapy of Cancer at the Vall d'Hebron University Hospital in Barcelona, Spain, where he was director and clinical head. Within that unit, he served as clinical head of the Early Clinical Drug Development Group, which develops targeted therapies, determines patient populations most likely to benefit from personalized molecular characterization, and identifies biomarkers of response.

Rodón earned his medical and doctoral degrees at the Universitat Autònoma de Barcelona, and completed a master of science program in experimental medicine at the Universitat de Barcelona. He spent two years in the Advanced Drug Development program at the Institute for Drug Development (IDD) in San Antonio, Texas, and completed his training in drug development in our department as a senior clinical research fellow. During his time at MD Anderson, Rodón also completed an internship at the Kleberg Center for Molecular Markers.

Over the course of his career, Rodón has been the principal or co-principal investigator on over 30 early phase clinical trials focusing on a range of advanced solid malignancies, partnering with leaders in industry including Novartis, Merck, Eli Lilly, Genentech, Sanofi, and others. He has contributed to about 60 peer-reviewed publications detailing both trial results and basic research findings. Rodón's most significant contributions to the field include the development of PI3K, FGFR, and TGF-β inhibitors, and multiple translational collaborations in those fields. ■

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Welcome to our new department administrator

Yagut Retondo, MHA, FACHE

Yagut Retondo, MHA, FACHE, assumed the role of administrator in the Department of Investigational Cancer Therapeutics on Sept. 1, 2016. "I am excited at the opportunity to serve as the next administrative lead for the department," she said. "My goal is to build on the existing infrastructure and expertise to further enhance our internal operations and collaborations with industry partners."

During the past three years, Department Chair Funda Meric-Bernstam, MD, has shepherded the department to become one of the largest Phase I programs in the world through relationships with pharmaceutical companies and academic collaborators. Retondo has been at MD Anderson for eight years. Since 2013, she was the administrator of the Department of Health Services Research, a new department that she launched in the Division of Cancer Prevention and Population Sciences. In this role, she established the administrative and financial structure of the department, created policies and procedures, supported the chair in recruiting faculty, and hired and trained all support staff.

Retondo originally came to MD Anderson as an administrative intern in the Leukemia Department upon completing her Master's in Healthcare Administration at Texas Woman's University in 2008. She took on the role of administrative manager in the Leukemia Department the following year, where she was the primary business officer for Leukemia's Clinical Research Services program, developing budget proposals for over 100 new research protocols and amendments to existing projects, and managing a $5 million budget and 20 employees. In 2011, Retondo was promoted to program manager. She directed all administrative and operational activities of Leukemia's Clinical Research Services program including strategic planning, laboratory operations, data and financial management, and personnel management. In addition, she managed collaboration with research investigators and industry sponsors and monitors, reviewed new research proposals for feasibility and ensured contractual obligations, and managed the program's $7 million budget. Before MD Anderson, Retondo held administrative and project management positions in the petroleum industry in Houston as well as in Azerbaijan. She earned her bachelor's degree in Education at the Institute of Foreign Languages in Baku, Azerbaijan, and served as a translator when she was first out of school. ■

Active Phase I Program Protocols

MAY 2017

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
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ADVANCED CANCERS

Protocol #	Title	Mechanism of Action	Principal Investigator	Age Requirement	Stable CNS metastasis allowed?
2014-0763	Phase I Study of Mogamulizumab (KW-0761) in Combination with MEDI4736 and Mogamulizumab in Combination with Tremelimumab in Subjects with Advanced Solid Tumors	Anti-CCR4 antibody combined with anti-PD-1 antibody or anti-CTLA-4 antibody	David Hong, MD	18	Yes
2014-0893	A Phase I/IIa, Dose-escalation Study of FF-10502-01 for the Treatment of Advanced Solid Tumors and Lymphomas	Pyrimidine nucleoside antimetabolite	Filip Janku, MD, PhD	18	Yes
2015-0656	An Open-label, Phase I/IB, Single-agent Study of RXDX-105 in Patients with Advanced Solid Tumors	RET/BRAF/EGFR inhibitor	Siqing Fu, MD, PhD	18	Yes
2015-0732	A Phase Ia/Ib Study of FPA008 in Combination with Nivolumab in Patients with Selected Advanced Cancers	Anti-CSF1R IgG4 monoclonal antibody combined with anti-PD-L1/L2 antibody	Sarina Piha-Paul, MD	18	Yes
2015-0896	Phase I Study of Oral PQR309 in Patients with Advanced Solid Tumors	Pan-PI3K/mTOR inhibitor	Filip Janku, MD, PhD	18	Yes
2015-1052	A Multicenter, Phase I, Open-label, Dose-escalation Study of ABBV-085, an Antibody-drug Conjugate, in Subjects with Advanced Solid Tumors	Antibody-drug conjugate	Vivek Subbiah, MD	18	Yes
2015-1115	A Phase I, Open-label, Multicenter Study of the Safety and Efficacy of MIW815 (ADU-S100) Administered by Intratumoral Injection to Patients with Advanced/Metastatic Solid Tumors or Lymphomas	Stimulator of interferon genes (STING) agonist	Funda Meric-Bernstam, MD	18	Yes
2015-1127	A Phase I Study of PF-05082566 as a Single Agent in Patients with Advanced Cancer, and in Combination with Rituximab in Patients with Non-Hodgkin's Lymphoma	Anti-4-1BB IgG2 monoclonal agonist antibody	David Hong, MD	18	Yes
2016-0277	A Phase I/Ib Open-label, Multicenter, Dose-escalation Study of GWN323 (Anti-GITR) as a Single Agent and in Combination with PDR001 (Anti-PD-1) in Patients with Advanced Solid Tumors and Lymphomas	Anti-GITR antibody alone and combined with anti-PD-1 antibody	Sarina Piha-Paul, MD	18	Yes
2016-0458	A Phase Ib Study of LY3039478 in Combination with Other Anticancer Agents in Patients with Advanced or Metastatic Solid Tumors	Notch inhibitor	Shubham Pant, MBBS	18	Yes
2016-0473	An Open-label, Phase Ia/Ib Study of Ramucirumab in Combination with Other Targeted Agents in Advanced Cancers	Anti-VEGFR2 monoclonal antibody combined with CDK4/CDK6 inhibitor or MET inhibitor	Siqing Fu, MD, PhD	18	No
2016-0582	A Phase I Study of LY3200882 in Patients with Solid Tumors	TGF-βRI inhibitor	Timothy Yap, MBBS, PhD	18	Yes
ECOGEAY131	Molecular Analysis for Therapy Choice (MATCH)	Various targeted agents	Funda Meric-Bernstam, MD	18	Yes
NCI9591	A Phase I Trial of Single-agent Trametinib (GSK1120212) in Advanced Cancer Patients with Hepatic Dysfunction	MEK inhibitor	Vivek Subbiah, MD	18	Yes

SOLID TUMORS

Protocol No	Title	Mechanism of Action	Principal Investigator	Age Requirement	Stable CNS metastasis allowed?
2014-0459	My Pathway: An Open-label Phase IIa Study Evaluating Trastuzumab/Pertuzumab, Erlotinib, Vemurafenib, and Vismodegib in Patients who have Advanced Solid Tumors with Mutations or Gene Expression Abnormalities Predictive of Response to One of These Agents	HER2, EGFR, BRAF, or hedgehog pathway inhibitors	Funda Meric-Bernstam, MD	18	Yes
2014-0640	Phase Ib Study to Evaluate the Safety of Selinexor (KPT-330) in Combination with Multiple Standard Chemotherapy Agents in Patients with Advanced Malignancies	SINE inhibitor combined with chemotherapy or immunotherapy	Aung Naing, MD	18	Yes
2014-0733	A Phase I, Open-label, Dose-escalation, Multicenter Study of ACT-PFK- 158, 2HCl in Patients with Advanced Solid Malignancies	PFKFB3 inhibitor	Siqing Fu, MD, PhD	18	No
2014-0753	A Phase I/II Study Exploring the Safety, Tolerability, and Efficacy of INCB024360 in Combination with MEDI4736 in Subjects with Selected Advanced Solid Tumors	IDO1 inhibitor combined with anti-PD-L1 antibody	Aung Naing, MD	18	Yes
2014-0959	A Phase I Study Evaluating the Safety and Pharmacokinetics of ABBV-075 in Subjects with Advanced Cancer	BET inhibitor	Sarina Piha-Paul, MD	18	Yes

CONTINUED

TREATMENT PLANNING CONFERENCE

Referring physicians and nurses who want to present patients for possible Phase I clinical trial inclusion are invited to attend the weekly treatment planning conference held every Wednesday from 8 to 8:30 a.m.

Contact Ly M. Nguyen, senior study coordinator, to add a case to the meeting agenda. (lmnguyen1@mdanderson.org; 713-563-2169)

Protocol No	Title	Mechanism of Action	Principal Investigator	Age Requirement	Stable CNS metastasis allowed?
2014-1005	A Phase I/Ib Study of MGCD516 in Patients with Advanced Solid Tumor Malignancies	MET, Axl, VEGFR, PDGFR, KIT, FLT3, Trk, RET, DDR2 and Eph inhibitor	Shubham Pant, MBBS	18	Yes
2014-1041	A Phase I/II Safety, Pharmacokinetic, and Pharmacodynamic Study of APS001F with Flucytosine and Maltose for the Treatment of Advanced and/or Metastatic Solid Tumors	Live bacterial suspension genetically engineered to overexpress cytosine deaminase gene	Siqing Fu, MD, PhD	18	No
2014-1052	A Phase I Study of MEDI4736 in Combination with Tremelimumab in Subjects with Advanced Solid Tumors	Anti-PD-L1 antibody combined with anti-CTLA-4 antibody	Aung Naing, MD	18	Yes
2014-1099	A Phase I, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects with Advanced Malignancies	FGFR inhibitor	Vivek Subbiah, MD	18	No
2015-0033	Phase I Open-label, Multicenter Study to Assess the Safety, Tolerability and Pharmacokinetics of Orally Administered CUDC-907, an HDAC and PI3K Inhibitor, in Subjects with Advanced/Relapsed Solid Tumors	HDAC/PI3K inhibitor	Sarina Piha-Paul, MD	18	Yes
2015-0035	A Phase 1 Study of COTI-2 for the Treatment of Advanced and Recurrent Gynecologic Malignancies	p53 agonist	Filip Janku, MD, PhD	18	Yes
2015-0075	Open-label, Multicenter Phase I/II Study of the Safety and Efficacy of PDR001 Administered to Patients with Advanced Malignancies	Anti-PD-1 IgG4 antibody	Aung Naing, MD	18	Yes
2015-0135	A Phase I Trial of Ipilimumab and MGN1703 in Patients with Advanced Solid Malignancies	Anti-CTLA-4 antibody combined with TLR9 agonist	David Hong, MD	18	Yes
2015-0220	Phase I Dose-escalation Study of Radio-labeled Immunotherapeutic, FF-21101(90Y), for the Treatment of Advanced Cancer	DOTA-conjugated anti-cadherin 3 monoclonal antibody	Vivek Subbiah, MD	18	Yes
2015-0239	An Open-label, Multi-cohort, Phase II Study of MPDL3280A in Advanced Solid Tumors	Anti-PD-L1 IgG1 monoclonal antibody	David Hong, MD	18	No
2015-0261	A First-in-human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies in Patients with Advanced Malignancies	Anti-PD-1 IgG4 monoclonal antibody	Aung Naing, MD	18	Yes
2015-0282	A Phase I/II, Multicenter, Open-label, Dose-escalation Study of AG-221 in Subjects with Advanced Solid Tumors, including Glioma, and with Angioimmunoblastic T-cell Lymphoma, that Harbor an IDH2 Mutation	IDH2 inhibitor	Filip Janku, MD, PhD	18	Yes
2015-0298	Phase I Evaluation of Intra-arterial Adenoviral p53 (Ad-p53) in Combination with Capecitabine in Patients with Unresectable Liver Metastases of Colorectal Carcinoma (CRC) That Have Completed All Standard Therapies and Have Refused or Progressed on Regorafenib Treatment	Adenoviral agent combined with DNA synthesis inhibitor	Vivek Subbiah, MD	18	Yes
2015-0353	A Phase Ib/II, Open-label, Multicentre Study Assessing the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumour Activity of MEDI4736 in Combination with AZD9150 or AZD5069 in Patients With Advanced Solid Malignancies and Subsequently Comparing AZD9150 and AZD5069 Both as Monotherapy and in Combination with MEDI4736 as Second-Line Treatment in Patients With Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck	Anti-PD-L1 antibody combined with STAT3 inhibitor antisense oligonucleotide or CXCR2 antagonist	David Hong, MD	18	Yes
2015-0405	A Phase Ib/II Dose-escalation and Cohort-expansion Study of the Safety, Tolerability and Efficacy of a Novel Transforming Growth Factor-Beta Receptor I Kinase Inhibitor (Galunisertib) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory Solid Tumours (Phase 1b) and in Recurrent or Refractory Non-Small Cell Lung Cancer, Hepatocellular Carcinoma, or Glioma (Phase 2)	TGF-βRI kinase inhibitor combined with anti-PD-1 antibody	David Hong, MD	18	Yes
2015-0411	A Multicenter Phase II Clinical Trial of Lurbinectedin (PM01183) in Selected Advanced Solid Tumors	DNA minor groove binder	Vivek Subbiah, MD	18	No
2015-0463	A Phase I/II, Multicenter, Open-label Study of Oral FGF401 in Adult Patients with Hepatocellular Carcinoma or Solid Malignancies Characterized by Positive FGFR4 and KLB Expression	FGFR inhibitor	Shubham Pant, MBBS	18	Yes
2015-0468	A Phase Ia/b Study to Evaluate the Safety and Tolerability of ETC-1922159 in Advanced Solid Tumours	Wnt signaling inhibitor	Vivek Subbiah, MD	18	Yes
2015-0597	Dose-escalating Safety Trial of Tissue Factor Specific Antibody-drug Conjugate (HuMax-TF-ADC) in Patients with Locally Advanced and/or Metastatic Solid Tumors Known to Express Tissue Factor	Anti-tissue factor human monoclonal antibody conjugated to microtubule inhibitor	David Hong, MD	18	Yes
2015-0641	An Open-label Randomized Two-arm Phase I Dose-escalation Study to Characterize the Safety, Tolerability, Pharmacokinetics, and Maximum Tolerated Dose of Oral BAY 1217389 in Combination with Weekly Intravenous Paclitaxel Given in an Intermittent Dosing Schedule in Subjects with Advanced Malignancies	Monopolar spindle 1 (MPS1) inhibitor combined with microtubule inhibitor	Vivek Subbiah, MD	18	Yes

CONTINUED

Protocol No	Title	Mechanism of Action	Principal Investigator	Age Requirement	Stable CNS metastasis allowed?
2015-0687	A Multi-arm, Open-label, Phase Ib Study of MLN2480 (an Oral A-, B-, and CRAF Inhibitor) in Combination With MLN0128 (an Oral mTORC 1/2 Inhibitor), or Alisertib (an Oral Aurora A Kinase Inhibitor), or Paclitaxel, in Adult Patients With Advanced Nonhematologic Malignancies	A-, B-, and CRAF Inhibitor combined with mTORC 1/2 inhibitor, aurora A kinase inhibitor, microtubule inhibitor, EGFR inhibitor, or DNA topoisomerase I inhibitor	Siqing Fu, MD, PhD	18	Yes
2015-0728	A Phase II Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects with NTRK Fusion-Positive Tumors	Tropomyosin receptor kinase (TRK) inhibitor	David Hong, MD	18	Yes
2015-0760	A Phase II Study of Abemaciclib in Patients with Brain Metastases Secondary to Hormone Receptor Positive Breast Cancer, Non-Small Cell Lung Cancer, or Melanoma	CDK4/6 inhibitor	Siqing Fu, MD, PhD	18	Yes
2015-0769	Phase II, Parallel-arm Study of MGCD265 in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with Activating Genetic Alterations in Mesenchymal-Epithelial Transition Factor	Tyrosine kinase inhibitor targeting Axl and MET receptors	David Hong, MD	18	Yes
2015-0838	Evaluation of an Alternative Schedule for CRLX101 Alone, in Combination with Bevacizumab and in Combination with mFOLFOX6 in Subjects with Advanced Solid Tumor Malignancies	Nanoparticle-drug conjugate targeting topoisomerase I and HIF-1α/2α combined with anti-VEGF monoclonal antibody or chemotherapy	Sarina Piha-Paul, MD	18	Yes
2015-0868	A Phase I Study of Folic Acid-Tubulysin Conjugate EC1456 in Patients with Advanced Solid Tumors	Folic acid-tubulysin B hydrazide (TubBH) conjugate	Siqing Fu, MD, PhD	18	Yes
2015-0877	An Open-label, Multicenter, Phase I Study of Ramucirumab plus MEDI4736 in Patients with Locally Advanced and Unresectable or Metastatic Gastrointestinal or Thoracic Malignancies	anti-VEGFR 2 monoclonal antibody combined with anti-PD-L1 antibody	Siqing Fu, MD, PhD	18	No
2015-0888	A Phase I, First-in-Human Study of MEDI9197, a TLR7/8 Agonist, Administered Intratumorally in Subjects with a Solid Tumor Cancer	TLR7/8 agonist	David Hong, MD	18	Yes
2015-0912	Open-label, Multicenter Phase I/II Study of Mogamulizumab in Combination with Nivolumab in Subjects with Locally Advanced or Metastatic Solid Tumors	Anti-CCR4 antibody combined with anti-PD-1 antibody	David Hong, MD	18	No
2015-0913	A Phase I Dose-finding Study of Oral LXH254 in Adult Patients with Advanced Solid Tumors Harboring MAPK Pathway Alterations	Pan-RAF inhibitor	Filip Janku, MD, PhD	18	Yes
2015-0942	A Phase I/Ib First-in-Human, Dose-escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of IPI-549 Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors	PI3K-γ inhibitor combined with anti-PD-1 antibody	David Hong, MD	18	Yes
2015-0948	Phase II Study for the Evaluation of Efficacy of Pembrolizumab (MK-3475) in Patients with Advanced Types of Cancers	Anti-PD-1 antibody	Aung Naing, MD	18	Yes
2015-0971	A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0011359C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications	Bifunctional PD-L1/TGF-β pathway inhibitor	Aung Naing, MD	18	Yes
2015-1003	A Phase I Dose-escalation Study Evaluating the Safety and Tolerability of PF-06671008 in Patients with Advanced Solid Tumors	Bispecific molecule targeting P-cadherin and CD3	David Hong, MD	18	Yes
2015-1075	An Open-label, Multicenter Phase Ia/IIa Trial Investigating the Safety, Tolerability and Antitumor Activity of Multiple Doses of Sym015, a Monoclonal Antibody Mixture Targeting MET, in Patients with Advanced Solid Tumor Malignancies	Anti-MET monoclonal antibody mixture	Filip Janku, MD, PhD	18	Yes
2015-1116	Phase I/IIa Dose-escalation Study of CRLX301 in Patients with Advanced Solid Tumor Malignancies	Docetaxel-containing nanoparticle	Sarina Piha-Paul, MD	18	Yes
2016-0104	A Phase I Dose-finding Study of Oral LTT462 in Adult Patients with Advanced Solid Tumors Harboring MAPK Pathway Alterations	ERK1/2 inhibitor	Filip Janku, MD, PhD	18	Yes
2016-0108	Phase II Clinical Trial Evaluating the Safety, Pharmacokinetics and Biological Effect of Intravenous AZD9150 (antisense STAT3) with MEDI4736 (anti-PD-L1) in Patients with Advanced Pancreated, Non-small Cell Lung Cancer, and Mismatch Repair Deficient Colorectal Cancer	STAT3 inhibitor antisense oligonucleotide combined with anti-PD-L1 antibody	David Hong, MD	18	Yes
2016-0144	A Phase Ib Study of AZD1775 and Olaparib in Patients with Refractory Solid Tumors	Wee1 inhibitor combined with PARP inhibitor	Siqing Fu, MD, PhD	18	Yes
2016-0153	A Phase I Study of MEDI1873 (GITR Agonist) in Adult Subjects With Select Advanced Solid Tumors	GITR agonist	Aung Naing, MD	18	Yes
2016-0212	A Phase I Dose-escalation Study of ARQ 751 in Adult Subjects with Advanced Solid Tumors with AKT1, 2, 3 Genetic Alterations, Activating PI3K Mutations or PTEN-Null	Pan-AKT inhibitor	Shubham Pant, MBBS	18	Yes
2016-0270	A Phase I/II Study of the Safety, Pharmacokinetics, and Pharmacodynamics of the Glutaminase Inhibitor CB-839 in Combination with Nivolumab in Patients with Clear Cell Renal Cell Carcinoma and Other Solid Tumors	Glutaminase inhibitor combined with anti-PD-1 antibody	Funda Meric-Bernstam, MD	18	Yes

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Protocol No	Title	Mechanism of Action	Principal Investigator	Age Requirement	Stable CNS metastasis allowed?
2016-0308	A Phase Ia/Ib Study of a Novel Anti-PD-L1 Checkpoint Antibody (LY3300054) Administered Alone or in Combination with Other Agents in Advanced Refractory Solid Tumors	Anti-PD-L1 antibody alone and combined with anti-VEGFR-2 monoclonal antibody, MET inhibitor, or CDK4/6 inhibitor	Timothy Yap, MBBS, PhD	18	Yes
2016-0345	A Phase I/II Dose-escalation and Cohort-expansion Study of Oral eFT508 in Subjects with Advanced Solid Tumors	Mitogen-activated protein kinase interacting kinase (MNK) 1 and 2 inhibitor	Funda Meric-Bernstam, MD	18	Yes
2016-0353	A Phase I/II Study of Safety and Efficacy of Ribociclib (LEE011) in Combination with Trametinib (TMT212) in Patients with Metastatic or Advanced Solid Tumors	CDK4/6 inhibitor combined with MEK inhibitor	Filip Janku, MD, PhD	18	Yes
2016-0382	Phase Ib, Open-label, Multicenter Study to Characterize the Safety, Tolerability and Pharmacodynamics (PD) of PDR001 in Combination with CJM112, EGF816, Ilaris (canakinumab) or Mekinist (trametinib)	Anti-PD-1 antibody combined with anti-IL-17A antibody, EGFR inhibitor, anti-IL-1β monoclonal antibody, or MEK inhibitor	Siqing Fu, MD, PhD	18	Yes
2016-0386	Phase I/II Multicenter Trial of ICOS Agonist Monoclonal Antibody (mAb) JTX-2011 Alone or in Combination With Nivolumab in Adult Subjects with Advanced Refractory Solid Tumor Malignancies	Anti-ICOS agonist antibody alone or combined with anti-PD-1 antibody	Timothy Yap, MBBS, PhD	18	Yes
2016-0393	A Phase Ib/II Clinical Study of BBI608 Administered in Combination with Immune Checkpoint Inhibitors to Adult Patients with Advanced Cancers	STAT3 inhibitor combined with anti-PD-1 antibody or anti-CTLA-4 antibody	Apostolia Tsimberidou, MD, PhD	18	Yes
2016-0394	A Phase Ib/II, Open-label, Multicenter Study of MCS110 in Combination with PDR001 in Patients with Advanced Malignancies	Anti-M-CSF antibody combined with anti-PD-1 antibody	Aung Naing, MD	18	Yes
2016-0481	A Phase I/II, Open-label, Dose-escalation, Safety and Tolerability Study of INCAGN01949 in Subjects with Advanced or Metastatic Solid Tumors	Anti-OX40 agonist antibody	Aung Naing, MD	18	Yes
2016-0515	Phase I Cell Dose-escalation Study to Assess the Safety and Tolerability of Genetically Engineered MAGE-A10 C796T in HLA-A2+ Subjects with MAGE-A10 Positive Urothelial, Melanoma or Head and Neck Tumors	Genetically engineered T-cells	David Hong, MD	18	Yes
2016-0529	A Phase I, Open-label, Multicenter Dose-escalation Study of FAZ053 as Single Agent and in Combination with PDR001 in Adult Patients with Advanced Malignancies	Anti-PD-L1 IgG4 antibody alone and combined with anti-PD-1 IgG4 antibody	Filip Janku, MD, PhD	18	Yes
2016-0532	Phase I Trial of ZW25 Alone and in Combination with Chemotherapy or Immunotherapy in Patients with HER2-expressing Cancers	Bispecific anti-HER2 antibody	Funda Meric-Bernstam, MD	18	Yes
2016-0533	Safety, Pharmacokinetics, and Pharmacodynamics of Escalating Oral Doses of the Arginase Inhibitor CB-1158 as a Single Agent and in Combination with Immune Checkpoint Therapy in Patients with Advanced/Metastatic Solid Tumors	Arginase inhibitor	Siqing Fu, MD, PhD	18	Yes
2016-0543	Multicenter, Open-label, Phase 1, Dose-escalation, Cohort-expansion, First-in-Human Study of KHK2455 Administered as Monotherapy and in Combination with Mogamulizumab (KW-0761) in Adult Subjects with Locally Advanced or Metastatic Solid Tumors	ID01 inhibitor alone and combined with anti-CCR4 monoclonal antibody	Timothy Yap, MBBS, PhD	18	Yes
2016-0544	A Phase I Study of an ERK1/2 Inhibitor (LY3214996) Administered Alone or in Combination with Other Agents in Advanced Cancer	ERK 1/2 inhibitor	Shubham Pant, MBBS	18	Yes
2016-0595	A Phase I/II Dose-escalation of USL311 as Single Agent and in Combination with Lomustine (CCNU) in Subjects with Advanced Solid Tumors, with Subsequent Single Agent and Combination Phase 2 Cohorts for Subjects with Relapsed/Recurrent Glioblastoma Multiforme (GBM)	CXCR4 antagonist alone and combined with DNA synthesis inhibitor	Filip Janku, MD, PhD	18	Yes
2016-0657	A Phase I/II, Open-label, Multicenter Study of the Safety and Efficacy of BLZ945 as Single Agent and in Combination with PDR001 in Adults Patients with Advanced Solid Tumors	CSF-1R inhibitor alone and combined with anti-PD-1 antibody	Aung Naing, MD	18	Yes
2016-0682	PiSARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin/Pegylated Liposomal Doxorubicin Combination Chemotherapy With or Without APR-246	Chemotherapy and pegylated liposomal doxorubicin alone and combined with p53 analogue	Siqing Fu, MD, PhD	18	Yes
2016-1067	A Phase I/II Study Exploring the Safety, Tolerability, Effect on the Tumor Microenvironment, and Efficacy of Azacitidine in Combination With Pembrolizumab and Epacadostat in Subjects With Advanced Solid Tumors and Previously Treated Stage IIIB or Stage IV Non–Small Cell Lung Cancer and Stage IV Microsatellite-Stable Colorectal Cancer	Hypomethylating agent combined with anti-PD-1 antibody and IDO1 inhibitor	Aung Naing, MD	18	Yes
NCI8808	An Early Phase I Study of ABT-888 in Combination With Carboplatin and Paclitaxel in Patients With Hepatic or Renal Dysfunction and Solid Tumors	PARP inhibitor combined with chemotherapy	Hussein Tawbi, MD, PhD	18	Yes