Department of Investigational Cancer Therapeutics

Phase I Clinical Trials

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THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Making Cancer History®

FROM THE CHAIR

Funda Meric-Bernstam, MD

Cancer cells are smart. They not only invade and spread, but they evade the immune system and molecularly evolve under treatment pressure. Clearly, one therapeutic approach will not be optimal for all.

With our portfolio of over 200 therapeutic Phase I/II trials, oncologists in our department can offer many options to patients who are interested in novel therapies. Incorporating previous oncologic history, using patient and tumor molecular and immunologic characteristics, and using patient preferences for therapy, we hope to offer patients with rare as well as common tumors more personalized therapy.

In this newsletter, we highlight one of the most compelling successes in precision medicine: the approval of larotrectinib for tumors with TRK fusions.[1] The TRK story is truly remarkable clinically but also highlights getting drugs approved for rare alterations requires programmatic efforts in genomics, and teamwork within and across centers to look for the "needle in the haystack." Admittedly, TRK may be one of the most compelling drivers. It is now increasingly apparent that strong genomic drivers such as BRAF and HER2 are drivers across a variety of tumor types. For many genes, the efficacy of targeted single-agent therapy may be greater with certain alterations as seen with FGFR, with the recent FDA approval of FGFR inhibitor erdafitinib in bladder cancer with FGFR mutations/fusions and strong signal of efficacy of several FGFR inhibitors in cholangiocarcinoma with FGFR fusions. However, some of these targets may need combinatorial therapy to overcome adaptive responses and increase efficacy, as seen with BRAFV600E in colon cancer.[2-4] For many targets the co-alterations may matter, as seen in the case of the effect of KRAS status on efficacy of HER2-targeted therapy in colon cancer.[5] The Precision Oncology Decision Support Team supported by the Cancer Prevention Institute of Texas helps our team not only incorporate this rapidly evolving data into our practice but also positions us to lead efforts in precision oncology.

Genomics is only a piece of the puzzle. We are exploring the utility of multiple new diagnostics in order to offer more comprehensive tumor characterization for treatment selection when appropriate. Further, we continue to build new biomarker-driven single-agent and combination therapy trials while also participating in national and international efforts in this front. We have increased our efforts in preclinical modeling to more rapidly test novel agents and rational combinations in clinically relevant models such as patient-derived xenografts generated from tumors with resistance to standard-of-care agents as well as emerging investigational agents. Our institutional commitment to large-scale comprehensive profiling studies for discovery is likely to lead to novel biological insights and novel therapeutics.

Immunotherapy remains an increasing part of our portfolio, with continued emergence of novel therapies and rational combinations. We are well positioned to bring new insights into mechanism of action of novel therapeutics.[6] We are actively working to convert our translational insights into better combinations and better patient selection in immunotherapy.

As you can tell, I am quite proud of our department. We now have over 250 employees, and we are all truly committed to state-of-the-art research-driven patient-centric care. Looking for a new treatment option for your patient? Looking for a collaborator? Looking for advice on how to design a trial? We are a phone call away. Detailed information on how to refer a patient is included in this newsletter. I am available by email (fmeric@mdanderson.org) and am also happy to chat by phone (cell # 832-483-8248). Looking forward to hearing from you. ■

1. Drilon A, Laetsch TW, Kummar S, DuBois SG, Lassen UN, Demetri GD, Meric-Bernstam F, Hong D, et al. Efficacy of larotrectinib in TRK fusion-positive cancers in adults and children. *N Engl J Med* 2018;378(8):731-9. PMC5857389.
2. Hong DS, Morris VK, El Osta B, Sorokin AV, Janku F, Fu S, et al. Phase IB study of vemurafenib in combination with irinotecan and cetuximab in patients with metastatic colorectal cancer with BRAFV600E mutation. *Cancer Discov* 2016;6(12):1352-65. PMC5562357.
3. Kopetz S, Grothey A, Yaeger R, Cuyle P-JA, Huijberts S, Schellens JHM, et al. Updated results of the BEACON CRC safety lead-in: Encorafenib (ENCO) + binimetinib (BINI) + cetuximab (CETUX) for BRAFV600E-mutant metastatic colorectal cancer (mCRC). *J Clin Oncol* 2019;37(4_suppl):688.
4. Kopetz S, McDonough SL, Morris VK, Lenz H-J, Magliocco AM, Atreya CE, et al. Randomized trial of irinotecan and cetuximab with or without vemurafenib in BRAF-mutant metastatic colorectal cancer (SWOG 1406). *J Clin Oncol* 2017;35(4_suppl):520.
5. Meric-Bernstam F, Hurwitz H, Raghav KPS, McWilliams RR, Fakih M, VanderWalde A, et al. Pertuzumab plus trastuzumab for HER2-amplified metastatic colorectal cancer (MyPathway): an updated report from a multicentre, open-label, phase 2a, multiple basket study. *Lancet Oncol* 2019;20(4):518-30.
6. Naing A, Infante JR, Papadopoulos KP, Chan IH, Shen C, Ratti NP, et al. PEGylated IL-10 (Pegilodecakin) induces systemic immune activation, CD8(+) T cell invigoration and polyclonal T cell expansion in cancer patients. *Cancer Cell* 2018;34(5):775-91 e3.

Pancreatic cancer patient in partial remission after experimental drug treatment

By Ronda Wendler

Allison Lippman was on top of the world. She'd just celebrated her 30th birthday, been promoted at work, and met the man of her dreams.

"I thought I'd stay single for a while and focus on my career," says Lippman, who managed a four-star hotel in Dallas. "Then I met Eric through a mutual friend, and we instantly became inseparable. Our first dinner date lasted three hours because we couldn't stop chatting."

The couple discovered they shared a love of travel, and embarked on a magical, weeklong tour of France. But when they returned home in April 2017, Lippman began feeling ill.

"I couldn't digest food, my side hurt all the time, and my energy disappeared," she says. "I'd always been healthy and active. Something was definitely wrong."

'Every person's cancer is genetically different, even when it begins in the same part of the body,' says Vivek Subbiah, M.D., shown here examining Allison Lippman. Photo: Wyatt McSpadden

Visits to various doctors produced no clear answers. Maybe a food allergy was to blame, they suggested, or work-induced stress.

"I was frustrated and lost," Lippman recalls. "I didn't know what to do or where to turn."

She toughed it out until one night when unbearable pain landed her in the emergency room. It was there that she got the shocking diagnosis: stage 4 pancreatic cancer. Lippman had a rare subtype called acinar cell carcinoma which affects only 1 percent of all pancreatic cancer patients. It was aggressive, doctors said, and had spread to her liver.

On her 31st birthday, Lippman met with her oncologist to discuss her treatment plan.

"All I heard was chemotherapy," she recalls, "and I knew my hair would fall out. It was the worst birthday ever."

Two months after she lost her curly blonde locks, Eric whisked Lippman away on a surprise day trip to Paris, Texas. At the base of the town's iconic Eiffel Tower replica with the big, red cowboy hat on top, Eric got down on one knee and proposed marriage. Lippman enthusiastically accepted.

"I tell people we got engaged in Paris," she says.

When the couple arrived home that evening, Eric had arranged for both their extended families to be there to celebrate their engagement.

"It was absolutely amazing and I couldn't stop smiling all day," Lippman says.

She continued chemo for seven months while planning a wedding.

"I was nauseated, weak, super skinny and bald" she remembers, "but I was in love and happy."

In the midst of this whirlwind, Lippman consulted a second doctor in Dallas who suggested sending tissue from her tumor to a lab for genetic testing — a practice known as comprehensive tumor profiling. If the test uncovered the genetic mutation that caused her cancer, Lippman then could be matched with a cancer drug that targets her specific mutation.

"He warned me not to get my hopes up, that it was a needle in a haystack," Lippman recalls. "But I could see how hopeful my fiancé and family members were. I knew I had to try."

It worked. The test revealed that a rare genetic alteration known as a RET fusion caused Lippman's tumor. The discovery meant she could enroll in a clinical trial at MD Anderson, where a drug named LOXO-292 was being tested in patients with RET-fusion-induced cancer.

"Every person's cancer is genetically different, even when it begins in the same part of the body," says Vivek Subbiah, M.D., associate professor of Investigational Cancer Therapeutics and leader of the MD Anderson arm of the national trial. "Two people with pancreatic cancer, for example, can have tumors with genetic profiles that look nothing alike."

These mutations can control how, or if, a tumor will respond to a specific treatment. For this reason, doctors increasingly are interested in profiling their patients' tumors.

Since starting the LOXO-292 trial in January 2018, Lippman says, "I've slowly recovered my strength, gained weight, and my hair has started to grow again."

Four months after joining the trial, she married Eric, a Delta Airlines pilot, and became Allison Lippman Kuban. On their wedding day, she removed her wig to reveal a short, pixie hairstyle.

Today, her tumors have shrunk nearly 50 percent and she no longer has to deal with the side effects of chemotherapy.

"There's still a long road ahead, but I'm on a positive path forward," says Lippman Kuban. "This time last year, I was in a dark place full of uncertainty and unknowns. To be in partial remission and on the road to recovery today is truly miraculous."

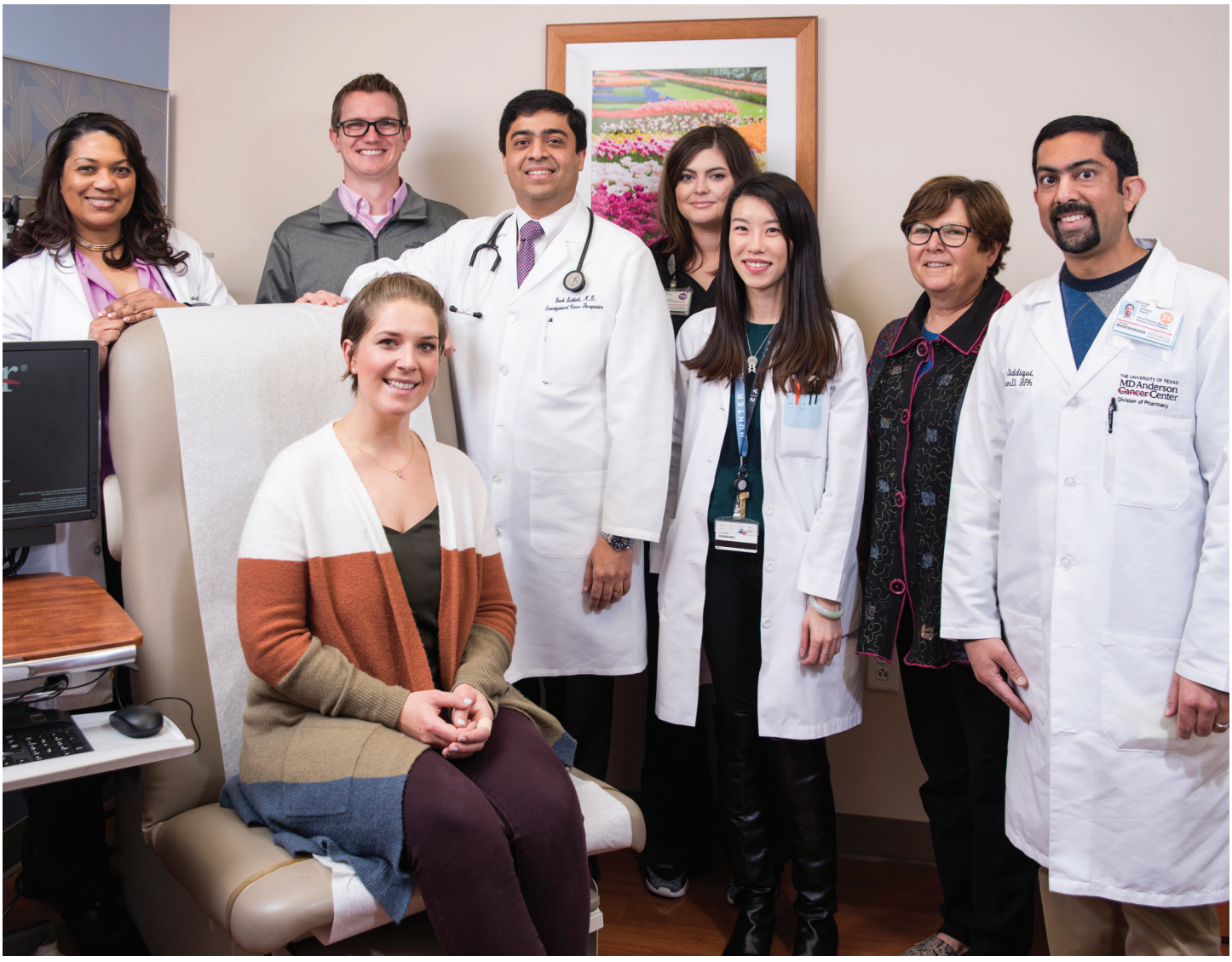
She and Eric recently moved to Houston to be closer to relatives and MD Anderson.

"My drive behind everything is my husband and my family," says Lippman Kuban. "I'm thankful I got the diagnosis, not them. I think it takes more strength for the family and friends watching than for the patient going through treatment."

She's in the midst of writing a book that she hopes will inspire others to explore all treatment options and never give up.

"Miracles do happen," she says. "You might be the needle in the haystack." ■

Shown below are Dr. Subbiah and Allison with her treatment and support team, from left: Anna Poullard, advanced practice registered nurse; husband Eric Kuban; Nicole Gettings, clinical nurse; Anna Lui, clinical studies coordinator; mother Jennifer Lippman; and Asif Siddiqui, clinical pharmacy specialist. Photo: Wyatt McSpadden



TRK inhibitor larotrectinib shows promising results

Histology-agnostic agent effective against many cancer types and sites

Larotrectinib (VITRAKVI, Loxo Oncology and Bayer) was granted accelerated approval by the Food and Drug Administration (FDA) on November 26, 2018, for the treatment of both pediatric and adult patients with a variety of solid tumors with neurotrophic receptor tyrosine kinase (NTRK) gene fusion. According to the FDA, this is the second histology-agnostic agent to receive approval for cancer treatment, representing a major paradigm shift for present and future development of anticancer agents that target specific biomarkers in tumors regardless of tissue location site. Additionally, larotrectinib has the distinction of being the first tropomyosin receptor kinase (TRK) inhibitor to be approved for patients who have advanced solid tumors demonstrating NTRK gene fusion, according to Loxo Oncology.

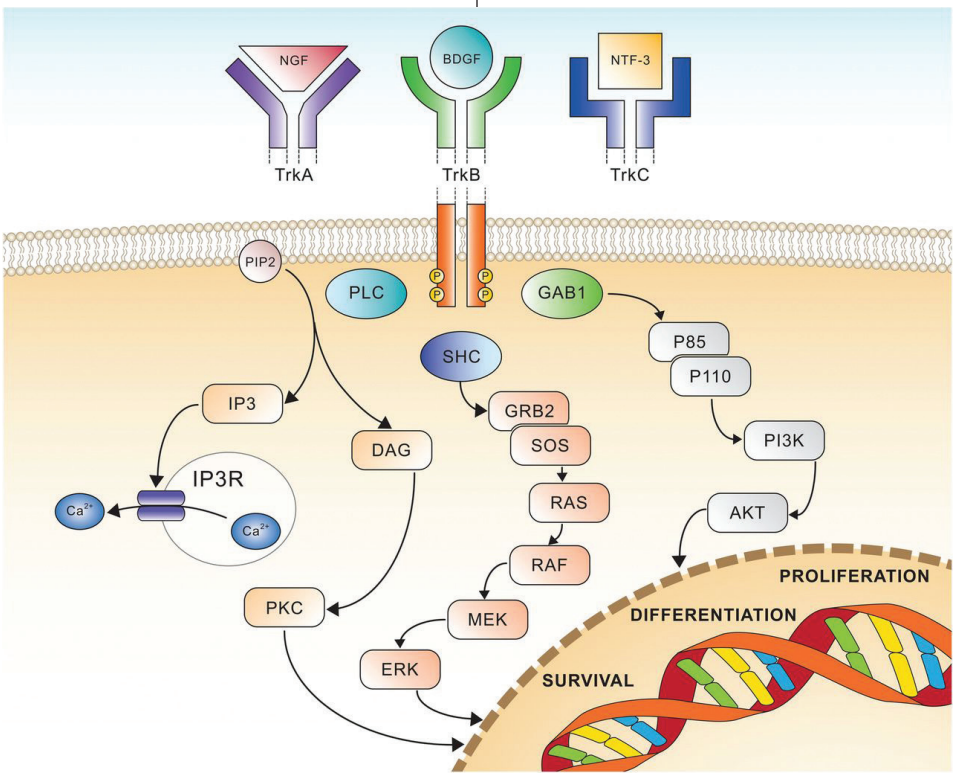


Figure 1. Schematic view of TRK receptors signaling, showing the three major pathways involved in cell differentiation and survival. AKT, v-akt murine thymoma viral oncogene homologue; BDGF, brain-derived growth factor; DAG, diacyl-glycerol; ERK, extracellular signal-regulated kinase; GAB1, GRB2-associated-binding protein 1; GRB2, growth factor receptor-bound protein 2; IP3, inositol trisphosphate; MEK, mitogen-activated protein kinase; NGF, nerve growth factor; NTF-3, neurotrophin 3; PI3K, phosphatidylinositol-4,5-bisphosphate 3-kinase; PIP2, phosphatidylinositol 4,5-bisphosphate; PKC, protein kinase C; PLC, phospholipase C; RAF, rapidly accelerated fibrosarcoma kinase; RAS, rat sarcoma kinase; SHC, Src homology 2 domain containing. (Reprinted with permission. Amatu A, Sartore-Bianchi A, Siena S. NTRK gene fusions as novel targets of cancer therapy across multiple tumour types. ESMO Open. 2016;1(2):e000023. doi:10.1136/esmoopen-2015-000023.)

NTRK gene fusions are well established as active drivers of cancer genesis in a variety of solid tumor types. Early results of larotrectinib trials for the treatment of tumors with NTRK fusions showed promising results. The TRK family includes TRKA, TRKB, and TRKC proteins, which are encoded by NTRK1, NTRK2 and NTRK3 genes, respectively. (See figure 1.)

Selective inhibition of TRK signaling may be beneficial among patients whose tumors vary in histologies but share underlying oncogenic NTRK gene alterations. Currently, several TRK-targeting compounds are in clinical development.[1] MD Anderson's David Hong and Ed Kheder published a paper discussing "Emerging Targeted Therapy for Tumors with NTRK Fusion Proteins" regarding the oncogenic characteristics of TRK fusion proteins within different types of cancer tumors.[2] This article examines several ongoing clinical trials of kinase inhibitors, with the conclusion that, among the tissue-agonist therapeutic agents that have been tested in patients, larotrectinib and entrectinib have proven to be "potent, safe and promising."

Encouraged by the preliminary results, our Phase I team launched and completed several trials that further advanced our understanding of the mechanisms, tolerability and efficacy of larotrectinib in treating patients with NTRK-driven tumors. Hong is the principal investigator of three multi-institutional clinical trials of TRK inhibitors—two of larotrectinib and one of LOXO-195—enrolling adult and pediatric patients. The results of this recently published Phase I trial showed that "larotrectinib was well tolerated and demonstrated activity in all patients with harboring NTRK gene fusions." Specifically, eight out of eight TRK fusion patients (100%) demonstrated an objective response to larotrectinib, in contrast to virtually no activity in tumors harboring other NTRK alterations.[3] This represents an unprecedented treatment option for these patients and helped prompt larotrectinib to enter the registration phase (NCT02122913).

A study by our group, published in February 2018, evaluated the safety and efficacy of larotrectinib in adults and children who had tumors with

one of the three known TRK fusions.[4] Patients were enrolled into one of three protocols: a Phase I study for adults, a Phase I/II study with pediatric patients, or a Phase II study with adolescents and adults. The primary endpoint for the combined analysis was the overall response rate; secondary endpoints included duration of response, progression-free survival, and safety. It was found that larotrectinib displayed excellent antitumor activity in patients with TRK fusion-positive cancers, regardless of the patient's age or tumor type.

Early phase targeted therapy studies involving TRK fusion inhibition are laying the groundwork for advancing novel and efficacious treatment options under the umbrella of personalized or precision medicine. TRK fusion is found as an oncogenic driver across a broad spectrum of tumor types including breast, thyroid, colorectal, non-small cell lung and sarcoma, to name a few. Fortunately, even at this early stage of research, molecular testing is available to help physicians identify this biomarker in a select number of cancer patients, allowing them to take advantage of novel therapies that have been developed thus far. Ongoing studies will continue to advance our knowledge and have the potential for further development of novel targeted therapies. ■

1 Khotskayaa YB, Holla VR, Farago AF, Mills Shaw KR, Meric-Bernstam F, Hong DS. Targeting TRK family proteins in cancer. Pharmacol Ther 2017;173:58-66. doi: 10.1016/j.pharmthera.2017.02.006.

2 Kheder ES, Hong DS. Emerging Targeted Therapy for Tumors with NTRK Fusion Proteins. Clin Cancer Res 2018;24(23):5807-5814. doi: 10.1158/1078-0432.CCR-18-1156.

3 Hong DS, Bauer TM, Lee JJ, Dowlati A, Brose MS, Farago A, Taylor FM, Shaw AT, Montez S, Meric-Bernstam F, et al. Larotrectinib in adult patients with solid tumors: a multi-center, open-label, phase I dose-escalation study. Ann Oncol 2019;30(2)325-31. doi: 10.1093/annonc/mdy539.

4 Drilon A, Laetsch TW, Kummar S, DuBois SG, Lassen UN, Demetri GD, … Meric-Bernstam F, … Hong D, et al. Efficacy of larotrectinib in TRK fusion-positive cancers in adults and children. N Engl J Med 2018;378(8):731-9. PMC5857389. doi: 10.1056/NEJMoa1714448.

ICT by the numbers

89[1] TOTAL NUMBER OF NEW THERAPEUTIC TRIALS OPENED

NUMBER OF EMPLOYEES
250[1]

Number of Patients Enrolled: 1,489[2]

16,245[1] TOTAL NEW PATIENTS, CONSULTS AND ESTABLISHED OUTPATIENTS

Number of Active Trials
By Agent & Phase[3]

PHASE I
single agent: 54 (29%)
combination: 66 (36%)

PHASE II
single agent: 23 (12%)
combination: 42 (23%)

NUMBER OF
Active Trials By Drug Type[3]
Immunotherapy: 95 (50%)
Targeted therapy: 84 (45%)
Other: 9 (5%)

1 Fiscal year 2018 (Sept. 1, 2017 – Aug. 31, 2018)
2 Calendar 2018
3 As of January 2019

Active Phase I Program Protocols May 2019

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Protocol	Title	Drugs & Mechanism of Action	PI
2019-0080	Long-term, Non-interventional, Observation Study Post Fate Therapeutics' Cellular Immunotherapy	FT500 (NK cell mediator) +/- Nivolumab, Pembrolizumab or Atezolizumab (immune checkpoint inhibitors)	Hong
2018-1079	A Phase I Cohort Dose-Escalation Trial to Determine the Safety, Tolerance, Maximum Tolerated Dose, and Preliminary Antineoplastic Activity of AVID200, a Transforming Growth Factor beta (TGFβ) Inhibitor, in Patients with Advanced or Metastatic Solid Tumor Malignancies	AVID200 (TGF-beta trap)	Yap
2018-1078	Phase 1 Dose Escalation and Dose Expansion Study of an Agonist Redirected Checkpoint Fusion Protein, SL-279252 (PD1-Fc-OX40L), in Subjects with Advanced Solid Tumors or Lymphomas	agonist redirected checkpoint	Hong
2018-1004	A Phase I, Multi-Center, Dose Escalation, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Evidence of Antitumor Activity of JAB-3068 in Adult Patients with Advanced Solid Tumors	JAB-3068 (SHP2 phosphatase inhibitor)	Piha-Paul
2018-0985	A Phase I, Open-label, Dose Escalation and Dose Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Anti-tumour Activity of IPN60090 as Single Agent and in Combination in Patients with Advanced Solid Tumours	IPN60090 (glutaminase inhibitor) +/- Pembrolizumab (anti-PD-1 mAB) or Paclitaxel (chemotherapy)	Yap
2018-0963	A Phase IB Dose-Escalation Study of Cabozantinib (XL184) Administered Alone or in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors	Cabozantinib (MET/RET/VEGFGR kinase inhibitor) + Atezolizumab (anti-PD-L1 mAB)	Subbiah
2018-0954	An Open-Label, Multicenter, Phase IB/II Study of Rebastinib (DCC-2036) in Combination with Carboplatin to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced or Metastatic Solid Tumors	Rebastinib (TIE2 inhibitor) + Carboplatin (chemotherapy)	Janku
2018-0891	A Phase 1a/1b Study of COM701 as Monotherapy and in Combination with an Anti-PD-1 Antibody in Subjects with Advanced Solid Tumors	COM701 (anti-PVRIG) +/- Nivolumab (anti-PD-1 mAB)	Dumbrava
2018-0883	A Phase I Dose-Escalation Study of FF-10832 for the Treatment of Advanced Solid Tumors	FF-10832 (gemcitabine liposome injection)	Janku
2018-0826	A Multicentre, Open-Label, Non-Randomised First in Human Study of NG-350A in Patients with Metastatic or Advanced Epithelial Tumours (FORTITUDE)	NG-350A (anti-CD40 mAB)	Naing
2018-0825	A Phase I/II, Open-Label, Multi-center Study of the Safety and Efficacy of KY1044 as Single Agent and in Combination with Anti-PD-L1 (Atezolizumab) in Adult Patients with Selected Advanced Malignancies	KY1044 (ICOS inhibitor) +/- Atezolizumab (anti-PD-L1 mAB)	Naing
2018-0820	A Phase I, Multicenter, Open-label Dose Finding Study of NJH395, Administered Intravenously in Patients with Non-breast HER2+ Advanced Malignancies	NJH395 (immune stimulator antibody conjugate targeting HER2-positive tumor)	Janku
2018-0765	A Phase I Study Exploring the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of INCB086550 in Participants with Advanced Solid Tumors	INCB086550 (PD-L1 inhibitor)	Piha-Paul
2018-0731	A Phase I/II, Open-Label Study to Investigate the Safety, Clinical Activity, Pharmacokinetics, and Pharmacodynamics of GSK3145095 Administered Alone and in Combination with Anticancer Agents Including Pembrolizumab in Adult Participants with Selected Advanced Solid Tumors	GSK3145095 (receptor interacting protein 1 [RIp1] inhibitor) +/- Pembrolizumab anti-PD-1 mAB)	Pant
2018-0707	A Phase I, First-In-Human, Multicenter, Open-Label Study of TT-00420, Administered Orally in Adult Patients with Advanced Solid Tumors and Triple Negative Breast Cancers	TT-00420 (pan kinase inhibitor)	Piha-Paul
2018-0692	A First-in-Human Phase I Trial to Determine the Safety and the Pharmacokinetic Profile of DSP-0509, a Synthetic Toll-Like Receptor 7 (TLR-7) Agonist, in Adult Patients with Advanced Solid Tumors	DSP-0509 (TLR-7 agonist)	Subbiah
2018-0686	A Phase I First Time in Human Open Label Study of GSK3745417 administered with and without Anticancer Agents in Participants with Advanced Solid Tumors	GSK3745417 (STING agonist)	Meric-Bernstam
2018-0682	An Open Label, Phase IA/IB Dose Finding Study with BI 894999 Orally Administered Once a Day in Patients with Advanced Malignancies with Repeated Administration in Patients with Clinical Benefit	BI 894999 (BET inhibitor)	Piha-Paul

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, clinical protocol administration manager, to add a case to the meeting agenda (lmnguyen1@mdanderson.org; 713-563-2169). See also: clinicaltrials.org.

Protocol	Title	Drugs & Mechanism of Action	PI
2018-0681	A Phase I, Open Label, Dose Escalation Study of MGD009, a Humanized B7-H3 x CD3 DART Protein, in Combination with MGA012, an Anti-PD-1 Antibody, in Patients with Relapsed or Refractory B7-H3-Expressing Tumors	MGD009 (humanized B7-H3 x CD3 DART protein) + MGA012 (anti-PD-1 mAB)	Fu
2018-0667	A Phase IB, Open-Label, Dose Escalation Study of PRS-343 in Combination with Atezolizumab in Patients with Specific HER2-Positive Advanced or Metastatic Solid Tumors	PRS-343 (bispecific protein targeting HER2 and CD137) + Atezolizumab (anti-PD-L1 mAB)	Piha-Paul
2018-0666	A phase I, open-label, dose-escalation study to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of GSK3368715 in participants with solid tumors and DLBCL	GSK3368715 (protein arginine methyltransferase [PRMT1] inhibitor)	Rodón Ahnert
2018-0643	A Randomized, Open-Label, Phase 2 Study of Nivolumab in Combination with Ipilimumab or Nivolumab Monotherapy in Participants with Advanced or Metastatic Solid Tumors of High Tumor Mutational Burden (TMB-H) CA209848	Nivolumab (anti-PD-1 mAB) +/- Ipilimumab (anti-CTLA4 antibody)	Naing
2018-0636	Phase I, Two-Part, Multicenter, Non-Randomized, Open-Label, Multiple Dose, First-In-Human Study of DS-1062a in Subjects with Advanced Solid Tumors.	DS-1062a (TROP2 [Trophoblast cell-surface antigen]2 antibody drug conjugate)	Meric-Bernstam
2018-0635	FT500 as Monotherapy and in Combination with Immune Checkpoint Inhibitors in Subjects with Advanced Solid Tumors	FT500 (NK cell mediator) +/- Nivolumab, Pembrolizumab or Atezolizumab (immune checkpoint inhibitors)	Hong
2018-0606	An Open-Label, Multicenter, First-in-Human, Dose-Escalation Phase I Study of INBRX-109 in Subjects with Locally Advanced or Metastatic Solid Tumors Including Sarcomas	INBRX-109 (DR5 agonist)	Subbiah
2018-0586	A Multicentre, Open-Label Phase I/II Study to Evaluate the Safety, Tolerability, Biodistribution and Anti-Tumour Activity of 177Lu-OPS201 with Companion Imaging 68Ga-OPS202 PET/CT in Previously Treated Subjects with Locally Advanced or Metastatic Cancers Expressing Somatostatin Receptor 2 (Sstr2)	177Lu-OPS201 (radiolabeled compound targeting sstr2) with companion imaging 68Ga-OPS202 PET/CT	Rodón Ahnert
2018-0563	Phase I/II Study of BMS-986310 Administered Alone and in Combination with Nivolumab in Participants with Advanced Solid Tumors	BMS-986310 (EP4 antagonist) +/- Nivolumab (anti-PD-1 mAB)	Janku
2018-0561	A Phase IB Study of ALRN-6924 in Combination with Paclitaxel in Wild-type TP53 Advanced or Metastatic Solid Tumors including Estrogen-Receptor Positive Breast Cancer	ALRN-6924 (dual inhibitor of MDM2/MDMX) + Paclitaxel (chemotherapy)	Meric-Bernstam
2018-0538	Phase 1 Study Evaluating Genetically Modified Autologous T Cells Expressing a T-Cell Receptor Recognizing a Cancer/Germline Antigen in Subjects with Relapsed and/or Refractory Solid Tumors (ACTengine IMA203-101)	(genetically modified autologous T cells)	Tsimberidou
2018-0531	A Phase I/IB, Open-Label, Multi-Center Study of NZV930 as a Single Agent and in Combination with PDR001 and/or NIR178 in Patients with Advanced Malignancies	NZV930 (anti-CD73 mAB) + PDR001 (anti-PD-1) +/- NIR178 (adenosine antagonist)	Fu
2018-0524	Phase I Dose-Finding, Safety Study of Oral AMXT 1501 Dicaprate and Difluoromethylornithine (DFMO) in Patients with Advanced Solid Tumors	AMXT 1501 Dicaprate (polyamine transport inhibitor) + DMFO (polyamine biosynthesis inhibitor)	Piha-Paul
2018-0493	An Open-Label, Multicenter, Phase IB/II Study of Rebastinib (DCC-2036) in Combination with Paclitaxel to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced or Metastatic Solid Tumors	Rebastinib (TIE2 inhibitor) + Paclitaxel (chemotherapy)	Janku
2018-0483	A Phase I/II First-in-Human Study of BMS-986249 Alone and in Combination with Nivolumab in Advanced Solid Tumors	BMS-986249 (anti-CTLA-4 mAB) +/- Nivolumab (anti-PD-1 mAB)	Piha-Paul
2018-0482	A Phase I/IIA Study of BMS-986253 in Combination with Nivolumab in Advanced Cancers	BMS-986253 (anti-IL-8 antibody) + Nivolumab (anti-PD-1 antibody) Escalation	Piha-Paul
2018-0458	A Phase I, First-in-Human, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 510 in Subjects with Advanced Solid Tumors with a Specific KRAS Mutation	AMG 510 (KRAS G12C-mutant inhibitor)	Hong
2018-0443	An Open-Label Phase IB Study of the Safety, Tolerability, and Preliminary Antitumor Activity of INCB059872 in Participants with Relapsed or Refractory Ewing Sarcoma	INCB059872 (LSD1 inhibitor)	Subbiah
2018-0435	An Open-Label, Phase I, First-in-Human, Dose Escalation and Expansion Study to Evaluate the Safety, Tolerability, Maximum Tolerated or Administered Dose, Pharmacokinetics, Pharmacodynamics and Tumor Response Profile of the ILDR2 Function-Blocking Antibody BAY 1905254 in Patients with Advanced Solid Tumors	BAY 1905254 (anti-ILDR2 antibody)	Subbiah
2018-0408	A Phase I Dose Escalation Study Evaluating Safety, Tolerability and Pharmacokinetics of PF-06952229 in Adult Patients with Advanced Solid Tumors	PF-06952229 (TGFBR1 inhibitor)	Yap
2018-0402	A Phase I/II Open-Label, Multi-Center, Safety, Preliminary Efficacy and Pharmacokinetic (PK) Study of Isatuximab (SAR650984) in Combination with Atezolizumab or Isatuximab Alone in Patients with Advanced Malignancies	Isatuximab (anti-CD38 mAB) =/- Atezolizumab (anti-PD-L1 mAB)	Pant

Protocol	Title	Drugs & Mechanism of Action	PI
2018-0401	A Phase IB/II Study to Evaluate Safety and Clinical Activity of Avelumab in Combination with Binimetinib with or without Talazoparib in Patients with Locally Advanced or Metastatic RAS-Mutant Solid Tumors	Avelumab (anti-PD-1 mAB) + Binimetinib (MEK 1/2 inhibitor) +/- Talazoparib (PARP inhibitor)	Rodón Ahnert
2018-0388	An Open-Label, Phase I Trial to Determine the Maximum-Tolerated Dose and Investigate Safety, Pharmacokinetics, and Efficacy of BI 754091 in Patients with Advanced Solid Tumours	BI 754091 (anti-PD-1 mAB)	Fu
2018-0355	Phase I/II, First-in-Human Study of CX-2029 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas	CX-2029 (anti-CD71 probody-drug conjugate / transferrin receptor 1)	Rodón Ahnert
2018-0349	External Beam Radiation to Eliminate Nominal Metastatic Disease (EXTEND): A Randomized Phase II Basket Trial Assessing the Efficacy of Upfront Local Consolidative Therapy (LCT) for Oligometastatic Disease	Radiation therapy	Tang
2018-0318	A Phase I-II, First-in-Human Study of A166 in Patients with Locally Advanced/Metastatic Solid Tumors which are Human Epidermal Growth Factor Receptor 2 (HER2)-Positive who did not Respond or Stopped Responding to Approved Therapies and Patients with HER2 Positive (by ISH or NGS) or Low Expressing (by IHC) Solid Tumors who did not Respond or Stopped Responding to Approved Therapies	A166 (HER2 inhibitor)	Rodón Ahnert
2018-0293	Open Label Phase II Study of Tisotumab Vedotin for Locally Advanced or Metastatic Disease in Solid Tumors	Tisotumab Vedotin (microtubule inhibitor)	Hong
2018-0290	A Phase I/II Open-Label, Safety and Preliminary Efficacy Study of MRx0518 in Combination with Pembrolizumab in Patients with Advanced Malignancies who Have Progressed on PD-1 Inhibitors	MRx0518 (oral Bifidobacterium) + Pembrolizumab (anti-PD-1 mAB)	Pant
2018-0282	A Phase I/II Dose Escalation and Dose Expansion Study of BA3021 in Patients with Advanced Solid Tumors	BA3021 (CAB [conditionally active biologic]-ROR2 [receptor tyrosine kinase orphan receptor] ADC	Fu
2018-0257	A Phase I Multiple Dose Study to Evaluate the Safety and Tolerability of XmAb?20717 in Subjects with Selected Advanced Solid Tumors (DUET-2)	XmAb20717 (bispecific anti-PD1 immune checkpoint inhibitor and CTLA4 inhibitor)	Pant
2018-0256	A Phase II Study to Evaluate Safety and Anti-Tumor Activity of Avelumab in Combination with Talazoparib in Patients with BRCA or ATM Mutant Tumors	Avelumab (anti-PD-L1) + Talazoparib (PARP inhibitor)	Yap
2018-0231	A Phase I, Open-Label, Dose-Finding Study of ASN007 in Patients with Advanced Solid Tumors	ASN007 (ERK 1/2 inhibitor)	Janku
2018-0218	A Phase IA/IB Study of FPA150, an Anti-B7-H4 Antibody, in Patients with Advanced Solid Tumors	FPA150 (anti-B7-H4 antibody)	Pant
2018-0208	A Phase I, Open-Label, Multicenter Trial Investigating the Safety, Tolerability, and Preliminary Antineoplastic Activity of Sym023 (Anti-TIM-3) in Patients with Advanced Solid Tumor Malignancies or Lymphomas	Sym023 (TIM-3 inhibitor)	Janku
2018-0188	A Phase I/II Study of OBI-3424 in Subjects with Solid Tumors, Hepatocellular Carcinoma and Castrate-Resistant Prostate Cancer	OBI-3424 (alkylating agent)	Tsimberidou
2018-0183	A Phase I, Open-Label Study of the Safety, Pharmacokinetics and Efficacy of RX108 in Patients with Locally Advanced or Metastatic Solid Tumors	RX108 (Na+/K+-ATPase [sodium pump] inhibitor)	Fu
2018-0150	An Open-Label, Phase I, First-in-Human, Dose Escalation and Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Tumor Response Profile of the Anti-CEACAM6 Antibody BAY 1834942 in Patients with Advanced Solid Tumors	BAy 1834942 (anti-CEACAM6 antibody)	Hong
2018-0060	A Phase I, Open-Label, Dose-Escalation, and Cohort Expansion First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Activity of FS118, a LAG-3/PD-L1 Bispecific Antibody, in Patients with Advanced Malignancies That Have Progressed On or After Prior PD-1/PD-L1 Containing Therapy	FS118 (LAG-3/PD-L1 bispecific antibody)	Yap
2018-0005	A Phase IB, Multicenter, Open-Label Study of DSP-7888 Dosing Emulsion in Combination with Immune Checkpoint Inhibitors Nivolumab or Atezolizumab in Adult Subjects with Advanced Solid Tumors	DSP-7888 (WT1-derived peptide vaccine) + Nivolumab or Atezolizumab (anti-PD-1/ PD-L1 Immune checkpoint inhibitors)	Subbiah
2017-1069	A Phase I, Open-Label, Dose Escalation and Cohort Expansion Study Evaluating the Safety, Pharmacokinetics (PK), Pharmacodynamics (PD), and Therapeutic Activity of OBI-888 in Patients with Locally Advanced or Metastatic Solid Tumors	OBI-888 (anti-Globo H mAB)	Tsimberidou
2017-1068	A Phase IB/IIA Dose Escalation and Confirmation Study of PT-112 in Advanced Solid Tumors in Combination with Avelumab	PT-112 (phosphorylated platinum) + Avelumab (anti-PD-L1 mAB)	Karp
2017-1067	A Parallel Phase II Study of Glesatinib, Sitravatinib or Mocetinostat in Combination with Nivolumab in Advanced or Metastatic Non-Small Cell Lung Cancer	Glesatinib (AXL/MET inhibitor), Sitravatinib (multiple RTK inhibitor) or Mocetinostat (HDAC inhibitor) and Nivolumab (anti-PD-L1 antibody)	Hong

Protocol	Title	Drugs & Mechanism of Action	PI
2017-1065	A Phase IB/II, Open-Label, Multicentre Study to Assess Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of AZD9150 plus Durvalumab alone or in Combination with Chemotherapy in Patients with Advanced, Solid Tumours and Subsequently in Patients with Non-Small-Cell Lung Cancer	AZD9150(STAT3 inhibitor) + Durvalumab (anti PD-L1 antibody) +/- chemotherapy	Hong
2017-1064	A Phase I/II Dose Escalation and Dose Expansion Study of BA3011 in Patients with Advanced Solid Tumors	BA3011 (CAB-Axl mAB)	Rodón Ahnert
2017-1057	A Phase I/II, Multicenter, Single-Arm, Open-Label, Dose-Escalation Study of Birinapant in Combination with Pembrolizumab (KEYTRUDA) in Patients with Relapsed or Refractory Solid Tumors	Birinapant (Second mitochondria-derived activator of caspase [SMAC]-mimetic) + Pembrolizumab (anti-PD-L1 antibody)	Fu
2017-1041	A Phase I Study of BMS-986299 as Monotherapy and in Combination with Nivolumab and Ipilimumab in Participants with Advanced Solid Cancers	BMS-986299 (Nucleotide-binding domain and leucine-rich repeat-containing protein 3 [NLRP3] agonist) +/- immunotherapy -	Janku
2017-1009	A Phase IA/B, Open-label, Dose-escalation Study of the Safety and Pharmacokinetics of BTRC4017A Administered Intravenously as a Single Agent and in Combination with Trastuzumab in Patients with Locally Advanced or Metastatic HER2-expressing Cancers	BTRC4017A (bi-specific HER2/CD3 antibody)	Yap
2017-0968	A Phase I, Open-Label Study of GSK1795091 Administered in Combination with Immunotherapies in Participants with Advanced Solid Tumors	GSK1795091 (toll-like receptor 4 (TLR4) agonist) +/- GSK3174998 (OX40 agonist)	Piha-Paul
2017-0932	A Phase I/II Open-Label, Multi-Center, Safety, Preliminary Efficacy and Pharmacokinetic (PK) Study of Isatuximab (SAR650984) in Combination with REGN2810 or Isatuximab Alone in Patients with Advanced Malignancies	Isatuximab (mAB targeting CD38 expression) +/- REGN2810 (anti-PD-1 mAB)	Pant
2017-0931	A Phase IB Study to Assess the Safety, Tolerability, and Clinical Activity of BGB-290 in Combination with Temozolomide (TMZ) in Subjects with Locally Advanced or Metastatic Solid Tumors	BGB-290 (PARP inhibitor) + Temozolomide (alkylating agent)	Fu
2017-0918	Phase I/IIA Dose Escalation and Expansion Study Evaluating Safety, Tolerability, Pharmacokinetic, Pharmacodynamics and Anti-tumor Activity of PF-06873600 as a Single Agent and in Combination with Endocrine Therapy	PF-06873600 (CDK inhibitor) monotherapy	Yap
2017-0904	Phase I Trial Evaluating Genetically Modified Autologous T cells Expressing a T-cell Receptor Recognizing a Cancer/Germline Antigen in Patients with Squamous Cell Non-Small Cell Lung Cancer or Hepatocellular Carcinoma (ACTengine IMA202-101)	ACTengine (genetically modified autologous T cells)	Tsimberidou
2017-0890	First in Human, Open Label, Dose-Escalation Trial with Expansion Cohorts to Evaluate Safety of GEN1029 in Patients with Malignant Solid Tumors	GEN1029 (DR5 inhibitor)	Rodón Ahnert
2017-0870	A Phase I Multiple Dose Study to Evaluate the Safety and Tolerability of XmAb 18087 in Subjects with Advanced Neuroendocrine and Gastrointestinal Stromal Tumors (DUET-1)	XmAb18087 (bi-specific antibody targeting SSTR2)	Pant
2017-0853	A Phase I Open-label, Multicenter Study of MK-2118 Administered by Intratumoral Injection as Monotherapy and in Combination with Pembrolizumab or by Subcutaneous Injection in Combination with Pembrolizumab for Patients with Advanced/Metastatic Solid Tumors or Lymphomas	MK-2118 (STING agonist) +/- Pembrolizumab (anti-PD-1 mAB)	Yap
2017-0851	NCT02988817First-in-Human, Open-label, Dose-escalation Trial with Expansion Cohorts to Evaluate Safety of Axl-specific Antibody-drug Conjugate (Enapotamab Vedotin, HuMax-AXL-ADC) in Patients with Solid Tumors	HuMax-AXL-ADC (Axl-specific ADC)	Piha-Paul
2017-0821	A Phase I/IB, Open-Label, Multi-Center Dose-Escalation and Dose-Expansion Study of the Safety and Tolerability of Intratumorally Administered LHC165 Single Agent and in Combination with PDR001 in Patients with Advanced Malignancies	LHC165 (TLR-7 agonist) +/- PDR001 (anti-PD1 mAB)	Meric-Bernstam
2017-0790	An Open-Label, Non-Randomized, Multicenter Study to Determine the Pharmacokinetics and Safety of Niraparib Following A Single Oral Dose in Patients with Advanced Solid Tumors and Either Normal Hepatic Function or Moderate Hepatic Impairment	Niraparib (PARP inhibitor)	Piha-Paul
2017-0779	A Phase I, Open-Label, Multicenter Trial Investigating the Safety, Tolerability, and Preliminary Antineoplastic Activity of Sym021 (Anti-PD-1) as Monotherapy and in Combination with either Sym022 (Anti-LAG-3) or Sym023 (Anti-TIM-3) in Patients with Advanced Solid Tumor Malignancies or Lymphomas	Sym021 (anti-PD-1 mAB) +/- Sym022 (anti-LAG-3) or Sym23 (anti-TIM-3)	Rodón Ahnert
2017-0719	A Phase IB Investigation of Pembrolizumab in Combination with Intratumoral Injection of Clostridium novyi-NT in Patients with Treatment-Refractory Solid Tumors	Pembrolizumab (PD-L1 inhibitor) + Clostridium novyi-NT (C. novyi-NT lyses tumor cells in hypoxic tumor cores)	Janku
2017-0703	A Phase I/II Study to Evaluate the Safety, Tolerability, and Efficacy of INCB001158 in Combination with Chemotherapy, in Subjects With Advanced or Metastatic Solid Tumors	INCB001158 (Arginase 1/2 inhibitor) + Chemotherapy	Naing
2017-0690	Phase IB Dose-finding Study of Niraparib or Carboplatin-Paclitaxel in Combination with TSR-042 in Patients with Advanced or Metastatic Cancer	Niraparib (PARP inhibitor) + TSR-42 (anti-PD-1 mAB)	Yap

Protocol	Title	Drugs & Mechanism of Action	PI
2017-0682	An Open-Label, Randomized-Sequence, Multicenter, Single-Crossover Study to Assess the Relative Bioavailability and Bioequivalence of Niraparib Tablet Formulation Compared to Niraparib Capsule Formulation in Patients with Advanced Solid Tumors	Niraparib (PARP inhibitor)	Piha-Paul
2017-0624	A Phase I Trial of MK-4280 as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors	MK-4280 (LAG-3 inhibitor) + Pembrolizumab (anti-PD-1 mAB)	Piha-Paul
2017-0614	A Two-Part, Phase I, Open-Label, Multicenter, Non-Randomized, Dose Escalation/Expansion Study to Evaluate the Safety and Tolerability of HTI-1066 in Subjects with Advanced Solid Tumors (Including c-Met Positive)	HTI-1066 (cMET inhibitory mAB)	Fu
2017-0567	The Targeted Agent and Profiling Utilization Registry (TAPUR) Study	Various FDA-approved targeted anti-cancer therapies	Meric-Bernstam
2017-0539	A Phase I Dose Escalation Study Evaluating the Safety and Tolerability of PF-06804103 in patients with Human Epidermal Growth Factor Receptor 2 (HER2) Positive Solid Tumors	PF-06804103 (HER2 ADC)	Meric-Bernstam
2017-0526	A Phase II, Multi-Center, Open Label Study of NIR178 in Combination with PDR001 in Patients with Selected Advanced Solid Tumors and Non-Hodgkin Lymphoma	NIR178 (adenosine A2a receptor antagonist) + PDR001 (anti-PD-1 IgG4 antibody)	Yap
2017-0524	A Phase IB/II Study to Evaluate Safety and Anti-Tumor Activity of Avelumab in Combination with the Poly (Adenosine Diphosphate (ADP)-Ribose) Polymerase (PARP) Inhibitor Talazoparib in Patients with Locally Advanced or Metastatic Solid Tumors	Avelumab (anti-PD-L1 monoclonal antibody) + Talazoparib (PARP inhibitor)	Yap
2017-0520	A Phase IB Study of Intratumoral IMO-2125 in Patients with Refractory Solid Tumors (Illuminate-101)	IMO-2125 (TLR9 [toll-like receptor] agonist)	Subbiah
2017-0446	An Exploratory Study of Nivolumab with or without Ipilimumab According to Tumor CD8 Expression in Patients with Advanced Cancer	Nivolumab (anti-PD-L1 mAB) +/- Ipilimumab (anti-CTLA4 mAB)	Tsimberidou
2017-0422	A Phase I Study of TAK-659 and Paclitaxel in Patients with Advanced Solid Tumors	TAK-659 (SYK [spleen tyrosine kinase] inhibitor) + Paclitaxel (chemotherapy)	Fu
2017-0418	A Phase I/II Study of the TRK Inhibitor LOXO-195 in Adult Subjects with NTRK Fusion (Previously Treated) or Non-Fusion NTRK Altered Cancers	LOXO-195 (TRK inhibitor)	Hong
2017-0391	A Phase I Dose Escalation and Cohort Expansion Study of TSR-022, an anti-TIM-3 Monoclonal Antibody, in Patients with Advanced Solid Tumors	TSR-022 (anti-TIM-3 mAB) + TSR-042 (anti-PD-L1 antibody)	Yap
2017-0376	A Phase I/II, Open-Label, Multiple Ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of AGEN2034 in Subjects with Metastatic or Locally Advanced Solid Tumors, with Expansion to Select Solid Tumors	AGEN2034 (anti-PD-1 mAB)	Subbiah
2017-0339	A Phase IB/II Trial of M7824 in Solid Tumors with Microsatellite Instability with Consensus Molecular Subtype 4 Metastatic Colorectal Cancer in Combination with Radiation, or in Colorectal Cancer Patients with Detectible Circulating tumor DNA following Definitive Therapy	M7824 (anti PDL1/TGF beta trap)	Morris
2017-0308	A Phase IB, Open Label, Multicenter Study of the Safety and Efficacy of MIW815 (ADU-S100) Administered by Intratumoral Injection with PDR001 to Patients with Advanced/Metastatic Solid Tumors or Lymphomas	MIW815 (STING agonist) + PDR001 (anti-PD-1IgG4 antibody)	Meric-Bernstam
2017-0307	A Phase I/II, Open-Label, Dose-Finding, Proof of Concept, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of CX-2009 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors	CX-2009 (CD166 probody)	Meric-Bernstam
2017-0297	A Phase I, Open-Label, Dose Escalation Study of PRS-343 in Patients with HER2-Positive Advanced or Metastatic Solid Tumors	PRS-343 (bispecific HER2+/CD137 antibody)	Piha-Paul
2017-0237	A Phase I/II Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination with Immune Therapies in Subjects with Advanced or Metastatic Malignancies	INCAGN1876 (GITR agonist) + Nivolumab (PD-L1 inhibitor) or Ipilimumab (anti-CTLA-4 antibody)	Subbiah
2017-0214	A Phase I, Multicenter, Open-label Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TAB001 in Subjects with Advanced Malignancies	TAB001 (PD-1 inhibitor)	Naing
2017-0202	A Phase I/II Study of Oral LOXO-292 in Patients with Advanced Solid Tumors, Including RET-Fusion Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors with RET Activation (LIBRETTO-001)	LOXO-292 (RET inhibitor)	Subbiah
2017-0186	An Open-Label, First-In-Human, Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose and / or Recommended Phase II Dose of the ATR Inhibitor BAY 1895344 in Patients with Advanced Solid Tumors and Lymphomas	BAY 1895344 (ATR inhibitor)	Yap

Protocol	Title	Drugs & Mechanism of Action	PI
2017-0180	Phase I Clinical Trial Evaluating the Safety and Response with PF-05082566, Cetuximab and Irinotecan in Patients with Advanced Colorectal Cancer	PF-05082566 (IgG2 mAB agonist of 4-1BB), Cetuximab (EGFR inhibitor) and Irinotecan (RAS inhibitor)	Hong
2017-0144	An Open Label Ascending Dose Study Evaluating The Safety/Tolerability, Pharmacokinetic and Pharmacodynamic Effects of KA2507 in Patients with Solid Tumors	KA2507 (HDAC6 inhibitor)	Tsimberidou
2017-0045	A Phase I, Open-Label, Dose-Escalation and Cohort Expansion First-in-Human Study of the Safety, Tolerability, Activity and Pharmacokinetics of REGN3767 (anti-LAG-3 mAb) Administered Alone or in Combination with REGN2810 (anti-PD-1 mAb) in Patients with Advanced Malignancies	REGN3767 (anti-LAG-3 monoclonal antibody) +/- REGN2810 (anti-PD-1 monoclonal antibody)	Yap
2017-0023	A Phase I Study to Evaluate the Safety and Tolerability of IACS-010759 in Subjects with Advanced Solid Tumors and Lymphoma	IACS-010759 (OXPHOS inhibitor)	Yap
2017-0014	Phase I/II Study to Evaluate the Safety and Tolerability of Avelumab in Combination with Other Anti-Cancer Therapies in Patients with Advanced Malignancies	Avelumab (anti-PD-L1 monoclonal antibody) + Utomilumab (anti-4-1BB monoclonal antibody) or PF-04518600 (OX40 agonist) + XRT	Naing
2016-1129	Evaluation of the Combination of Selumetinib and Olaparib in Endometrial, Ovarian and Other Solid Tumors with Ras Pathway Alterations, and Ovarian Tumors with PARP Resistance	Selumetinib (MEK inhibitor) + Olaparib (PARP inhibitor)	Westin
2016-1107	Phase I Dose Escalation, Multi-tumor Study to Assess the Safety, Tolerability and Antitumor Activity of Genetically Engineered MAGE-A4c1032T in HLA-A2+ Subjects with MAGE-A4 Positive Tumors	MAGE-A4c1032T (engineered T cells against MAGE-A4-directed T-cell receptors)	Hong
2016-1097	A Phase I Study Evaluating the Safety and Efficacy of MAGE-A3/A6 T Cell Receptor Engineered T Cells (KITE-718) in HLA-DPB1*04:01 Positive Subjects with Advanced Cancers	KITE-718 (Engineered T cells against MAGE-A3-directed T cell receptors)	Kebriaei
2016-1092	A Phase IB Study of OMP-305B83 plus Weekly Paclitaxel in Subjects with Platinum Resistant Ovarian, Primary Peritoneal or Fallopian Tube Cancer	OMP-305B83 (DLL4 antibody) + Paclitaxel (chemotherapy)	Fu
2016-1029	A Phase I Immunotherapy Study of Evofosfamide in Combination with Ipilimumab in Patients with Advanced Solid Malignancies	Evofosfamide (Br IPM [bromo-isophosphoramide mustard] pro-drug)	Hong
2016-1007	A Phase I Study of the Highly-selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors	BLU-667 (RET inhibitor)	Subbiah
2016-0994	Phase I Trial Evaluating Genetically Modified Autologous T cells Expressing a T cell Receptor Recognizing a Cancer/Germline Antigen in Patients Having Solid Tumors with Emphasis on Non-Small Cell Lung Cancer or Head and Neck Squamous Cell Carcinoma (ACTengine IMA201-101)	ACTengine (genetically modified autologous T cells)	Blumenschein
2016-0965	A Multicenter, Phase I, Open-Label, Dose-Escalation Study of ABBV-927 and ABBV181, an Immunotherapy, in Subjects with Advanced Solid Tumors	ABBV-927 (anti-CD 40)	Subbiah
2016-0845	A Phase I Study of TAK-228 (MLN0128) in Combination with Carboplatin plus Paclitaxel in Patients with Advanced Malignancies	TAK228 (mTOR inhibitor) + Paclitaxel + Carboplatin (chemotherapy)	Subbiah
2016-0842	Phase I study of TTI-101, an Oral Inhibitor of Signal Transducer and Activator of Transcription (STAT) 3, in Patients with Advanced Cancers	TTI-101 (STAT3 inhibitor)	Tsimberidou
2016-0834	A Phase I, Open-Label, Dose Escalation and Dose Expansion Trial Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Effects of Orally Administered CA-170 in Patients with Advanced Tumors and Lymphomas	CA-170 (anti-PD-L1 immune checkpoint inhibitor)	Meric-Bernstam
2016-0798	A Phase I Open-Label Pharmacokinetics and Safety Study of Talazoparib (MDV3800) in Patients with Advanced Solid Tumors and Normal or Varying Degrees of Hepatic Impairment	Talazoparib (formerly BMN 673) (PARP inhibitor)	Piha-Paul
2016-0780	A Phase I Study of RGX-104, a Small Molecule LXR Agonist, with or without Nivolumab in Patients with Advanced Solid Malignancies and Lymphoma with an Expansion in Select Malignancies	RGX-104 (LXR agonist)	Pant
2016-0708	An Open-Label, Dose-Finding and Proof of Concept Study of the PD-L1 Probody Therapeutic, CX-072, as Monotherapy and in Combination with Yervoy (Ipilimumab) or with Zelboraf (Vemurafenib) in Subjects with Advanced or Recurrent Solid Tumors or Lymphomas	CX-072 (anti-PD-L1 probody treatment) with Yervoy (anti-CTLA4 antibody) or Vemurafenib (anti-CTLA4 antibody)	Naing
2016-0673	A Phase IB/II Study to Assess the Safety and Efficacy of HBI-8000 in Combination with Nivolumab in Patients with Advanced Solid Tumors Including Melanoma, Renal Cell Carcinoma (RCC) and Non-Small Cell Lung Cancer (NSCLC)	HBI-8000 (HDAC inhibitor) + Nivolumab (anti-PD-L1 antibody)	Fu
2016-0666	Phase IB, Open-label, Multi-center Study to Characterize the Safety, Tolerability and Pharmacodynamics (PD) of PDR001 in Combination with LCL161, Everolimus (RAD001) or Panobinostat (LBH589)	PDR001 (PD-L1 checkpoint inhibitor) + LCL161 (TNF death receptor inhibitor), Everolimus (mTOR inhibitor) or Panobinostat (HDAC inhibitor)	Pant
2016-0657	A Phase I/II, Open-Label, Multi-Center Study of the Safety and Efficacy of BLZ945 as Single Agent and in Combination with PDR001 in Adults Patients with Advanced Solid Tumors	BLZ945 (CSF-1R inhibitor) and PDR001 (PD-L1 checkpoint inhibitor)	Naing

Protocol	Title	Drugs & Mechanism of Action	PI
2016-0618	A Multicenter, Phase I/IB, Open-Label, Dose-Escalation Study of ABBV-399, an Antibody Drug Conjugate, in Subjects with Advanced Solid Tumors	ABBV-399 (ADC binding cMET) +/- Nivolumab (anti-PD-1 antibody)	Hong
2016-0596	A Phase I/II, Multicenter, Open-Label Study of MAK683 in Adult Patients with Advanced Malignancies	MAK683 (EED inhibitor)	Subbiah
2016-0582	A Phase I Study of LY3200882 in Patients with Solid Tumors	LY3200882 (TGF-βRI inhibitor)	Yap
2016-0573	Strategic Alliance: Adoptive cellular therapy with endogenous CD8+ T-cells (ACTolog; IMA101) in patients with relapsed and/or refractory solid cancers	ACTolog (immunotherapy with endogenous CD8+ T cells)	Tsimberidou
2016-0544	A Phase I Study of an ERK1/2 Inhibitor (LY3214996) Administered Alone or in Combination with Other Agents in Advanced Cancer	LY3214996 (ERK 1/2 inhibitor)	Pant
2016-0543	Multi-center, Open-label, Phase I, Dose-escalation, Cohort-expansion, First-in-Human Study of KHK2455 Administered as Mono-therapy and in Combination with Mogamulizumab (KW-0761) in Adult Subjects with Locally Advanced or Metastatic Solid Tumors	KHK2455 (IDO1 inhibitor) +/- Mogamulizumab (anti-CCR4 monoclonal antibody)	Yap
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	CB-1158 (arginase inhibitor) +/- Pembrolizumab (anti-PD-1)	Naing
2016-0532	Phase I Trial of ZW25 Alone and in Combination with Chemotherapy or Immunotherapy in Patients with HER2-expressing Cancers	ZW25 (Her2 inhibitor)	Meric-Bernstam
2016-0529	A Phase I, Open-Label, Multi-Center Dose Escalation Study of FAZ053 as Single Agent and in Combination with PDR001 in Adult Patients with Advanced Malignancies	FAZ053 (anti-PD-L1 antibody) monotherapy	Janku
2016-0515	Phase 1 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	MAGE-A10c796T (genetically engineered T-cells)	Hong
2016-0458	A Phase IB Study of LY3039478 in Combination with Other Anticancer Agents in Patients with Advanced or Metastatic Solid Tumors	LY3039478 (Notch inhibitor) + Taladegib (hedgehog/Smo antagonist) or LY3023414 (PI3K/mTOR inhibitor) or Abemaciclib (CDK4/6 inhibitor) or Cisplatin/ Gemcitabine or Cisplatin/Carboplatin (chemotherapies)	Pant
2016-0430	Phase I Study of the Pan-ERBB Inhibitor Neratinib Given in Combination with Everolimus, Palbociclib or Trametinib in Advanced Cancer Subjects with EGFR Mutation/Amplification, HER2 Mutation/ Amplification or HER3/4 Mutation or KRAS Mutation	Neratinib (HER2 inhibitor) + Everolimus (mTOR inhibitor), Palbociclib (CDK4/CDK6 inhibitor), or Trametinib (MEK inhibitor)	Piha-Paul
2016-0394	A Phase IB/II, Open Label, Multicenter Study of MCS110 in Combination with PDR001 in Patients with Advanced Malignancies	MCS110 (CSF-1 inhibitor) plus PDR001 (anti-PD-L1 antibody)	Naing
2016-0386	Phase I/II Multicenter Trial of ICOS Agonist Monoclonal Antibody (mAb) JTX-2011 Alone and in Combination with Nivolumab, Ipilimumab, or Pembrolizumab in Adult Subjects with Advanced and/or Refractory Solid Tumor Malignancies	JTX-2011 (ICOS agonist), Nivolumab or Pembrolizumab (anti-PD-1 mAb) or Ipilimumab (antiCTLA4 mAb)	Yap
2016-0382	Phase IB, Open-Label, Multi-Center Study to Characterize the Safety, Tolerability and Pharmacodynamics (PD) of PDR001 in Combination with CJM112, EGF816, Ilaris (Canakinumab) or Mekinist (Trametinib)	PDR001 (anti-PD-L1) with canukinumab (anti-IL-1beta monoclonal antibody), CJM112 (anti-IL-17A antibody), EGF816 (EGFR inhibitor), or Trametinib (MEK inhibitor)	Fu
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	Ribociclib (CDK4/6 inhibitor) + Trametinib (MEK inhibitor)	Janku
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	LY3300054 (anti PDL1 antibody) alone or with Abemaciclib (CDK4/6 inhibitor) or LY3321367 (TIM3) or Meristinib (MET inhibitor)	Yap
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 Advanced/Metastatic Melanoma, Renal Cell Carcinoma and Non-Small Cell Lung Cancer	CB-839 (glutaminase inhibitor) plus Nivolumab (anti-PD-L1)	Meric-Bernstam
2016-0262	A Dose Escalation Study to Evaluate Safety, Tolerability, Pharmacokinetics, Dosimetry, Maximum Tolerated Dose and Preliminary Efficacy of Intra-Lesionally Injected AvidinOX, followed by Systemic IV Administration of Escalating Doses of [177Lu]DOTA-Biotin in Patients with Solid Tumors or Lymphomas with Injectable Neoplastic Lesions.	AvidinOX (radiotherapy prologation system) followed by [177Lu]DOTA A-biotin (radiotherapy)	Subbiah
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, or other known actionable PTEN mutations	ARQ 751 (AKT inhibitor)	Pant

Protocol	Title	Drugs & Mechanism of Action	PI
2016-0144	A Phase IB Study of AZD1775 and Olaparib in Patients with Refractory Solid Tumours	AZD1775 + Olaparib (Wee1 inhibitor combined with PARP inhibitor)	Fu
2016-0108	Phase II Clinical Trial Evaluating Intravenous AZD9150 (antisense STAT3) with MEDI4736 (anti-PD-L1) in Patients with Advanced Pancreatic, Non-small Cell Lung Cancer, and Mismatch Repair Deficient Colorectal Cancer	AZD9150 + MEDI4736 (STAT3 with anti-PD-L1)	Hong
2016-0021	A Phase I Open-Label Study of the Safety, Tolerability and Efficacy of KPT-9274, a Dual Inhibitor of PAK4 and NAMPT, in Patients with Advanced Solid Malignancies or Non-Hodgkin's Lymphoma	KPT-9274 (PAK4 and NAMPT inhibitor)	Naing
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	STING agonist	Meric-Bernstam
2015-1075	An Open-label, Multicenter Phase IA/2A 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	Sym015 (MET inhibitor)	Janku
2015-1009	A Phase IB/II, Multicenter, Open-label Trial to Evaluate the Safety of Talimogene Laherparepvec Injected into Liver Tumors Alone and in Combination with Systemic Pembrolizumab	T-VEC (dendritic cell activation)	Subbiah
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	MSB0011359C (anti-PD-L1 antibody/TGFß receptor)	Naing
2015-0948	Phase II Study for the Evaluation of Efficacy of Pembrolizumab (MK-3475) in Patients with Advanced Types of Cancers	Pembrolizumab (PD-1 inhibitor)	Naing
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 Nivolumab in Subjects with Advanced Solid Tumors	IPI-549 (PI3K-ipa inhibitor) + Nivolumab (PD-L1 inhibitor)	Hong
2015-0913	A Phase I Dose Finding Study of Oral LXH254 in Adult Patients with Advanced Solid Tumors Harboring MAPK Pathway Alterations	LXH524 (BRAF/CRAF inhibitor)	Janku
2015-0688	A Phase I Study of Ixazomib and Erlotinib in Advanced Solid Tumor Patients	Ixazomib (Proteasome inhibitor) and Erlotinib (EGFR inhibitor)	Hong
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	BAY 1217389 (monopolar spindle 1 [MPS1] inhibitor)	Subbiah
2015-0621	A Multicenter Phase I, Open-Label, Dose-Escalation Study of DCC-2618 to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced Malignancies	DCC-2618 (KIT inhibitor)	Janku
2015-0468	A Phase IA/B Study to Evaluate the Safety and Tolerability of Etc-1922159 in Advanced Solid Tumours	ETC-1992159 (Wnt signaling regulator)	Subbiah
2015-0465	A Phase I/IIA 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	ALRN-6924 (MDM2 inhibitor)	Meric-Bernstam
2015-0353	A Phase IB/II, Open-Label, Multicentre Study Assessing the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumor 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	MEDI4736 (IgG1 kappa monoclonal antibody) + AZD9150 (STAT3 inhibitor) or AZD5069 (CRCX2 antagonist)	Hong
2015-0300	Registry Study for Personalized Cancer Therapy	Registry Study	Meric-Bernstam
2015-0298	Phase I/II Evaluation of Adenoviral p53 (Ad-p53) in Combination with Capecitabine or Anti-PD-1 in Patients with Unresectable Liver Metastases of Colorectal Carcinoma (CRC) and Other Solid Tumors, Recurrent Head and Neck Squamous Cell Carcinoma (HNSCC) and Primary Hepatic Cancers with Known Disease Progression on Standard Therapy	Ad-p53 (Adenoviral agent) + Capecitabine (DNA synthesis inhibitor)	Subbiah
2015-0220	A Phase I Dose-Escalation Study of Radio-labeled Antibody, FF-21101(90Y) for the Treatment of Advanced Cancer	FF-21101(90Y) (DOTA-conjugated chimeric human/mouse monoclonal antibody)	Subbiah
2015-0135	A Phase I Trial of Ipilimumab (Immunotherapy) and MGN1703 (TLR Agonist) in Patients with Advanced Solid Malignancies	Ipilimumab + MGN1703 (Immunotherapy combined with TLR agonist)	Hong
2015-0129	An Open Label Phase II Study of Tipifarnib in Advanced Non-Hematological Malignancies With HRAS Mutations	Tipifarnib (FTase [farnesyltransferase] inhibitor)	Hong

Protocol	Title	Drugs & Mechanism of Action	PI
2014-1099	A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects with Advanced Malignancies	INCB054828 FGFR inhibitor + various chemotherapies	Subbiah
2014-1045	A Phase I, Gene Alteration-Based, Open Label, Multicenter Study of Oral Debio 1347 (CH5183284) in Patients with Advanced Solid Malignancies, whose Tumours Have an Alteration of the FGFR 1, 2 or 3 Genes	Debio 1347 (CH5183284) FGFR pan-inhibitor	Meric-Bernstam
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	APS001F (live bacteria suspension genetically engineered to express cytosine deaminase gene)	Fu
2014-1005	A Phase I/IB Study of MGCD516 in Patients with Advanced Solid Tumor Malignancies	MGCD516 (MET, Axl, VEGFR, PDGFR, KIT, FLT3, Trk, RET, DDR2 and Eph inhibitor)	Pant
2014-0893	A Phase I/IIA, Dose-Escalation Study of FF-10502-01 for the Treatment of Advanced Solid Tumors	FF-10502 (Pyrimidine nucleoside antimetabolite)	Janku
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	Arm B - Selinexor (KPT-330) + Paclitaxel	Naing
2014-0459	MY Pathway: An Open-Label Phase I IA Study Evaluating Trastuzumab/Pertuzumab, Erlotinib, Vemurafenib/Cobimetinib, Vismodegib, Alectinib and Atezolizumab in Patients who Have Advanced Solid Tumors with Mutations or Gene Expression Abnormalities Predictive of Response to One of These Agents	Various FDA-approved anti-cancer agents	Meric-Bernstam
2014-0186	Phase I Study of TAK-228 (MLN0128) in Combination with Metformin in Patients with Advanced Cancers	TAK-228 + Metformin (mTOR inhibitors)	Subbiah
2014-0069	A Dose-Finding Phase I Study of TAS-120 in Patients with Advanced Solid Tumors with or without Fibroblast Growth Factor/Re5ceptor (FGF/FGFR)-Related Abnormalities Followed by a Phase II Study in Patients with Advanced Solid Tumors or Multiple Myeloma with FGF/FGFR-Related Abnormalities	TAS-120 FGFR inhibitor	Meric-Bernstam
2014-0066	A Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Pharmacokinetics, and Clinical Effects of Intravenously Administered PT-112 Injection in Subjects with Advanced Solid Tumors	PT-112 (phosphorylated platinum)	Karp
2013-0961	Phase II Study of the PARP Inhibitor BMN 673 (talazoparib tosylate) in Advanced Cancer Patients with Somatic Alterations in BRCA1/2, Mutations/Deletions in PTEN or PTEN loss, a Homologous Recombination Defect, Mutations/Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (not breast or ovarian cancer)	BMN 673 Arms 1 - 3PARP inhibitor	Piha-Paul
2013-0904	An Open-Label, Phase II Study of Neratinib in Patients with Solid Tumors with Somatic Human Epidermal Growth Factor Receptor (EGFR, HER2, HER3) Mutations or EGFR Gene Amplification	Neratinib (EGFR,HER2, HER3 inhibitor)	Piha-Paul
2013-0665	Phase I Study of MLN0128 (TAK-228) (NSC# 768435) in Combination with Ziv-Aflibercept (NSC# 724770) in Patients with Advanced Cancers	MLN0128 + Aflibercept (2013-0665)mTOR inhibitor + VEGF inhibitor	Naing
2013-0257	A Phase I Multiple Ascending Dose Study of DS-3032b, an oral MDM2 inhibitor, in subjects with advanced solid tumors or lymphomas	DS-3032b (MDM2 inhibitor)	Hong
2012-0784	A Phase I Trial of Ipilimumab (Immunotherapy) and Imatinib Mesylate (c-Kit Inhibitor) in Patients with Advanced Malignancies	anti CTLA-4 antibody (Ipilimumab) combined with tyrosine kinase inhibitor (Imatinib)	Hong
2012-0061	A Phase I Trial of Bevacizumab, Temsirolimus Alone and in Combination with Valproic Acid or Cetuximab in Patients with Advanced Malignancy	Bevacizumab + Temsirolimus (anti VEGF + mTOR inhibitor)	Piha-Paul
2011-0953	A Phase I Trial of Vandetanib (A Multi-Kinase Inhibitor of EGFR, VEGFR and RET inhibitor) in Combination with Everolimus (an mTOR inhibitor) in Advanced Cancer	Vandetanib + Everolimus (EGFR/VEGFR/ RET inhibitor and mTOR inhibitor)	Subbiah
2011-0686	A Phase I, Open-label, Dose Escalation Study of Oral LGK974 in Patients with Melanoma and Lobular Breast Cancer	LGK974 (Wnt pathway inhibitor)	Janku
S1609	DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors	Ipilimumab (Anti-CTLA4) + Nivolumab (anti-PD-1)	Naing
ECOGEAY131	Molecular Analysis for Therapy Choice (MATCH)	NCI MATCH (ECOGEAY131)	Meric-Bernstam
NCI9944	Phase II Study of M6620 (VX-970) in Combination with gemcitabine versus gemcitabine alone in Subjects with Platinum-Resistant Recurrent Ovarian or Primary Peritoneal Fallopian Tube Cancer	VX-970 (ATR [ataxia telangiectasia mutated and Rad3-related kinase] inhibitor) with Gemcitabine (chemo)	Fu
NCI9881	A Phase II Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors	Cediranib (VEGFR tyrosine kinase inhibitor) + Olaparib (PARP-1/PARP-2 inhibitor)	Fu
NCI9771	Phase I Study of Veliparib (ABT-888), an Oral PARP Inhibitor, and M6620 (VX-970), an ATR Inhibitor in Combination with Cisplatin in Patients with Refractory Solid Tumors	Veliparib (PARP inhibitor) + VX-970 (ATR inhibitor) + Cisplatin (chemotherapy)	Piha-Paul

Protocol	Title	Drugs & Mechanism of Action	PI
NCI9598B	A Phase II Therapeutic Trial of the Use of Dabrafenib and Trametinib in Patients with BRAF V600E Mutation Positive Lesions in Erdheim Chester Disease	Dabrafenib (BRAF inhibitor) + Trametinib (MEK inhibitor)	Janku
NCI9591	A Phase I Trial of Single Agent Trametinib (GSK1120212) in Advanced Cancer Patients with Hepatic Dysfunction	Trametinib for hepatic dysfunction	Subbiah
NCI9149	Molecular Profiling-Based Assignment of Cancer Therapy for Patients With Advanced Solid Tumors	AZD1775 (WEE1 inhibitor) and Carboplatin (chemotherapy) or Everolimus (mTOR inhibitor) or Trametinib (MEK inhibitor) or Veliparib (PARP inhibitor) + Temozolomide (alkylating agent)	Raghav
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	ABT-888 (PARP inhibitor) + Carboplatin and Paclitaxel (chemo)	Tawbi
NCI10145	Phase IB Combination Study of Copanlisib and Nivolumab in Advanced Solid Tumors and Lymphomas	Copanlisib (PI3K inhibitor) + Nivolumab (anti-PD-1 mAB)	Yap
NCI10136	A Phase II Study of AZD1775, a WEE1 Inhibitor, in Patients with CCNE1 Amplification	AZD1775 (WEE1 inhibitor)	Fu
NCI10131	A Phase I Study of AZD8186 in Combination with Docetaxel in Patients with PTEN Mutated or PIK3CB mutated Advanced Solid Tumors, Potentially Amenable to Docetaxel	AZD8186 (PI3Kβ/δ inhibitor) + Docetaxel (chemotherapy)	Dumbrava
NCI10129	A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) in IDH1 and IDH2 mutant Advanced Solid Tumors	Olaparib (AZD2281)	Rodón Ahnert
NCI10014	A Pilot Study of Atezolizumab (MPDL3280A) Following Adoptive Cell Transfer in Active Hematologic or Solid Tumor Malignancies	Atezolizumab (anti-PD-L1 mAB)	Hong

How to refer patients for our clinical trials

Many of the new experimental medicines tested at MD Anderson are offered to patients through the Clinical Center for Targeted Therapy. The center is a leader in treating patients with drugs that are in Phase I of the clinical trials process.

The center offers many different types of experimental medications, such as new immunotherapies and chemotherapies. It also offers targeted therapies, which interfere with molecules that support cancer's growth, progression and spread. In some cases, the center carries out Phase II trials of these drugs.

The Clinical Center for Targeted Therapy is located on the 11th floor of the main hospital building.

Existing patients are referred to the center when one of our clinical trials offers the best treatment option. To make these decisions, we are in constant collaboration with MD Anderson's primary care centers. We also accept external physician referrals and patient self-referrals.

The center recently added on-site pharmacokinetics (PK) interval testing for patients on clinical trials with oral agents, and expansion plans are under discussion to add a phlebotomy room for on-site blood draws.

To request an appointment, call the patent referral hotline at 713-563-1930 and have the following information ready:

- Patient name, telephone number and insurance information
- Referring physician's name, office address, telephone and fax numbers
- Diagnosis, date of diagnosis, and method of diagnosis (physical exam, biopsy, other)
- What treatment has taken place and over what time period the treatment occurred
- Specific medical and pathology reports may also be requested for review before the patient's first visit

Not all referrals qualify for our clinical trials. Our staff will work with the patient or referring physician to determine if all qualifications are met and to schedule the first appointment. ■

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NEW FACULTY

Ecaterina Ileana Dumbrava, M.D.

Ecaterina Ileana Dumbrava, M.D., joined MD Anderson Cancer Center an assistant professor in August 2018. Her main research interest lies in developing genomically matched combination therapies and personalized immunotherapy clinical trials. She completed her medical oncology training at Gustave Roussy Cancer Center in Villejuif, France, followed by a Master of Science Degree in Oncology from Paris-South University and a postdoctoral fellowship in the Department of Translational Molecular Pathology at MD Anderson. Dr. Dumbrava joined the Department of Investigational Cancer Therapeutics in August 2018 following her two-year clinical fellowship in the department, where she was elected chief fellow, and following her monthlong fellowship at the National Institutes of Health/National Cancer Institute Cancer Therapy Evaluation Program (CTEP), working closely with medical officers in reviewing letters of intent and protocols for early phase clinical trials. Dr. Dumbrava has contributed to many peer-reviewed articles, some of which have been published in prominent journals such as *Lancet Oncology, Cancer Discovery* and *Clinical Cancer Research,* and she was an author and section editor for the *Handbook of Targeted Therapy and Immunotherapy.* Dr. Dumbrava is the 2019 recipient of the NIH's Paul Calabresi Career Development Award for Clinical Oncology (K12). ■