Innovative Solutions and Best Practices: Excellence in Cancer Clinical Research

Howard A. Burris, III, MD
ASCO President
Chief Medical Officer, Sarah Cannon
THE CHANGING LANDSCAPE: FROM WEEKLY PACLITAXEL TO PILLS AND CHECKPOINTS

• Drugs: Chemo to ADC’s, TKI’s, and IO
• Trials: Phase 1 to 3 is now FIM to POC
• Approach: “one size fits all” to “personalized driven by biology”
Comparison of Four Chemotherapy Regimens for Advanced Non–Small-Cell Lung Cancer

Joan H. Schiller, M.D., David Harrington, Ph.D., Chandra P. Belani, M.D., Corey Langer, M.D., Alan Sandler, M.D., James Krook, M.D., Junming Zhu, Ph.D., and David H. Johnson, M.D. for the Eastern Cooperative Oncology Group

N = 1207

January 10, 2002
DOI: 10.1056/NEJMoa011954
2018-2019 SINGLE ARM TRIAL HEMATOLOGY/ONCOLOGY APPROVALS (WWW.FDA.GOV)

• Pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. N=83

• Ruxolitinib (JAKAFI, Incyte Corporation) for steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. N=49

• Ivosidenib (TIBSOVO, Agios Pharmaceuticals, Inc.) for newly-diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test, in patients who are at least 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy. N=28

• Erdafitinib (BALVERSA, Janssen Pharmaceutical Companies) for patients with locally advanced or metastatic urothelial carcinoma, with susceptible FGFR3 or FGFR2 genetic alterations, that has progressed during or following platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. N=87

• Tagraxofusp-erzs (ELZONRIS, Stemline Therapeutics), a CD123-directed cytotoxin, for blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older. N=13

• Calaspargase pegol-mknl (ASPARLAS, Servier Pharmaceuticals LLC), an asparagine specific enzyme, as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years. N=124

• Pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC). N=50

• Gilteritinib (XOSPATA, Astellas Pharma US Inc.) for treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with FLT3 mutation as detected by an FDA-approved list. N=138

• Larotrectinib (VITRAKVI, Loxo Oncology Inc. and Bayer) for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment. N=55

• Pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
CHALLENGES IN CLINICAL RESEARCH

• Vast numbers of trials
• Expansion cohorts
• Rare mutations
• Education
• Eligibility criteria
• Patient access
• Trial complexity
• Overwhelming paperwork
• Data (volume, interpretation)
INNOVATIVE SOLUTIONS:
Genospace and Molecular Cancer Conferences
NGS TESTING - IN THE NEWS

Next-Generation Sequencing Proves Cost-Effective in Metastatic NSCLC
18/7/18
An economic model comparing different types of genetic testing in metastatic non-small cell lung cancer (NSCLC) showed that next-generation sequencing (NGS) is more cost-effective than testing for one or a limited number of genes at a given time.

Next-Generation Sequencing for Metastatic NSCLC Associated With Substantial Cost Savings
Angelica Welch
Published Online: 5:05 PM, Wed May 16, 2018

All Cancer Patients Should Have Access To Genomic Testing

Days after Thanksgiving, the FDA approved Foundation Medicine’s comprehensive genetic test for evaluating cancer. The idea—and practice—of testing tumors for specific DNA or protein abnormalities is not new. Previously, the agency listed several dozen approved companion diagnostic tests; these earlier tools check one or a few molecules to inform the cancer subtype, prognosis, and likelihood of response to treatments.
WHY DO WE NEED TO PROFILE PATIENTS

• For the patient/individual benefit
• For clinical research/drug development (trial accrual)
• For cancer research/benefit of all (biology, resistance)
THE CHALLENGE OF PRECISION MEDICINE


As new data and technologies emerge, clinicians are required to interpret and act upon increasingly complex information.

An increasing number of SOC treatment options and clinical trials require the knowledge of a molecular alteration.

Molecular reports do not present information in an easily clinically actionable format.

Sarah Cannon’s Personalized Medicine program is uniquely positioned to address the opportunities for our partnered medical oncologists, molecular profiling vendors, and pharmaceutical industry partners.
GENOSPACE: ENABLING THE CONVERGENCE OF CLINICAL RESEARCH AND CLINICAL CARE

Large-scale clinical-genomic data aggregation

Clinical Decision Support

Discovery & Trial Recruitment

WISDOM

Data

Action

Insight
REVIEW AND MANAGE YOUR PATIENT’S THERAPY OPTIONS

Annotate patient-trial matches to communicate with other clinical users.
MOLECULAR ONCOLOGY SUPPORT SERVICES

Molecular Cancer Conferences
- Regularly-occurring office-specific teleconference
- >1000 MCC reviews in 12 months
- ~18% enrollment rate
- >2x increase in MP ordering
- ~23 physician-hours/month

Molecular Oncology Support Services

Personalized Molecular Insights
- Powered by Genospace
- Real-time Patient-level review of molecular profiles:
- Since 8/6/2018, all new molecular profiles from late-phase clinics at TO have been annotated in Genospace and abstracted into Personalized Medicine Data Warehouse

“On-Call” Molecular Insights
- Ad hoc (concierge-level) germline and somatic mutational analysis
- ~4-5 ad hoc cases/week from FCS and TO
**DATA AVAILABILITY:**

**Strategic Sites**
- Tennessee Oncology, Nashville
- Tennessee Oncology, Chattanooga
- Florida Cancer Specialists-East, West Palm Beach
- Florida Cancer Specialists-North, St. Petersburg
- Florida Cancer Specialists-Panhandle, Tallahassee
- Florida Cancer Specialists-South, Ft. Myers
- HCA Midwest Health, Kansas City

**DDU/Phase 1**
- Sarah Cannon, Denver
- Florida Cancer Specialists, Sarasota
- Tennessee Oncology, Nashville

**RAPID ADOPTION OF TISSUE- AND PLASMA-BASED NGS FROM PRIVATE MEDICAL ONCOLOGY PRACTICES**
MUTATION ANALYSIS OF TISSUE-BASED NGS AND PLASMA-BASED NGS

TISSUE-BASED NGS

PLASMA-BASED NGS

TWO TRENDS, ONE TRIAGE DECISION

Precision Medicine

NGS Profiling

Immuno-Oncology

Actionable Genomic Alterations

MSI, TMB, DDR

Efficacy of Larotrectinib in TRK Fusion–Positive Cancers in Adults and Children

Actionable Genomic Alterations

Crizotinib versus Chemotherapy in Advanced ALK-Positive Lung Cancer

PD-1 Blockade in Tumors with Mismatch-Repair Deficiency

Nivolumab plus Ipilimumab in Lung Cancer with a High Tumor Mutational Burden
TMB FROM COMMERCIAL NGS VENDORS IN THE COMMUNITY SETTING

TMB across tumor types in Sarah Cannon data largely mirrors data from previous reports.
MSI-HIGH SPECIMENS ARE A SUBSET OF HIGH TMB SPECIMENS (N = 46,465)

• The majority of MSI-H specimens (~84%) are TMB-H, but not the reverse
  – Only 14.5% of TMB-H specimens are also MSI-H

P Stephens  AACR 2017
FDA grants accelerated approval to pembrolizumab for first tissue/site agnostic indication

On May 23, 2017, the U.S. Food and Drug Administration granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co.) for adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options or with MSI-H or dMMR colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

This is the FDA’s first tissue/site-agnostic approval.

The approval was based on data from 149 patients with MSI-H or dMMR cancers enrolled across five uncontrolled, multi-cohort, multi-center, single-arm clinical trials. Ninety patients had colorectal cancer and 39 patients were diagnosed with one of 14 other cancer types. Patients received either pembrolizumab 200 mg every 3 weeks, or pembrolizumab, 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity, or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or associated with a decline in performance status. A maximum of 24 months of treatment was administered.

The major efficacy measures were objective response rate (ORR) assessed by blinded independent central radiologists’ review according to RECIST 1.1, and response duration. ORR was 39.6% (95% CI: 31.7, 47.5). Responses lasted six months or more for 78% percent of those who responded to pembrolizumab. There were 11 complete responses and 45 partial responses. ORR was similar irrespective of whether patients were diagnosed with CRC (36%) or a different cancer type (46% across the 14 other cancer types).

Objective response: 53%
Complete response: 21%
Disease control rate: 77%
Median PFS and OS not yet reached (median follow up 12.5 months)

Le et al. Science 2017 July 28;357 (6349): 409 - 413
CORRELATION BETWEEN TMB AND RESPONSE RATE TO PD1-INHIBITION

Yarchoan et al. NEJM 2017;377;25:2500-2501
KEYNOTE 189 and KEYNOTE 21 both demonstrated TMB not significantly associated with OS, PFS, or ORR.

Garassino et al. Abstract OA04.06
Langer et al. Abstract OA04.05
TWO TRENDS, ONE TRIAGE DECISION

Precision Medicine

Precision Medicine

NGS Profiling

Efficacy of Larotrectinib in TRK Fusion-Positive Cancers in Adults and Children

Efficacy of Larotrectinib in TRK Fusion-Positive Cancers in Adults and Children

Actionable Genomic Alterations

Actionable Genomic Alterations

Immuno-Oncology

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MSI, TMB, DDR

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PD-1 Blockade in Tumors with Mismatch-Repair Deficiency
**TARGETED THERAPIES HAVE BEEN APPROVED FOR SPECIFIC TYPES OF CANCER (WWW.CANCER.GOV)**

- **Brain cancer:** Bevacizumab (Avastin®), everolimus (Afinitor®)
- **Lung cancer:** Bevacizumab (Avastin®), ixabepilone (Vxn™), pemetrexed (Alimta®), erlotinib (Tarceva®), gefitinib (Iressa®), afatinib (Gilotriff®), ceritinib (LDK378/Zykadia™), ramucirumab (Cyramza®), nivolumab (Opdivo®), pembrolizumab (Keytruda®), osimertinib (Tagrisso™), necitumumab (Portrazza™), neratinib (Gerfin®), sugemustine (Bavencio®), azadoscumab (Zepzelca™), inebuzumab (RO7.4111™), ranibizumab (Lucentis®), bevacizumab (Avastin®), tocilizumab (Actemra®), cediranib (Avanex™), olaparib (Lynparza™)
- **Liver cancer:** Atezolizumab (Tecentriq™), brigatinib (Alunbrig®), trametinib (Mekinist®), dabrafenib (Tafinlar®), durvalumab (Imfinzi™)
- **Lymphoma:** Ibrutinib (Imbruvica®), rituximab (Rituxan®), vorinostat (Zolinza®), romidodip (Lustodax®), hexarotene (Tagretin®), hortezomib (Velcade®), pralatrexate (Foltyxo®), ibritumomab (Imbruvica®), siltuximab (Sylvanta®),idelisib (Zycteglok®)
- **Cervical cancer:** Bevacizumab (Avastin®)
- **Colorectal cancer:** Cetuximab (Erbitux®), panitumumab (Vectibix®), bevacizumab (Avastin®), ziv-aflibercept (Zaltrap®), regorafenib (Stivarga®), ramucirumab (Cyramza®), nivolumab (Opdivo®)
- **Dermatofibrosarcoma protuberans:** Imatinib mesylate (Gleevec®)
- **Endocrine/neuroendocrine tumors:** Lanreotide acetate (Somatuline® Depot), avelumab (Bavencio®), lutetium Lu 177-dotatate (Lutathera®)
- **Head and neck cancer:** Cetuximab (Erbitux®), pembrolizumab (Keytruda®), nivolumab (Opdivo®)
- **Gastrointestinal stromal tumor:** Imatinib mesylate (Gleevec®), sunitinib (Sutent®), regorafenib (Stivarga®)
- **Giant cell tumor of the bone:** Denosumab (Xgeva®)
- **Kidney cancer:** Bevacizumab (Avastin®), sorafenib ( Nexavar®), sunitinib (Sutent®), pazopanib (Votrient®), temsirolimus (Torisel®), everolimus (Afinitor®), axitinib (Inlyta®), nivolumab (Opdivo®), cabozantinib (Cabometyx™), lenvatinib mesylate (Lenvima®), ipilimumab (Yervoy®)
- **Leukemia:** Tretinoin (Vesanoid®), imatinib mesylate (Gleevec®), dasatinib (Sprycel®), nilotinib (Tasigna®), bosutinib (Bosulif®), rituximab (Rituxan®), alemtuzumab (Campath®), ofatumumab (Arzerra®), obinutuzumab (Gazyva®), ibritumomab (Imbruvica®), idelalisib (Zydelig®), blinatumomab (Blyskto®), venetoclax (Venclexta™), ponatinib hydrochloride (Iclusig®), midostaurin (Rydapt®), enasidenib mesylate (Idhifa®), inotuzumab ozogamicin (Besponsa®), tisagenlecleucel (Kymriah®), gemtuzumab ozogamicin (Mylotarg™), rituximab and hyaluronidase human (Rituxan Hycele™)
- **Liver cancer:** Sorafenib ( Nexavar®), regorafenib (Stivarga®), nivolumab (Opdivo®)
- **Lung cancer:** Bevacizumab (Avastin®), crizotinib (Xalkori®), erlotinib (Tarceva®), gefitinib (Iressa®), afatinib dimaleate (Gilotriff®), ceritinib (LDK378/Zykadia™), ramucirumab (Cyramza®), nivolumab (Opdivo®), pembrolizumab (Keytruda®), osimertinib (Tagrisso™), necitumumab (Portrazza™), neratinib maleate (Nerlynx™), abemaciclib (Verzenio™), olaparib (Lynparza™)
- **Multiple myeloma:** Denileukin difitox (Ontak®), brentuximab vedotin (Adcetris®), rituximab (Rituxan®), vorinostat (Zolinza®), romidodip (Lustodax®), hexarotene (Tagretin®), hortezomib (Velcade®), pralatrexate (Foltyxo®), ibritumomab (Imbruvica®), siltuximab (Sylvanta®),idelisib (Zycteglok®)
- **Myelodysplastic syndrome:** Ibrutinib (Imbruvica®), rituximab (Rituxan®), vorinostat (Zolinza®), romidodip (Lustodax®), hexarotene (Tagretin®), hortezomib (Velcade®), pralatrexate (Foltyxo®), ibritumomab (Imbruvica®), siltuximab (Sylvanta®),idelisib (Zycteglok®)
- **Lung cancer:** Bevacizumab (Avastin®), ixabepilone (Vxn™), pemetrexed (Alimta®), erlotinib (Tarceva®), gefitinib (Iressa®), afatinib dimaleate (Gilotriff®), ceritinib (LDK378/Zykadia™), ramucirumab (Cyramza®), nivolumab (Opdivo®), pembrolizumab (Keytruda®), osimertinib (Tagrisso™), necitumumab (Portrazza™), neratinib maleate (Nerlynx™), abemaciclib (Verzenio™), olaparib (Lynparza™)
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TUMOR AGNOSTIC FDA APPROVAL --- LAROTRECTINIB (NTRK FUSION)

Estimated 1,500–5,000 patients harbor TRK fusion-positive cancers in the United States annually.

FDA APPROVED
November 26, 2018

Presented By David Hyman at 2017 ASCO Annual Meeting

**SQSTM1-NTRK1 lung cancer patient**

Presented By David Hyman at 2017 ASCO Annual Meeting

**Presented By David Hyman at 2017 ASCO Annual Meeting**

Baseline

Cycle 4

45F NSCLC & paraneoplastic hypertrophic osteoarthropathy

Prior therapy: platinum/pemetrexed

Larotrectinib ongoing in month 8, resolution of paraneoplastic symptoms

FDA APPROVED
November 26, 2018

Baseline

Day 6

Day 20

14F, prior therapy: 4 lines of chemotherapy and repeated resections
Treated with larotrectinib under expanded access
EXPANDED LAROTRECTINIB RESPONSE AND DURABILITY OF RESPONSE

Hyman et al. ESMO 2019 Abstract 445PD.
TISSUE AGNOSTIC FDA APPROVAL--- ENTRECTINIB (NTRK FUSION)

FDA APPROVED
August 15, 2019

Demetri GD et al. ESMO 2018

Results per Blinded Independent Central Review (BICR)

ORR (55% CI) 57.4% (43.2–70.8)

Best % change from baseline

Sarcoma NSCLC MASC Breast Thyroid CRC Pancreatic Neuroendocrine tumours Gynaecological Cholangiocarcinoma

Cutoff date: 31 May 2018

Note: Patients (n=6) without matched pre/post therapy scans were excluded from this plot. CI: confidence interval, CRC: colorectal cancer, MASC: mammary analogue secretory carcinoma, NSCLC: non-small cell lung cancer

Confidential – Contains proprietary information. Not intended for external distribution.
Inside drugmakers' strategy to boost cancer medicines with 'Lazarus effect'

According to Dr. Brian Alexander, chief medical officer of Roche’s gene testing company Foundation Medicine, only about 15% of U.S. patients with advanced cancers get comprehensive genomic profiling. Another 25% get single-gene testing, he said, and a large proportion “are not getting any testing at all.”

At MD Anderson, which sees 100,000 new cancer patients a year, only around 10,000 eventually have their tumors sequenced.
Registral Trial Results of LIBRETTO-001: A Phase 1/2 Trial of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Lung Cancers


Efficacy of Selpercatinib: Primary Analysis Set (n=105)

**Best Tumor Response (%)**

<table>
<thead>
<tr>
<th>Overall (n=105)</th>
<th>CNS** (n=11)</th>
</tr>
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<tbody>
<tr>
<td><strong>ORR (95% CI)</strong></td>
<td>68% (58%–76%)*</td>
</tr>
<tr>
<td>CR</td>
<td>2%</td>
</tr>
<tr>
<td>PR</td>
<td>66%</td>
</tr>
<tr>
<td>SD</td>
<td>26%</td>
</tr>
<tr>
<td>PD</td>
<td>2%</td>
</tr>
<tr>
<td>NE</td>
<td>5%</td>
</tr>
</tbody>
</table>

Median DOR 20.3 months

Investigator response assessments as of June 17th, 2019. 5 patients not shown in waterfall plot: 3 discontinued prior to any post-baseline imaging assessments, 1 did not have measurable disease at baseline, and 1 deemed not evaluable on study by the Investigator. NE—Not evaluable, n=5 patients: 3 discontinued prior to any post-baseline imaging assessments, 1 deemed not evaluable on study by the Investigator, and 1 discontinued after a single post-baseline imaging assessment showing SD, less than 6 weeks after starting treatment. Total % may be different than the sum of the individual due to rounding. *N=105 dataset includes 2 unconfirmed PRs awaiting confirmatory response assessments. **Patients with CNS target lesions at baseline. Chemo—platinum-doublet chemotherapy; ICI—immune checkpoint inhibitors (anti-PD-1/PD-L1); MKI—multikinase inhibitors.
Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics (PK) and Efficacy of AMG 510, a Novel Small Molecule KRAS$^{G12C}$ Inhibitor, in Advanced Solid Tumors

Marwan G Fakih, MD; Bert Howard O’Neil, MD; Timothy J Price, MBBS, FRACP; Gerald S Falchook, MD; Jayesh Desai, MBBS, FRACP; James Kuo, MBBS, FRACP; Ramaswamy Govindan, MD; Erik Rasmussen, MS; Phuong Khanh Morrow, MD; Jude Ngang, PharmD; Haby Henary, MD; David Hong, MD

1City of Hope, Duarte, CA, USA; 2Indiana University, Simon Cancer Center, Indianapolis, IN, USA; 3The Queen Elizabeth Hospital, Woodville South, AU; 4Amgen Inc, Thousand Oaks, CA, USA; 5Sarah Cannon Research Institute, Denver, CO, USA; 6Peter MacCallum Cancer Centre, Melbourne, AU; 7Scientia Clinical Research, Randwick, AU; 8Washington University, St Louis, MO, USA; 9MD Anderson Cancer Center, Houston, TX, USA
NSCLC: Best Tumor Response* (n=10)

IASLC 2019 World Conference on Lung Cancer UPDATE

N = 23
DCR = 96%  PR 11/23 (48%); SD 11/23; PD 1/23

RP2D N = 13
PR 7/13 (54%); SD 6/13

Govindan et al. Abstract OA.02.02

* Based on local radiographic scans every 6 weeks using RECIST 1.1 criteria
1 patient had clinical progression prior to week 6 and is not on this graph
☑ Confirmed response
‡ 2 additional patients had confirmed PR post data cutoff
$Patient had a CR of the target lesions at week 18, post data cutoff

Planned Dose

- 180 mg
- 360 mg
- 720 mg
- 960 mg
NEXT GENERATION GENOMIC TRIAL DESIGNS

a  Basket Trial

b  Umbrella Trial


ASCO TAPUR TRIAL: 120 LOCATIONS, 22 STATES

1621 Patients Enrolled (9/16/19)
<table>
<thead>
<tr>
<th>DRUG</th>
<th>TUMOR TYPE</th>
<th>VARIANT</th>
<th>SIGNAL</th>
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</thead>
<tbody>
<tr>
<td>Palbociclib</td>
<td>Gallbladder/biliary</td>
<td>CDKN2A mutation/loss</td>
<td></td>
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<tr>
<td>Palbociclib</td>
<td>Pancreas</td>
<td>CDKN2A mutation/loss</td>
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<tr>
<td>Cetuximab</td>
<td>Breast</td>
<td>KRAS,NRAS, BRAF wt</td>
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</tr>
<tr>
<td>Cetuximab</td>
<td>NSCLC</td>
<td>KRAS,NRAS, BRAF wt</td>
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</tr>
<tr>
<td>Sunitinib</td>
<td>Colorectal</td>
<td>FLT3 mutation/amp</td>
<td></td>
</tr>
<tr>
<td>Palbociclib</td>
<td>NSCLC</td>
<td>CDKN2A mutation/loss</td>
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<tr>
<td>Pembrolizumab</td>
<td>Breast/Colorectal</td>
<td>High TMB</td>
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<tr>
<td>Pertuzumab + Trastuzumab</td>
<td>Colorectal</td>
<td>ERBB2 amplification</td>
<td></td>
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<tr>
<td>Vemurafenib + Cobimetinib</td>
<td>Colorectal</td>
<td>BRAF V600E/D/K/R mut</td>
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</table>
WHO BENEFITS IF THE TAPUR TRIAL SUCCEEDS?

- **Patients** receive targeted agent matched to tumor genomic profile; drugs at no cost
- **Physicians** receive guidance in interpretation of genomic test results and treatment options, access to drugs, clinical data on off-label use
- **Pharma** receives data on drug use and outcomes to inform R&D plans and life cycle management
- **Payers** receive data on test and drug use and outcomes to inform future coverage decisions
- **Regulators** receive data on extent and outcomes of off label drug and test use and real world safety data
ASCO’s Membership Is Stable & Global
2019 Meeting Data

Attendance

<table>
<thead>
<tr>
<th>2019 AM Registration Report</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Attendees</td>
<td>&gt; 42000</td>
<td>39401</td>
<td>38004</td>
</tr>
<tr>
<td>Professional Attendees</td>
<td>&gt; 34000</td>
<td>32011</td>
<td>31023</td>
</tr>
</tbody>
</table>

Abstracts

- 6,205 submissions
- 3,046 International/3,159 Domestic (49%/51%)
- 2,450 accepted: (260 oral, 2190 poster +/- discussion)
- 3,265 online publication only

Video Credit: ASCO Staff Leader Mandy Davis
Aiken
Opening Session: Educate and Connect

"[To our patients]...thank you for giving us the honour of sharing a very difficult process...thank you for being our greatest teachers."

Edmond Ang, MBBCh, MRCP tells the incredible story of Chemoboy and the patients who inspire him.

At the @ASCO #OpeningSession #ASCO19

Highlight of the day was hearing @Atul_Gawande stress the importance of asking patients what their #goals are. It’s of the utmost importance in oncology!

#ASCO19
#compassionatecare

Photo Credit: Meeting Attendee

OM Ezeoke
@OME_ResidentMD

Angela Saver
@a_saver
Affordable Care Act Medicaid Expansion Impact on Racial Disparities in Time to Cancer Treatment

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¹ Flatiron Health, Inc. | ² Yale University
OVERALL SURVIVAL (OS) RESULTS OF A PHASE III RANDOMIZED TRIAL OF STANDARD OF CARE THERAPY WITH OR WITHOUT ENZALUTAMIDE FOR METASTATIC HORMONE SENSITIVE PROSTATE CANCER (mHSPC)

ENZAMET (ANZUP 1304):
AN ANZUP-LED INTERNATIONAL CO-OPERATIVE GROUP TRIAL
(NHMRC CTC, CCTG, CTI, DFCI)

Christopher Sweeney, Andrew Martin, Robert Zielinski, Alastair Thomson, Thean Hsiang Tan, Shahneen Sandhu, M. Neil Reaume, David Pook, Francis Parnis, Scott North, Gavin Marx, John McCaffrey, Ray McDermott, Nicola Lawrence, Lisa Horvath, Mark Frydenberg, Simon Chowdhury, Kim Chi, Martin Stockler, Ian Davis

Presented By Christopher Sweeney at 2019 ASCO Annual Meeting
ANNOUNCE: A randomized, placebo-controlled, double-blind, phase 3 trial of doxorubicin + olaratumab vs doxorubicin + placebo in patients with advanced soft tissue sarcomas


On behalf of the ANNOUNCE investigators
Olaparib as maintenance treatment following first-line platinum-based chemotherapy in patients with a germline BRCA mutation and metastatic pancreatic cancer: Phase III POLO trial

Hedy L Kindler,1 Pascal Hammel,2 Michele Reni,3 Eric Van Cutsem,4 Teresa Macarulla,5 Michael J Hall,6 Joon Oh Park,7 Daniel Hochhauser,8 Dirk Arnold,9 Do-Youn Oh,10 Anke Reinacher-Schick,11 Giampaolo Tortora,12 Hana Algül,13 Eileen M O’Reilly,14 David McGuinness,15 Karen Y Cui,16 Katia Schlienger,17 Gershon Y Locker,16 Talia Golan18

1The University of Chicago, Chicago, IL, USA; 2Hôpital Beaujon (AP-HF), Clichy and University Paris VII, Paris, France; 3IRCCS Ospedale San Raffaele Scientific Institute, Milan, Italy; 4University Hospitals Gasthuisberg and KU Leuven, Leuven, Belgium; 5Vall d’Hebron University Hospital and Vall d’Hebron Institute of Oncology, Barcelona, Spain; 6Fox Chase Cancer Center, Philadelphia, PA, USA; 7Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; 8University College London Cancer Institute, London, UK; 9Asklepios Tumorzentrum Hamburg AK Altona, Hamburg, Germany; 10Seoul National University Hospital, Seoul, South Korea; 11St. Josef-Hospital, Ruhr University Bochum, Bochum, Germany; 12Azienda Ospedaliera Universitaria Integrata Verona, Verona and Fondazione Policlinico Universitaria Gemelli IRCCS, Rome, Italy; 13Klinikum Rechts der Isar, Department of Internal Medicine II, Technische Universität München, Munich, Germany; 14Memorial Sloan Kettering Cancer Center, New York, NY, USA; 15AstraZeneca, Cambridge, UK; 16AstraZeneca, Gaithersburg, MD, USA; 17Merck & Co, Inc, Kenilworth, NJ, USA; 18The Oncology Institute, Sheba Medical Center at Tel-Hashomer, Tel-Aviv University, Tel-Aviv, Israel

ClinicalTrials.gov identifier: NCT02184195. This study was sponsored by AstraZeneca and is part of an alliance between AstraZeneca and Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Inc, Kenilworth, NJ, USA (MSD)
# 1. Impact of broadening clinical trial eligibility criteria for advanced non-small cell lung cancer patients: Real-world analysis

Harvey et al., ASCO Annual Meeting 2019, Abstract # LBA108

<table>
<thead>
<tr>
<th>Original Cohort</th>
<th>10,500 (100%)</th>
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<tr>
<td><strong>Traditional Exclusions</strong></td>
<td></td>
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<tr>
<td>Pts excluded for brain mets</td>
<td>2,226 (21.2%)</td>
</tr>
<tr>
<td>Pts excluded for prior/concurrent malignancy</td>
<td>2,254 (21.5%)</td>
</tr>
<tr>
<td>Pts excluded for CrCl &lt; 60 mL/min</td>
<td>1,509 (14.4%)</td>
</tr>
<tr>
<td>Total pts included by traditional criteria</td>
<td>5,495 (52.3%)</td>
</tr>
<tr>
<td>Pts excluded by 1 of 3 traditional criteria</td>
<td>5,005 (47.7%)</td>
</tr>
<tr>
<td><strong>Expanded Criteria</strong> (Permits brain mets and prior/concurrent malignancy)</td>
<td></td>
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</tbody>
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Using expanded clinical trial eligibility criteria would enable ~2x # of advanced NSCLC pts to consider trial participation

# 2. Real-world outcomes of patients w/ advanced NSCLC receiving immune checkpoint inhibitors w/ and w/o autoimmune disease (AD)

Khozin et al., ASCO Annual Meeting 2019, Abstract # 9110

- Time to treatment discontinuation (TTD)
- Time to next treatment (TTNT)
- Real-world progression-free survival (rwPFS)
- Overall survival (OS)

No statistical difference in outcomes in patients with and without AD
Real World Evidence

How FDA, Pfizer, and Flatiron Health did it

Approval of Ibrance for men affords a glance at use of real world data

By Paul Goldberg

Real world data played a role in FDA’s recent decision to expand the indications for Pfizer’s drug Ibrance (palbociclib) to include men.

On April 4, Ibrance joined the ranks of cancer drugs that were approved partly based on data extracted from electronic medical records and other data related to actual experience with the drug, as opposed to clinical studies. Approvals relying on such data have been occurring infrequently, and it appears that they haven’t been analyzed systematically.
ASCO Research Priorities Identified

- Identify strategies that better predict response to immunotherapies
- Better define the patient populations that benefit from post-operative (adjuvant) therapy
- Translate innovations in cellular therapies for hematological malignancies to solid tumors
- Increase precision medicine research and treatment approaches in pediatric cancers
- Optimize care for older adults with cancer
- Increase equitable access to cancer clinical trials
- Reduce the long-term consequences of cancer treatment
- Reduce obesity’s impact on cancer incidence and outcomes
- Identify strategies to detect and treat premalignant lesions
UNITE AND CONQUER: ACCELERATING PROGRESS TOGETHER

Bridging Gaps and Connecting People to Find a Better Way

Scientific Program Chair
Melissa Johnson, MD
Sarah Cannon

Education Program Chair
Tatiana Prowell, MD
FDA/Johns Hopkins
ASCO 2020 - UNITE AND CONQUER: ACCELERATING PROGRESS TOGETHER

• Bringing together stakeholders (physicians, patients, nurses, pharma, regulators, payers, scientists)

• Leading research initiatives (eligibility, access, profiling, etc.)

• Expanding our membership

• Being the preeminent cancer meeting
“One of my greatest priorities is to reduce the price of prescription drugs.”

PRESIDENT DONALD J. TRUMP

Drug Pricing Blueprint

- **Competition**: Lower drug prices and increase innovation through more competition
- **Seniors**: Give Medicare Part D plans tools to negotiate lower prices for seniors
- **Incentives**: Develop incentives for drug makers to lower their list prices
- **More Options**: Offer more drug options, which will lower out-of-pocket spending
Congress’ Potential Fall Agenda

• Healthcare:
  • Drug pricing
  • Appropriations
  • Surprise medical billing
  • E-cigarettes

• Outside healthcare:
  • Impeachment
  • Gun control
  • Trade deals
  • Surveillance issues
  • National Defense Authorization Act
What ASCO Has Supported

- **Price Transparency**: Allowing greater transparency on all aspects of drug pricing
- **Pay for delay/evergreening/product hopping**: Preventing manufacturers from participating in anti-competitive behaviors
- **Reducing Market Exclusivity**: Reducing the time it takes before a generic/biosimilar can enter the market
- **Patient Out of Pocket Maximums in Part D**
Where ASCO Has Raised Concerns

• Policy changes that could negatively impact cancer patients and Medicare Part B drug reimbursement:
  • Including value of coupons in the determination of Average Sales Price
  • Establishing a Maximum Add-on Payment for Part B drugs