Melanoma

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Objectives:

- Identify new immunotherapy treatment options for advanced melanoma
- Identify clinical trial option available to melanoma patients
- Discuss how genomics and tumor tissue are being used to advance the care of melanoma patients
Melanoma Program Update
Intermountain Medical Center

Huntsman-Intermountain Cancer Care Program
August 25, 2016
Tawnya Bowles, MD, FACS
Surgical Oncology
Utahns are at high risk for melanoma
“Utah Melanoma Program”

How can we best combine efforts to tackle this cancer together--bringing together the best from each institution for our patients?
<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Stage</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>Polynoma/MAVIS Vaccine Study</td>
<td>Phase III randomized placebo-controlled trial of a polyvalent melanoma vaccine</td>
<td>IIB/C, III</td>
<td>Ongoing</td>
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<tr>
<td>SWOG 1404 (Dr. Grossmann PI)</td>
<td>Phase III Randomized Trial of Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High-Risk Resected Melanoma</td>
<td>III, IV</td>
<td>Ongoing</td>
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<tr>
<td>Amgen MASTERKEY</td>
<td>Pembrolizumab With or Without Talimogene Laherparepvec or Talimogene Laherparepvec Placebo in Unresected Melanoma</td>
<td>Unresectable III, IV</td>
<td>Ongoing</td>
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<td>Biovex extension study (Amgen)</td>
<td>An Extension Protocol to Evaluate the Efficacy and Safety of Extended Use Treatment with OncoVEXGM-CSF or GM-CSF for Eligible Melanoma Patients Participating in Study 005/05</td>
<td>III, IV</td>
<td>Ongoing</td>
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<td><strong>DERMA</strong> (GSK; CLOSED to accrual)</td>
<td>Phase III trial of RecMAGE-A3 + AS15 ASCI vs. placebo for MAGE-A3 positive resected Stage IIIB/C melanoma</td>
<td>IIIB/C</td>
<td>Study did not show benefit</td>
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<td><strong>Vical</strong> (CLOSED to accrual)</td>
<td>Phase III trial of Allovectin-7 immunotherapeutic for metastatic melanoma</td>
<td>IV</td>
<td>Study did not show benefit (390 pts)</td>
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<tr>
<td><strong>MSLT-II</strong> (John Wayne Cancer Inst.)</td>
<td>Randomized trial of US of lymph node basin vs. completion lymphadenectomy in pts with positive SLN biopsy</td>
<td>III</td>
<td>2nd highest accrual in the world; results pending</td>
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<tr>
<td><strong>BioVex Oncolytic Virus</strong> (AMGEN)</td>
<td>Randomized Phase III trial of OncoVEX&lt;sup&gt;GM-CSF&lt;/sup&gt; vs. GM-CSF alone in unresectable Stage IIIB/C and Stage IV melanoma</td>
<td>IIIB/C and IV</td>
<td>Extension trial open</td>
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<tr>
<td><strong>ECOG 1609</strong> (Eastern Cooperative Oncology Group)</td>
<td>Phase III randomized trial comparing ipilimumab and interferon for Stage IIIB/C</td>
<td>IIIB/C</td>
<td>Accrued well</td>
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Melanoma Clinical Database

- Database developed in parallel with HCI to allow for collaboration on clinical projects
- Received grant funding from Intermountain Research Foundation for chart abstraction
- Goal of 750 charts abstracted for grant project; we are at ~800 charts of invasive melanoma completely abstracted
- Concurrent goal of developing prospective database
Multidisciplinary melanoma treatment planning conference

- Held bimonthly in collaboration with Huntsman Cancer Institute

- Videoconferencing allows participation at IMC and HCI (Utah Cancer Specialist participation at IMC site)

- Offers opportunity for up to date clinical trial eligibility discussion for patients
Outreach efforts

- Free skin cancer screenings at both institutions (separately run)
- AIM at melanoma Patient Forum (Dr. Grossmann, HCI)
- Melanoma Research Foundation, Miles for Melanoma 5K (second annual on Sept. 10)
- Education through media (radio, TV, Twitter)
Clinical projects

- Quality improvement projects for melanoma
  - Unique opportunity for Intermountain to contribute to joint efforts
  - Genentech grant for a prevention project for melanoma

- Recent published collaborative projects

- Ongoing clinical project of surgical treatment/sentinel lymph node biopsy for melanoma of the external ear (joint database project)
Challenges

- Information technology/privacy challenges in doing joint clinical database projects
- Running joint clinical trials that are sponsored by pharma
- Joining together as “Utah Melanoma Program” in research efforts, including prevention
- Molecular profiling of tumors—sharing data/tissue and advancing clinical trials and treatment options from this