Rose Bengal

Small Molecule Ablative Immunotherapy

A first-in-class halogenated xanthene with unique therapeutic properties for fighting cancer and inflammatory dermatoses.
This presentation contains "forward-looking statements" as defined under U.S. federal securities laws. These statements reflect management’s current knowledge, assumptions, beliefs, estimates, and expectations and express management’s current views of future performance, results, and trends and may be identified by their use of terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," and other similar words. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. Readers should not place undue reliance on forward-looking statements. Such statements are made as of the date hereof, and we undertake no obligation to update such statements after this date. Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the U.S. Securities and Exchange Commission (including those described in items 1A of our Annual Report on 10-K for the year ended December 31, 2015). Provectus Biopharmaceuticals, Inc. (“Provectus”) assumes no obligation to update any forward-looking statements or information that speaks as to their respective dates.

No claims with respect to Provectus’ investigational drug PV-10 for solid tumor cancers and/or investigational drug PH-10 for inflammatory dermatoses are intended regarding safety or efficacy in the context of the forward-looking statements in this presentation.

Company presentations are made publicly available at the time of delivery, and may be found at www.pvct.com/presskit.html along with other presentations, including this one.
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Investigational Oncology Compound PV-10

• **PV-10:** A 10% solution of small molecule and halogenated xanthene Rose Bengal
  – Administered by direct injection into solid tumor cancers (e.g., melanoma, liver, breast, etc.)
  – Not designed to rely on a single pathway, receptor or antigen to work; no known resistance

• **First-in-class ablative immunotherapy:** Intended to kill only diseased cells upon injection into tumors; proper cell death would be the subsequent upstream trigger for a systemic anti-tumor response
  – Potentially agnostic to disease presentation and orthogonal to other cancer treatments

• **Rose Bengal:** A diagnostic agent for >100 years; long and established history of use in humans
  – Original/first medicinal use: an intravenous hepatic diagnostic (\(^{131}\)I-radiolabeled Rose Bengal/Robengatope®) and topical ophthalmic diagnostic (Rosettes®, Minims®)
  – Physical chemistry properties; not metabolized; half-life of ~30 minutes in the blood stream

• **Therapeutic use:** Advanced by Provectus Biopharmaceuticals in both oncology and dermatology
  – Global intellectual property protection for the entire class of halogenated xanthenes
  – Second medicinal use (as a therapeutic), Method of use, Formulation (including trade secrets), Synthesis (to ICH Guidelines specification), Combination (with other cancer treatments)
PV-10: Small molecule ablative immunotherapy
- **Ablation**: destruction of injected tumors
- **Immunotherapy**: subsequent tumor-specific immune response

**Rose Bengal weighs <1,000 g/mol**
- Not a macromolecule, polymer or biomolecule; best classified as a small molecule, albeit a very heavy one
- Good, consistent pharmacokinetic properties
- May occupy “natural-product-like” chemical space

**Potentially an understood mechanism of action**
- Injection of Rose Bengal results in necrosis of tumor cells and the release of High Mobility Group Box 1 (HMGB1), with increased dendritic cell infiltration into draining lymph nodes and the activation of tumor-specific T cells

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\[^1\] Liu et al., Oncotarget 2016
An Opportunity for a Global Impact on Cancer

• Potentially viable for multiple cancer indications
• Potentially agnostic to disease presentation
• Intended to be synergistic in combination with other cancer treatments
• Intended to be orthogonal to other cancer treatments when combined

• Designed for ease of physician/provider use and/or re-use
• Designed to be supportive of patient compliance
• Designed for ease of shipment, storage and handling (all at room temperature)
• Globally affordable
Implications of Emerging Immunology Data

- **PV-10 has been implicated in each step of the Cancer Immunity Cycle**:¹,²
  - Release of cancer antigens–1; cancer antigen presentation–2; priming and activation–3; trafficking of T cells to tumors–4; infiltration of T cells into tumors–5; recognition of cancer cells by T cells–6; killing of cancer cells–7
  - PV-10 is as much about “starting the engine” and “stepping on the gas pedal” of the immune system as it is about “releasing the brakes”
  - **International, pivotal, monotherapy trial-in-progress**: PV-10 vs. Chemotherapy or Oncolytic Viral Therapy³

- **Potentially agnostic to disease presentation**
  - e.g., melanoma, cancers of the liver, breast cancer, colon cancer, pancreatic cancer, etc.

- **Potentially orthogonal to other cancer treatments when combined**
  - Synergistic: “induce and boost” an immune response (PV-10 would induce the immune response, and the partner treatment would boost it); minimal risk of clinically relevant drug-drug interaction⁴
  - **Combination therapy trials-in-progress**: PV-10 + anti-PD-1 pembrolizumab⁵; + radiotherapy⁶
  - Completed pre-clinical work: PV-10 + chemotherapy⁷; + anti-CTLA4⁸,⁹; + anti-PD-1¹⁰; + anti-PD-L1¹⁰

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PV-10: Oncology Meets Immunology


**Priming and Activation**
- Toomey et al., PLoS1 2013
- Liu et al., ACR 2014
- Sarnaik et al., ASCO 2014
- Pardiwala et al., SSO 2015
- Liu et al., Oncotarget 2016
- Melanoma (p, c)
- Colon cancer (p)

**Cancer Antigen Presentation**
- Liu et al., AACR 2014
- Liu et al., SITC 2015
- Liu et al., Oncotarget 2016
- Melanoma (p, c)

**Release of Cancer Cell Antigens**
- Thompson et al., Mel Res 2008
- Agarwala et al., ASCO 2009
- Toomey et al., PLoS1 2013
- Liu et al., ACR 2014
- Sarnaik et al., ASCO 2014
- Pardiwala et al., SSO 2015

**Trafficking of T cells to Tumors**
- Liu et al., ACR 2014
- Sarnaik et al., ASCO 2014
- Melanoma (p, c)

**Infiltration of T cells into Tumors**
- Liu et al., Oncotarget 2016
- Melanoma (p, c)

**Recognition of Cancer Cells by T Cells**
- Liu et al., AACR 2014
- Sarnaik et al., ASCO 2014
- Liu et al., SITC 2015
- Liu et al., Oncotarget 2016
- Melanoma (p, c)

**Killing of Cancer Cells**
- Goldfarb et al., ESMO World GI 2015
- Thompson et al., Ann Surg Oncol 2015
- Liu et al., ACR 2014
- Melanoma (p, c)
- Breast cancer (p)
- Colon cancer (p)
- Hepatocellular carcinoma (p, c)
- Pancreatic cancer (p)
### Ablative Immunotherapy: A Two-Prong Approach to Fighting Cancer

#### Local Effect:
**Tumor destruction**  
(ablative)

- Intended for a patient’s tumor burden to be rapidly reduced after injection of PV-10 into his or her cancerous lesions/tumors
- Rose Bengal’s selective targeting of diseased cells is intended to minimize side effects
- PV-10 is not designed to rely on a single immunologic signaling pathway, cell receptor or tumor antigen to work
- Rose Bengal/PV-10 has no known resistance

#### Systemic Effect:
**Tumor-specific immune response**  
(immunotherapy)

- PV-10 intended to cause regression of untreated (i.e., non-injected) tumors
- Potentially prolongs progression-free survival (PFS)
- PV-10 is designed to be combined with different immunotherapies, targeted therapies, chemotherapy and radiotherapy for lesions/tumors not accessible to injection
- A recent study demonstrated PV-10 may have potential positive implications for overall survival (OS) and other clinical measures for the treatment of cutaneous melanoma metastases

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1 Read et al., Intralesional PV-10 Chemoablation Therapy for the Treatment of Cutaneous Melanoma Metastases – Results of a Prospective, Non-Randomised, Single Centre Study. *ANZ J Surg.* 2016; 86 (S1).
PV-10's Dual Mechanism of Action

APC, antigen presenting cell; DC, dendritic cell.

Tumor Ablation 1-2 hours

Systemic, tumor-specific immune response 1-2 weeks
Reproducibility: The Hallmark of Western Science

• **Key collaborators:** H. Lee Moffitt Cancer Center and Research Institute (Moffitt), Maker Laboratory at the University of Illinois at Chicago (UIC)

• Moffitt and UIC independently reproduced and also expanded upon Provectus’ original work; did so independently of the company and each other\(^1,2,3\):
  – Tumor ablation, the local effect of destroying (ablating) injected tumors
  – A tumor-specific immune response, the systemic effect of destroying untreated (non-injected) tumors
  – Tumor-specific IFN-\(\gamma\) production
  – Multi-indication viability in solid tumor cancers (melanoma, breast cancer and colorectal cancer)

• **Mouse-to-man-to-mouse:** An exemplary demonstration of translational medicine\(^4,5\)
  – Moffitt identified important immunologic markers in model systems; verified key facets in humans
  – Similarly identified other markers in humans; substantiated these in mouse models

\(^{1}\) Toomey et al., SSO 2012. \(^{2}\) Toomey et al., PLoS1 2013. \(^{3}\) Pardiwala et al., SSO 2015. \(^{4}\) NCT01760499. \(^{5}\) Liu et al., Intralexional rose bengal in melanoma elicits tumor immunity via activation of dendritic cells by the release of high mobility group box 1, *Oncotarget* (2016).
Valuation Drivers: Clinical Development Program

- **Melanoma:**
  - **Ongoing Pivotal Phase 3:** PV-10 vs. Chemotherapy or Oncolytic Viral Therapy for Treatment of Locally Advanced Cutaneous Melanoma
  - **Ongoing Phase 1b:** PV-10 in Combination With Pembrolizumab for Treatment of Metastatic Melanoma

- **Cancers of the liver:**
  - **Ongoing expanded Phase 1:** PV-10 Chemoablation of Cancer of the Liver
  - **Ongoing Phase 1:** PV-10 Chemoablation of Neuroendocrine Tumors (NET) Metastatic to the Liver
  - **Planned:** A Phase 1b/2 study of PV-10 and standard of care(s) for Hepatocellular carcinoma (HCC) in Asia

- **Inflammatory dermatoses:**
  - **Ongoing Phase 2:** Cellular and Immunologic Changes in the Skin of Subjects Receiving PH-10
  - **Planned:** Potentially pivotal Phase 3 trials for atopic dermatitis and psoriasis
Intralesional (IL) Therapy: Increasing Awareness & Acceptance

• Until 2015, there was no history of clinical success and regulatory approval for nearly 40 years
  – Before Amgen's IL drug talimogene laherparepvec (Imlygic®) was approved in October 2015 for advanced melanoma, recent failure included Vical's velimogene aliplasmid (Allovectin-7®)
  – Before Allovectin-7®’s failure in 2013 (advanced melanoma), bacillus Calmette-Guérin (BCG) failed in 1978 for advanced melanoma too

• As a result of Imlygic® and PV-10’s positive clinical data to date, there is more regulatory, medical and pharmaceutical community acceptance and awareness of the category of IL treatment; clinical studies and data to date have demonstrated:
  – Notable and lengthy tumor destruction upon injection
  – Loco-regional and systemic immune responses
  – Minimal toxicity
  – Use in earlier disease settings of cancer
  – Immune system priming to allow other immunomodulatory drugs to boost and sustain its response
### PV-10: An NDA-stage, Wholly-owned, IL Cancer Asset

<table>
<thead>
<tr>
<th>Intralesional agent</th>
<th>Proprietary name</th>
<th>Company</th>
<th>+ Medical device</th>
<th>As a monotherapy</th>
<th>In combination with</th>
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<tbody>
<tr>
<td>bacillus Calmette-Guerin (BCG)</td>
<td>n.a.</td>
<td>No</td>
<td>1967-74</td>
<td>P1, 2013-</td>
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<tr>
<td>+ melanoma</td>
<td></td>
<td></td>
<td>1974-1978</td>
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<tr>
<td>Velimogene alplasmid</td>
<td>Allovector-7</td>
<td>Vical</td>
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<td>2002-11</td>
<td>2006-14</td>
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<td>talimogene laherparepvec (T-Vec)</td>
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<td>Amgen (BioVex)</td>
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<td>+ melanoma, neoadjuvant to surgery</td>
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<td>+ pancreatic cancer</td>
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<td></td>
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<td>2006-16</td>
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<td>+ HCC, liver mets</td>
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<td></td>
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<td>2015-</td>
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<td>+ breast cancer</td>
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<td>2016-</td>
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<td>+ soft tissue sarcoma</td>
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<td>+ pediatric non-CNS tumors</td>
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<td>+ expanded access program, melanoma</td>
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<td>Rose bengal</td>
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<td>Proventus Bio</td>
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<tr>
<td>+ HCC, liver mets</td>
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<td>+ NET liver mets</td>
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<td>2005-8</td>
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<td>+ expanded access program</td>
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<td>Electroporation of plasmid interleukin-12</td>
<td>ImmunoPulse</td>
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<td>+ cutaneous lymphoma</td>
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<td>2012-2016</td>
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<td>+ breast cancer</td>
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<td></td>
<td></td>
<td>2015-</td>
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<tr>
<td>+ head &amp; neck cancer</td>
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<td></td>
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<td>2015-</td>
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<td>coxackievirus A21</td>
<td>CAVATAK, CVA21</td>
<td>Viralytics</td>
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<td>2010-15</td>
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<td>+ melanoma</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>+ head &amp; neck cancer</td>
<td></td>
<td></td>
<td></td>
<td>2009-12</td>
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<tr>
<td>Herpes simplex virus type 1</td>
<td>HF10</td>
<td>Takara Bio</td>
<td>No</td>
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<td>+ melanoma, breast cancer, head &amp; neck cancer</td>
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<td>2015-15</td>
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<tr>
<td>+ melanoma</td>
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<td>P2, 2014-</td>
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</table>

Dates (years) above from ClinicalTrials.gov: First received-Last updated, except for investigator-initiated (Australia) study of PV-10 + radiation.
Combination Therapy: ‘Induce and Boost’ the Immune Response

- **PV-10**: Intended to kill only diseased cells upon injection into tumors; proper cell death would be the subsequent upstream trigger for a systemic anti-tumor response

- **Immune activation after PV-10 injection**: Immunogenic cell death and signaling via release of HMGB1, dendritic cell recruitment and infiltration into draining lymph nodes, activation of tumor-specific T cells, and killing of non-injected tumors upon infiltration by these T cells¹

- **In combination**: PV-10 is designed to provide the requisite pre-existing anti-tumor immunity for co-inhibitory blockade (i.e., checkpoint inhibitors) to potentially improve their clinical benefit

¹ Liu et al., Oncotarget 2016
Compassionate Use (Expanded Access) Program

- Began in Australia in 2009 (special access scheme), and later expanded to the U.S. in the same year
  - Available for cancer indications that did/do not involve visceral organs, and to patients who were/are not subject to enrollment in on-going clinical trials
  - **Eight participating sites:** St. Luke’s Hospital & Health Network (Bethlehem, PA), MD Anderson Cancer Center (Houston, TX), University of Louisville (Louisville, KY), Sharp Memorial Hospital (San Diego, CA), Melanoma Institute Australia (Sydney), Princess Alexandra Hospital (Brisbane, Australia), Royal Adelaide Hospital (Adelaide), Peter MacCallum Cancer Centre (Melbourne)
- Originally designed for 115 patients; an initial target of 25-30 patients
  - Approximately 160 patients treated through 2015; more treated in 2016
- The program will be wound down at the end of this year
  - **Rationale:** Two clinical trials¹,² are underway (currently recruiting) for a substantial fraction of Stage III/IV melanoma patients; reached and exceeded the program’s accrual design and targets

¹ NCT02288897. ² NCT02557321.
Publications: Compassionate Use (Expanded Access) Program

- Data publications in 2016 for >65 patients from two Australian sites’ experiences: Princess Alexandria (Brisbane)\(^1\), Peter MacCallum (Melbourne)\(^2\)

- “PeterMac:” Lippey et al., Intralesional PV-10 for in-transit melanoma-A single-center experience, J Surg Oncol, 2016 May 30
  - 68% disease control (complete or partial response or disease stability); 26% complete response; N = 19
  - **Patient population:** Unresectable local recurrence and in-transit metastasis of cutaneous melanoma, or American Joint Committee on Cancer (AJCC) Stage IIIB and IIIC — **Pivotal trial population:** Stage IIIB-IVM1a\(^3\)
  - **Treatment with PV-10:** Most patients received only one course of treatment; a majority of patients did not have all of their lesions injected because of the number of lesions present — **Pivotal trial treatment:** Designed to treat all disease (i.e., all of a patient’s lesions)
  - **Predictors of response:** Predictors of complete response were age and lesion size; the presence of ulceration, blistering, eschar, or pain following injection also was predictive of response; the number of injected lesions and time from primary diagnosis to treatment were not predictive — **Pivotal trial efficacy measures:** PFS (primary), complete response rate (CRR) (secondary), duration of complete response (secondary), OS (secondary)

\(^1\) Read et al., Intralesional PV-10 Chemoablation Therapy for the Treatment of Cutaneous Melanoma Metastases - Results of a Prospective, Non-Randomised, Single Centre Study, ANZ J Surg 2016, 86 (S1). \(^2\) Lippey et al., Intralesional PV-10 for In-Transit Melanoma - A Single Centre Experience. ANZ J Surg. 2016, 86 (S1). \(^3\) NCT02288897.
Globally-Protected Intellectual Property

- **Protection (through at least 2031):** Second medicinal use, Method of use, Formulation, Synthesis, Combination
  - **Synthesis:** Process for the synthesis of 4,5,6,7-tetrachloro-3',6'-dihydroxy-2',4',5',7'-tetraiodo-3H-spiro[isoben-zofuran-1,9'-xanthen]-3-one (rose bengal) and related xanthenes
    - The process under which pharmaceutical-grade Rose Bengal and related xanthenes are produced per International Conference on Harmonisation (ICH) Guidelines; covers the use of alternative raw material when manufacturing Rose Bengal
    - Approved in the U.S. (#8,530,675); allowed in China; filed in multiple other global jurisdictions
    - Supported by Cambrex Corporation
  
- **Combination:** Combination of local and systemic immunomodulative therapies for enhanced treatment of cancer
  - The treatment combination of PV-10 and immunomodulatory therapeutic agents, including anti-CTLA-4, PD-1 and PD-L1 compounds
  - Approved in the U.S. (#9,107,887); filed in multiple other global jurisdictions
  - Jointly owned with Pfizer Inc.
## References

<table>
<thead>
<tr>
<th>Author</th>
<th>Affiliation</th>
<th>Title</th>
<th>Venue &amp; Year</th>
<th>Indication</th>
<th>Pre-/Clinical</th>
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<tbody>
<tr>
<td>Thompson et al.</td>
<td>Clinical trial investigators, Provectus</td>
<td>Chemoablation of metastatic melanoma using intralesional Rose Bengal [Phase 1 study]</td>
<td>Melanoma Research (Mel Res) 2008</td>
<td>Melanoma</td>
<td>Clinical</td>
</tr>
<tr>
<td>Agarwala et al.</td>
<td>Clinical trial investigators, Provectus</td>
<td>Chemoablation of Melanoma with Intralesional Rose Bengal (PV-10)</td>
<td>American Society of Clinical Oncology (ASCO) 2009</td>
<td>Melanoma</td>
<td>Clinical</td>
</tr>
<tr>
<td>Toomey et al.</td>
<td>Moffitt Cancer Center</td>
<td>Intralesional Injection of Melanoma with Rose Bengal Induces Regression of Untreated Synchronous Melanoma In a Murine Model</td>
<td>Society of Surgical Oncology (SSO) 2012</td>
<td>Melanoma</td>
<td>Pre-clinical</td>
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<tr>
<td>Dees et al.</td>
<td>Provectus</td>
<td>Generation of an Antitumor Response and Immunity Using a Small Molecule Drug (PV-10)</td>
<td>Society for Immunotherapy of Cancer (SITC) 2012</td>
<td>HCC, Melanoma, Pancreatic cancer, Colon cancer</td>
<td>Pre-clinical</td>
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<tr>
<td>Wachter et al.</td>
<td>Provectus</td>
<td>Combination of PV-10 Immuno-chemoablation and Systemic anti-CTLA-4 Antibody Therapy in Murine Models of Melanoma</td>
<td>American Association for Cancer Research (AACR) 2013</td>
<td>Melanoma</td>
<td>Pre-clinical</td>
</tr>
<tr>
<td>Toomey et al.</td>
<td>Moffitt Cancer Center</td>
<td>Intralesional Injection of Rose Bengal Induces a Systemic Tumor-Specific Immune Response in Murine Models of Melanoma and Breast Cancer</td>
<td>PLoS ONE (PLoS1) 2013</td>
<td>Melanoma, Breast Cancer</td>
<td>Pre-clinical</td>
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<td>Author</td>
<td>Affiliation</td>
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<tr>
<td>Liu et al.</td>
<td>Moffitt Cancer Center</td>
<td>Induction of anti-melanoma immunity after intralesional ablative therapy</td>
<td>AACR 2014</td>
<td>Melanoma</td>
<td>Pre-clinical</td>
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<tr>
<td>Sarnaik et al.</td>
<td>Moffitt Cancer Center</td>
<td>Assessment of immune and clinical efficacy after intralesional PV-10 in injected and uninjected metastatic melanoma lesions</td>
<td>ASCO 2014</td>
<td>Melanoma</td>
<td>Clinical</td>
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<tr>
<td>Pilon-Thomas et al.</td>
<td>Moffitt Cancer Center</td>
<td>Efficacy of Intralional Injection with PV-10 in Combination with Co-Inhibitory Blockade in a Murine Model of Melanoma</td>
<td>SITC 2014</td>
<td>Melanoma</td>
<td>Pre-clinical</td>
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<td>Pardiwala et al.</td>
<td>University of Illinois at Chicago</td>
<td>Intralesional Injection of Rose Bengal Induces an Anti-tumor Immune Response and Potent Tumor Regressions in a Murine Model of Colon Cancer</td>
<td>SSO 2015</td>
<td>Colon cancer</td>
<td>Pre-clinical</td>
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<td>Goldfarb et al.</td>
<td>Clinical trial investigators, Provectus</td>
<td>&quot;Phase 1 Study of PV-10 for Chemoablation of Hepatocellular Cancer and Cancer Metastatic to the Liver&quot;</td>
<td>ESMO World GI 2015</td>
<td>HCC, Liver mets</td>
<td>Clinical</td>
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<td>Thompson et al.</td>
<td>Clinical trial investigators, Provectus</td>
<td>Phase 2 Study of Intralional PV-10 in Refractory Metastatic Melanoma</td>
<td>Ann Surg Oncol 2015</td>
<td>Melanoma</td>
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<td>Liu et al.</td>
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<td>T cell Mediated Immunity After Combination Therapy with Intralesional PV-10 and Co-Inhibitory Blockade in a Melanoma Model</td>
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<td>Oncotarget 2016</td>
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