368 Activated B cells as Therapeutic Cancer Vaccine Platform

Asset Overview

Product Type	Vaccine
Indication	Oncology
Current Stage	Preclinical
Target(MoA)	Activation of CD8+ T cells
Brief Description	• Developed a novel B-cell vaccine platform that holds potential benefits compared to dendritic cell (DC) and CAR-T-based immunotherapies • A proprietary activating agent is used to activate and expand B cells ex vivo prior to loading with antigen and adjuvant • Platform has demonstrated the ability to elicit an immune response to numerous distinct antigens. The platform is amenable to a broad range of antigens that are tumor specific, pathogen-related and/or neoantigens • Accompanied by a robust multi-species preclinical data package • Robust efficacy in animal models as a monotherapy and in combination with checkpoint inhibitors • Ease of manufacturing, stability and administration relative to CAR-T and DC therapies
Organization	The Ohio State University

Differentiation

□ **Therapeutic DC based Vaccines**

- Provenge® (sipuleucel-T, dendreon pharmaceuticals): FDA approval in 2010 Cancer vaccine strategies based on autologous dendritic cells (DCs) pulsed with tumor antigens have been widely studied. For example, a phase III clinical trial testing peptide pulsed DCs as a first-line treatment in advanced melanoma patients has been performed, but DC vaccination was ineffective compared to chemotherapy
- A randomized phase II/III clinical trial is currently ongoing in glioblastoma patients to test a DC-based vaccine (NCT03548571)
- Many parameters such as DC-based vaccine administration, maintenance of DC viability and maturation as well as standardization of ex vivo generation can be limiting

□ **Advantages**

- First-in-class cellular therapy platform: There are no current FDA-approved B cell-based cellular therapies
- Amenable to customization for any targetable antigen: Efficacy in three distinct murine cancer models is achieved using three distinct antigens
- Robust efficacy and immune memory: The platform is able to produce CD8+ T-cell epitope spreading and protection from tumor re-challenge
- Fresh and cryopreserved ABCs are similarly efficacious
- Off-the-shelf potential: Autologous and allogeneic ABCs demonstrate comparable efficacy
- Efficacy validated externally: In vivo efficacy study was successfully replicated by an independent CRO
- Earliest IP filing priority date: February 10, 2015

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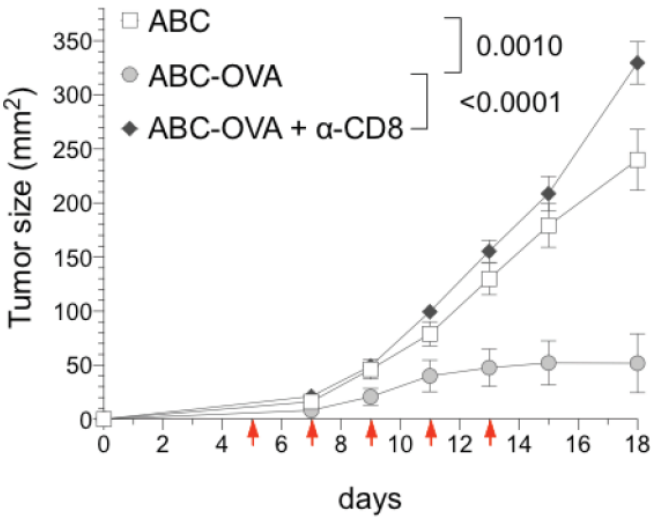
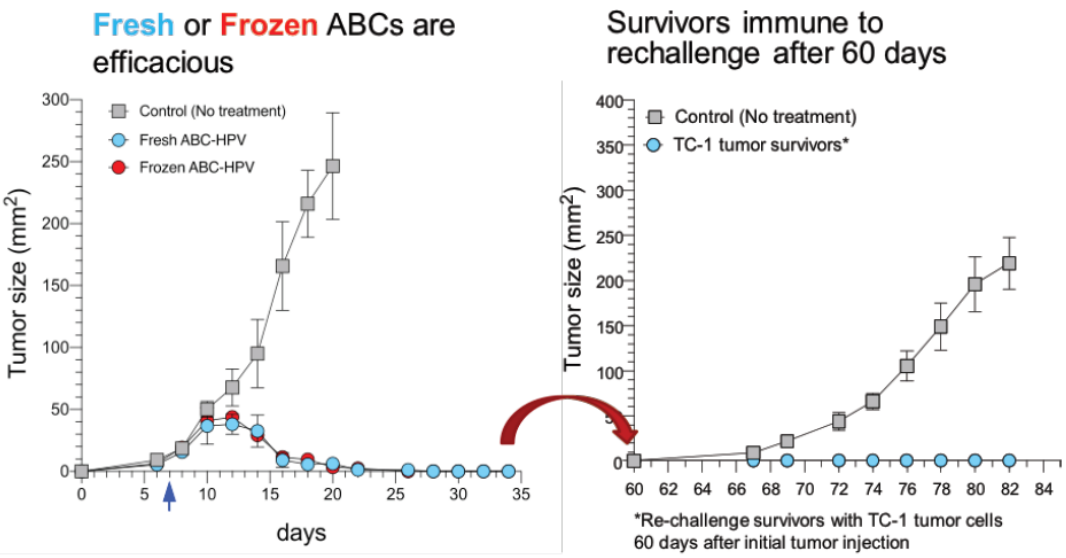
Key Data

ABCs induce anti-tumor efficacy via activation of CD8+ T cells *in vivo*



ABC: Activated B-Cells, i.v. administration, 10^7 cells/dose QOD x 5 doses
Control, activated B cells with no antigen
α-CD8, 100ug anti-CD8 depleting antibody administered i.p. QOD from day 4
Tumor Model: EG7.Ovalbumin; 0.75 x 10^6 EG7-OVA tumor cells

Strong *in vivo* efficacy and generation of memory (HPV-associated Tumor Model)



AB, optimized activated B cells, administered as a single dose, 2 x 10^7 cells
Tumor model: TC-1 HPV+ tumor cells (HPV16 E6/E7)

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Intellectual Property

Patent No.	PCT/US2016/017338 PCT/US2016/061062 PCT/US2017/041948 PCT/US2018/024007
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Status	Application Pending
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