Rationale Development of Combination Cancer Immunotherapy through Collaborations

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Co-Chairs:

Eric Masson, AstraZeneca

Paul Statkevich, Bristol-Myers Squibb

Combination Cancer Immunotherapy

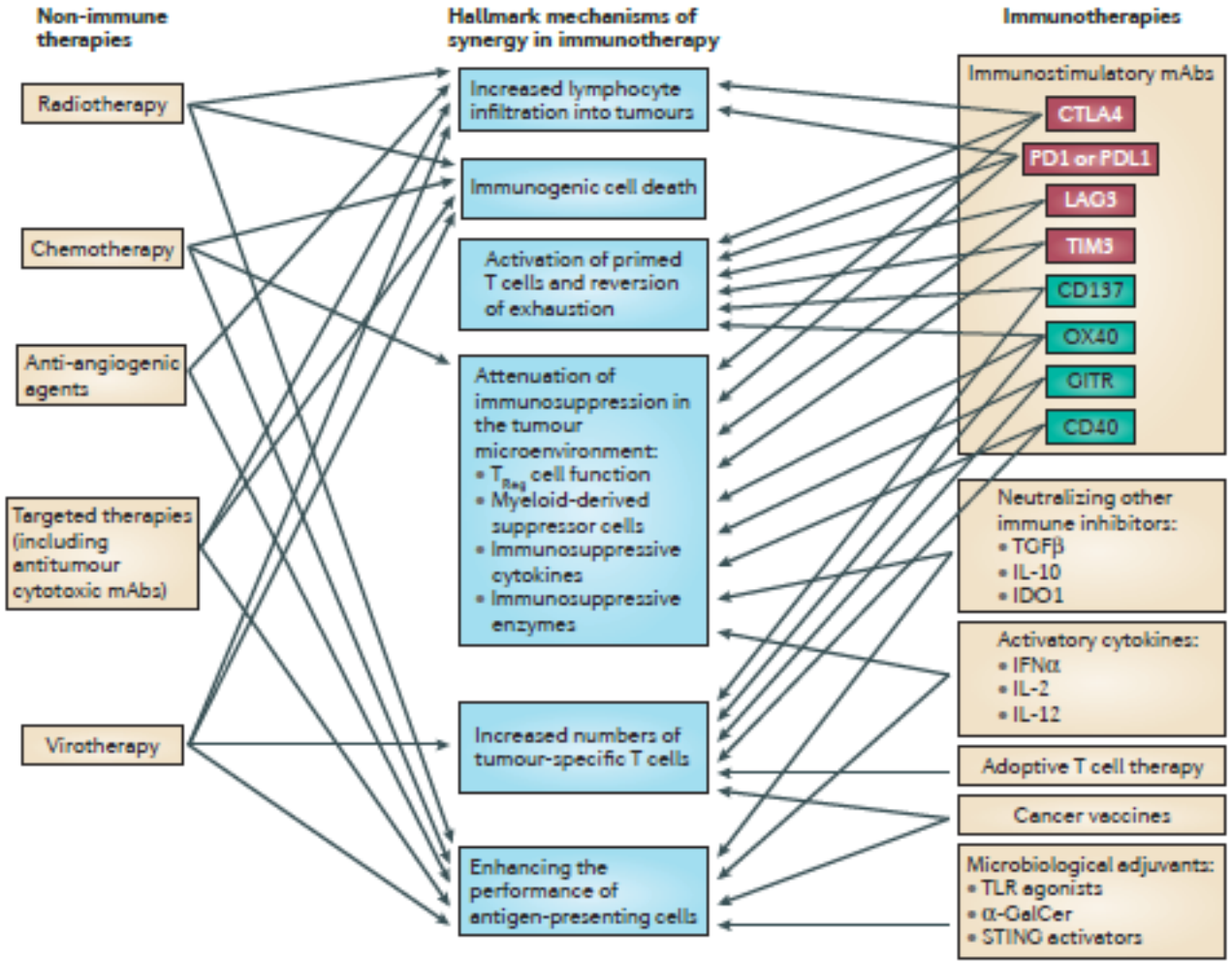

Figure 3 | **Schematic representation of the main mechanisms of action postulated to mediate synergistic effects of combined immunotherapies.**

Melero I, Berman D, et al., Nature Reviews, Evolving synergistic combinations of targeted immunotherapies to combat cancer. Volume 15, August 2015, 457-472.

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Agenda:

- **Role of Translational Science in Immuno-Oncology Combination Development**
  - *John Kurland, Ph.D., MedImmune*
- **Quantitative Clinical Pharmacology for Early Decision Making During Combination Immunotherapy Development**
  - *Shruti Agrawal, Ph.D., Bristol-Myers Squibb*
- **Regulatory Considerations for Immuno-Oncology Combination Drug Development**
  - *Atiqur Rahman, Ph.D., US Food and Drug Administration*

Workshop Objectives:

1) Highlight the current challenges in development of immunotherapy in combination with other treatment modalities in oncology such as combination selection based on biomarker strategies, clinical trial design, initial dosing scenarios, evaluation of safety and efficacy, and potential solutions for overcoming challenges and faster clinical development.

2) Describe case studies where immune check point inhibitors in combination have resulted in benefit to patients in terms of response and elaborate challenges and issue resolution in combination drug development, integrated quantitative exposure-response analyses of combination immunotherapy, and analysis to guide decision making.

3) Review the regulatory perspective on challenges in translational and clinical development of combination immunotherapy