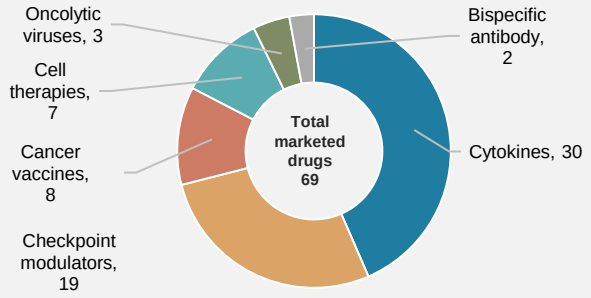
ADVANCEMENTS IN IMMUNO-ONCOLOGY

CURRENT OVERVIEW OF IMMUNO-ONCOLOGY

Between 2017 and August 2020, immuno-oncology (IO) agents increased by 233%, totaling 4,720 across six categories, including innovative therapies. Emerging treatments targeting CD47, CD19, CD3, and TAA receptors show promise alongside anti-PD-1/L1 antibodies. Clinical needs in IO trials involve improved predictive biomarkers for patient selection and lower therapy toxicity to enhance quality of life.

CURRENT APPROVED IMMUNO-ONCOLOGY LANDSCAPE



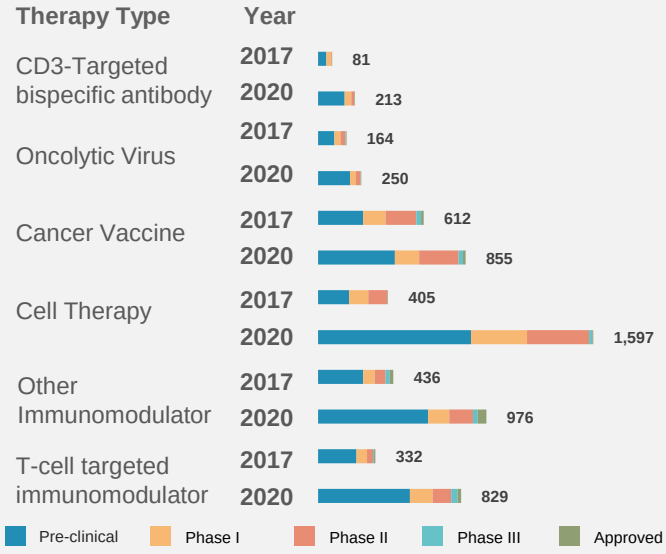
- There are currently 69 marketed IO agents in the 7MM.
- Cytokines products lead the category with 30 products, followed by checkpoint modulators with 19 approved drugs.

Key Players Involved

MERCK · Bristol Myers Squibb · Roche · AstraZeneca · GILEAD

TRIAL ANALYSIS:

I. Global Immuno-oncology Drug Development Pipeline



Comparison of immuno-oncology pipeline in 2017 vs 2020: **233%** growth in 3 years

- In August 2020, a total of 4,720 IO agents across six primary categories were identified, reflecting a substantial 233% surge since 2017.
- The IO drug pipeline encompasses six therapy types: CD3-targeted bispecific antibody, oncolytic virus, cancer vaccine, cell therapy, T-cell targeted immunomodulators, and other immunomodulators.
- Notably, the emergence of novel cell therapies, cancer vaccines, and various immunomodulators has generated promising indicators of innovation.
- These advancements hold the potential to bring about more successful treatments, leading to improved outcomes for a broader range of patients.

II. Clinical Unmet Needs

The key clinical unmet needs in IO include reducing and managing treatment toxicity effectively for enhanced long-term quality of life and the development of more reliable predictive biomarkers.

Toxicity-related Needs

Reducing toxicity as well as managing toxicity more effectively to promote long-term quality of life:

- Physicians have identified unmet needs regarding treatment toxicity, aiming to reduce adverse effects of IO therapies, particularly cytokine release syndrome and neurological issues.
- They seek enhanced strategies to manage IO-related toxicities and improve patients' quality of life.
- Progress has been achieved in handling short-term effects such as the cytokine release syndrome.
- Many companies are developing new, less toxic agents, including outpatient-friendly cell therapies, to address these concerns.

Personalized Care-related Needs

Need for better predictive biomarkers:

- Given the costs and potential toxicities of IO treatments, identifying patients likely to benefit is crucial.
- Using predictive biomarkers to target responsive patients has gained attention.
- Dissatisfaction over missing biomarkers in recent IO trials has been noted among physicians and payers.
- Advancing immune biology understanding gives rise to optimism, with expectations that companies would improve biomarker integration in IO trials, thus refining patient selection and treatment outcomes.

CURRENT COMMERCIAL UNMET NEEDS

The continued high prices for IO agents, despite market entrants, raises concerns about their future viability in most markets. Addressing logistics challenges is also crucial.

Rising Cost-related Needs

Reducing cost of therapy to facilitate access in more markets and patient scenarios

- The rising cost of IO therapies stems from significant research and development expenses, complex manufacturing processes, personalized medicine approaches, limited patient populations, insufficient competition, intellectual property protection, and supply chain challenges.
- Addressing these issues requires a comprehensive strategy involving regulatory reforms, increased competition, value-based pricing, international collaboration, government negotiations, and patient assistance programs.

Logistics-related Needs

Improving or overcoming logistics issues pertaining to more than one class of IO

- Logistics challenges in IO drugs, spanning various classes, include issues such as specialized handling and transportation requirements, complex global supply chains, personalized medicine complexities, global distribution obstacles, management of clinical trial logistics, short shelf-life concerns, ensuring patient access, collaborative research logistics, implementing risk mitigation strategies, and adhering to diverse regulatory standards.
- Addressing these challenges demands a coordinated effort involving pharmaceutical companies, logistics providers, regulatory bodies, and international organizations to establish standardized procedures and enhance infrastructure for efficient and secure global distribution of IO drugs.

Right from understanding key issues to advising you through the right set of insights and recommendations, Aranca provides research, consolidation, and insightful analysis to aid in-depth understanding of therapy and effective decision-making.

HOW CAN ARANCA HELP?

01 **Epidemiological Analysis:** Prevalence and diagnosis of diseases based on geography, gender, race, and ethnicity etc.

02 **Diagnosis and Treatment Paradigm:** Analysis of diagnosis and treatment algorithm adopted in clinical practice

03 **Current and Future Landscape:** Current treatments and latest pipeline landscape assessment for a particular therapy area

04 **Humanistic, Economic Burden, and Unmet Need Analysis:** Impact of a disease on patients' mental and economic well-being

05 **Health Technology Assessment:** Analysis of various HTA decisions published by different countries

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