Biotechnology Innovation Organization

Update on New Vaccines and Immunizations in the Pipeline

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Pipeline Analysis – Sources and Process

- BIO uses a public database called BioMedTracker – detailed global information on all bio-pharmaceuticals in development or submitted for regulatory approval
- Supplemented with analysis of company websites and ClinicalTrials.gov
- Look at:
  - Vaccines under FDA review or in Phase II or III in their clinical trails
  - Monoclonal antibody products being researched primarily for preventive use (may include post-exposure prophylaxis)

Vaccines

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Since our last Pipeline Review…

- Multiple new vaccines have been approved or filed with the FDA:
  - Three RSV vaccines for adults and pregnant persons
  - One RSV monoclonal antibody for infants
  - Two Meningococcal ABCWY vaccines for adolescents (one approved, one pending approval)
  - One 21-valent Pneumococcal vaccine for adults
  - One Chikungunya vaccine
  - Updated Covid-19 vaccines across multiple platforms

Seasonal respiratory pipeline is expanding to new ages, new combinations and next generation technologies

Disease	Phase I & II	Phase III	
SARS CoV-2	7	6	Next generation vaccines Multiple vaccines using other platform technologies; partnership between US and Indian company
RSV	3	1	Multiple types of vaccines in development for adults and infants, including next generation mRNA and live attenuated vaccines
Seasonal Influenza	8	3	New mRNA and protein-based vaccines; updated, adjuvanted vaccines; new technologies for universal seasonal flu vaccines
Covid + Flu	2	2	Novel combinations across the life course
Covid + RSV	2		Novel combinations across multiple vaccine types
Flu + RSV	2		Novel combinations across multiple vaccine types
Covid + Flu + RSV	1		Novel combination across multiple vaccine types

Vaccines in Late-Stage (Phase III) Development or BLA filed

Disease	Number of Products	Phase III or FDA Review
Chikungunya	2	Updated vaccines and new platform (VLP)
Clostridium difficile	1	Updated formulation
Cytomegalovirus (CMV)	1	mRNA based vaccine for healthy young adult women 16-40 to prevent disease in the mother and newborn
Dengue	1	
Escherichia Coli	1	
Ebola / Marburg	1	Outbreak response in Africa and protection from known bio-threat for the military
Lyme	1	Protein subunit vaccine partnership between 2 companies
Norovirus	1	
Rabies	1	

Vaccines in Phase II Development – Part 1

Disease	Number of Products	Phase III or FDA Review
Pneumococcal	4	New mechanisms for developing higher valency vaccines (24-31 strains) for pediatric and adult populations
Malaria	3	New approaches leveraging mosquitos for malaria vaccines; adjuvanted version of existing vaccine
Group B Streptococcus (GBS)	1	Vaccine focused or pregnant persons for maternal immunization
Cytomegalovirus (CMV)	2	Vaccine focused on healthy young women
Pertussis	1	Live, attenuated nasal vaccine
Varicella	2	Live attenuated with updated strains; mRNA platform
Zoster	1	New mRNA vaccine for older adults
Chikungunya	1	Recombinant vaccine
Norovirus	3	Multiple technologies including mRNA, and bivalent oral tablet

Vaccines in Phase II Development – Part 2

Disease	Number of Products	Phase III or FDA Review
HIV	1	Adenovirus platform
Shigella	2	
Salmonella	2	
MMR+ Varicella	1	Updated live attenuated combination
Mening ABCWY	2	Next generation
Dengue	1	Next generation
Lyme	2	Several technologies including mRNA
Yellow Fever	1	Novel vero cell vaccine
Zika	2	Several technologies including mRNA

Trends is Earlier Stage R&D

- There are over 90 new strategies for COVID-19 vaccines in development around the world
- Many companies are investing in next generation mRNA technologies for more than Covid-19 vaccines
- Companies are working on vaccines for:
  - New approaches to Mpox vaccines
  - HPV, Herpes Simplex, pediatric combination vaccines
  - Hospital-acquired bacterial infections
  - STI vaccines like Gonorrhea
  - New approaches to universal influenza vaccination
  - New vaccines to combat emerging infectious diseases (Nipah, Lassa)

Monoclonal Antibodies

Monoclonal Antibodies in Development – Trends

- Increasing research of this new preventive / treatment modality is leading to a deep pipeline of possible products
- Many may be indicated for both prevention of severe disease in specific populations as well as treatment of early-stage disease
- The following therapeutic areas have mAbs on interest in development:
  - RSV
  - COVID
  - Influenza
  - HIV (Prep and prevention of severe disease)
  - Hospital-acquired infections for those at risk
  - Treatment and prevention of Sepsis

Questions