At present, Dr. Rahul G. Ingle working on the promising area of biopharmaceuticals (e.g., monoclonal antibodies, nucleic acids, mRNA, gene therapy, fused proteins, etc.). Dr. Rahul Ingle's contribution to the field is attached in the best publication section.

Global significance of biopharmaceutical formulations are depicted below.

It is the need of hour to highlight the manufacturing, post-manufacturing, shipping, long-term storage (stability), and drug delivery challenges of biopharmaceuticals.

Recently, numerous monoclonal antibodies (mAbs) (e.g., abciximab, adalimumab, anifrolumab, bevacizumab, rituximab, pertuzumab, tezepelumab, etc.), therapeutic nucleic acids (e.g., lumasiran, inclisiran, mipomersen, pegaptanib, eteplirsen, nusinersen, patisiran, etc., RNA, and DNA vaccines), gene therapies (e.g., alipogene tiparvovec, onasemnogene abeparvovec-xioi, etc.) have approved by **United States-Food and Drug Administration (US-FDA)** and **European Medicines Agency (EMA)**. Currently, many entered the clinical stages amongst them **mAbs** and **mRNA** becomes a therapeutic target of interest in many severe disorders (i.e., cancer, multiple sclerosis, chronic kidney diseases, severe pancreatitis, retinal dystrophy, spinal muscular atrophy, polyneuropathy, etc). Lately, **US-FDA** approved outstanding biopharmaceutical **mRNA vaccine** candidates' tozinameran (BNT162b2, **Pfizer/BioNTech**) and elasomeran (mRNA-1273, **Moderna**) along with few **mAbs** (e.g., regdanvimab, sotrovimab, tocilizumab, bamlanivimab, etesevimab, and cocktail of casirivimab with imdevimab) under the **Emergency Use Authorization (EUA)** for the control of global pandemic **COVID-19**. In addition, **Indian-based Gennova biopharmaceuticals** have received approval to carry a phase-2 clinical trial for mRNA (HGCO19) vaccine to prevent COVID-19. mRNA vaccine is available in **freeze-dried (lyophilized)** powder form. The global sales for mRNA-based vaccines are at top USD12 billion in 2022 and expected to grow at 9.6% to reach USD27.7 billion by 2032 alone.

Auspiciously, on dated December 8, 2021, for immediate basis **US-FDA** issued **EUA** for **AstraZeneca**'s first long-acting mAbs combo of tixagevimab with cilgavimab to treat COVID-19. Lately, on dated October 13, 2021, **Sorrento** received **US-FDA** clearance to proceed with a clinical trial for anti-TROP-2 ADC for multiple solid tumors, and on October 11, 2021, **Roche** has received gantenerumab approval for Alzheimer's. In addition, a broadly neutralizing mAb PGT121 clears the phase-1 clinical trial against HIV-1 (*Nature Medicine*). On dated September 24, 2021, **World Health Organization (WHO)** added a new recommendation for the COVID-19 mAbs combo whereas; on September 21, 2021, the

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European Commission had signed a contract with global giant **Eli Lilly group** for mAbs supply to treat COVID-19 (*Press release*). In addition, dated September 2021, **US-FDA** approved ranibizumab as the first mAb in ophthalmology as well as **Hetero's** generic version of tocilizumab to treat COVID-19 and **AstraZeneca's** selumetinib for neurofibromatosis received a green signal from the **Drugs Controller General of India (DCGI). In India,** on dated June 04, 2021, the **Zydus group** gets **DCGI** permission to undertake clinical trials for the mAbs cocktail (i.e., ZRC-3308).

The global business line dated May 23, 2021, reported that the pandemic thrust **India** onto the launch pad for a global leader in **mAbs manufacturing** because mAbs are going to be a **game-changer** in many severe, communicable, and infectious diseases (e.g., HIV, Zika, Nipah, Ebola outbreak) in near future. **WHO** is already progressing on strategies to strengthen global defense against hidden future pandemics.

In India, the **National Biopharma Mission (NBM)** was launched in 2017 under the direction of the **Biotechnology Industry Research Assistance Council (BIRAC)** which is established under the supervision of the **Department of Biotechnology (DBT)**. This mission has been designed to give a boost to the '**Make in India**' and '**Start-Up India**' schemes launched by the **Government of India**. This mission was a necessity to achieve a target of $ 100 billion Biotech industry in India by 2025. On dated March 23, 2021, DBT has initiated the "**Industry-Academia Collaborative Mission for Acceleration Discovery Research to Early Development for Biopharmaceuticals**" under the supervision of **NBM** (*Press release*).

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