Table 40: Status of Biotherapeutic Therapies for COVID-19

Facilitators –
Tura Camilli, Amgen Inc.
Sameer Parbatani, Merck & Co., Inc.
Daniel Peng, Merck & Co., Inc.

Scope:
The SARS-Cov2 pandemic has brought the need for therapies to be developed at unprecedented speed, challenging both Industry and regulators to partner in developing strategies to address these new challenges.

Points of discussions will include an assessment of the therapeutic SARS-Cov2 landscape, a discussion of the technical, operational, and regulatory hurdles in development of these therapies, and a conversation around the needs and challenges ahead.

Questions for Discussions:
1. What do companies and regulators perceive as the greatest technical hurdles to rapid development?
2. What have been strategies to mitigate impact to existing manufacturing network operations and ensure continued supply?
3. What are some of the challenges associated with Global submissions?
4. What are some lessons learned from the development of these therapeutics to other emerging infectious viral diseases?
5. As the pandemic evolves, what are the foreseen needs and challenges ahead?
Discussion Notes:

February 1 –

1. One participant shared the FDA website for Coronavirus Treatment Acceleration Program (CTAP), which has lots of useful information and dashboard to see the holistic development program.

2. Discussed ongoing treatment being studied: anti-virus, Cell and Gene Therapies, Immunomodulators, plasm-based therapies, Fusion protein, Neutralizing antibodies, etc..

3. Discussed the challenges regarding short timeline, and limited resources for these urgent unmet medicine development