COVID-19 Press Briefing

October 6, 2021
TOTAL Cases Reported Since 1/22/20
43,773,573

NEW Cases Reported to CDC on 10/4/21
71,127

Change in 7-Day Case Average
-12.5%

Current 7-Day Case Average (9/28/21 - 10/4/21)
97,910

Prior 7-Day Case Average (9/21/21 - 9/27/21)
111,852
New Admissions of Patients with Confirmed COVID-19, US
August 1, 2020 – October 03, 2021

Patients Currently Hospitalized with COVID on 10/3/21
60,065

New Admissions on 10/3/21
6,160

Peak in New Admissions (1/5/21)
17,958

Change in 7-Day Average of New Admissions
-14.6%

Current 7-Day Average of New Admissions (9/27/21 - 10/3/21)
7,464

Prior 7-Day Average of New Admissions (9/20/21 - 9/26/21)
8,739
TOTAL Deaths Reported Since 1/22/2020
702,360

NEW Deaths Reported to CDC on 10/4/21
1,032

Change in 7-Day Death Average
-3.2%

Current 7-Day Death Average (9/28/21 - 10/4/21)
1,444

Prior 7-Day Death Average (9/21/21 - 9/27/21)
1,492

Forecasted Total Deaths by 10/23/21
724,000 to 753,000
Selected COVID-19 Therapeutics

Targeting the virus
- Remdesivir – FDA approved
- Other antivirals – clinical trials
- Anti-SARS-CoV-2 monoclonal antibodies – EUA
  - Regeneron (casirivimab + imdevimab)
  - Eli Lilly (bamlanivimab + etesevimab)
  - GSK & Vir (sotrovimab)

Moderating host responses
- Dexamethasone – recommended for hospitalized patients on oxygen
- Tocilizumab (EUA) or Baricitinib (EUA) – recommended for certain patients on dexamethasone
- Other immunomodulators – clinical trials
Targeted design of direct-acting, orally available antiviral drugs remains a very high priority in the COVID-19 therapeutics research response. The spectacular successes of this approach in the development of combinations of antiretroviral drugs for HIV and the development of curative therapies for hepatitis C serve as a model.
FOR IMMEDIATE RELEASE
June 17, 2021

Biden Administration to Invest $3.2 Billion from American Rescue Plan as Part of COVID-19 Antiviral Development Strategy

The **Antiviral Program for Pandemics (APP)** aims to catalyze the development of new medicines to combat COVID-19 and prepare for other pandemic threats.
SARS-CoV-2 Replication Cycle: Targets for Antiviral Therapeutics

**Preclinical, Phase 1, Phase 2/3**
- Spike protein
- RNA
- SARS-CoV-2
- Entry Inhibitors
- ACE2
- TMPRSS2
- Viral entry
- Viral RNA
- Viral protease
- Polypeptide chains
- Uncoating/virion RNA translation
- Endoplasmic reticulum
- Golgi apparatus
- Replication-transcription complex
- Translation & RNA replication
- Packaging & lysosomal trafficking
- Virus release

**Protease Inhibitors**

**Polymerase Inhibitors**

**Preclinical, Phase 2, Phase 3**
APP Will Utilize a Two-Pronged Approach for New Medicines Against Viruses of Pandemic Potential

**Development**
- Accelerate clinical testing of promising antiviral medicines

**Discovery**
- Expand basic science knowledge and discover new antiviral medicines
Examples of Direct-Acting Antiviral Agents for SARS-CoV-2 Already in Development

- **Protease inhibitors** – several in development, e.g.
  - PF-07321332 (Pfizer) in clinical trials

- **Polymerase inhibitors** – several approved or in development, e.g.
  - Remdesivir (Gilead) – FDA-approved
  - Molnupiravir (MK-4482 -- Ridgeback/Merck) in clinical trial for post-exposure prophylaxis, EUA filing is imminent for treatment
  - AT-527 (Atea/Roche) in clinical trials
Molnupiravir: Clinical Data Announced Oct. 1, 2021 by Merck and Ridgeback

- Placebo-controlled trial of ~1500 people; DSMB stopped study early at first analysis of 775 people

- End point: prevention of hospitalization or death

- 7% hospitalization in treatment arm and 14% hospitalization or death in placebo arm → 50% decrease

- Placebo – 8 deaths; treatment – 0 deaths
Biden Administration Announces U.S. Government Procurement of Merck’s Investigational Antiviral Medicine for COVID-19 Treatment

$1.2 billion purchase agreement for 1.7 million 5-day treatment courses of molnupiravir from Merck, pending emergency use authorization (EUA) or approval from the U.S. Food and Drug Administration (FDA).
Molnupiravir Development: A Cross-Sector Collaboration

- Basic research and product development funded by NIAID and Defense Threat Reduction Agency (DTRA) at Emory University, Georgia State, University of Alabama at Birmingham, University of North Carolina, Vanderbilt University

- Drug developed by Drug Innovation Ventures at Emory (DRIVE), a not-for-profit biotechnology company

- DRIVE licensed drug to Ridgeback Biotherapeutics, who partnered with Merck
Another Tool in the Anti-COVID Toolbox

- Molnupiravir: A promising oral drug that people could take at home soon after COVID-19 diagnosis to reduce the risk of severe outcomes

- Vaccines: remain our best tools against COVID-19 – they can prevent you from getting COVID-19 in the first place