Heading home – will be in Miami Friday after stop in San Juan yesterday.

This will be last update until next week (I hope).

FDA Advisers Narrowly Recommend Authorization of Molnupiravir to Treat COVID-19
A divided FDA advisory panel voted 13-10 to recommend the oral antiviral molnupiravir for emergency use authorization (EUA) for adults at high risk of progressing to severe COVID-19 on Tuesday.

While votes at the Antimicrobial Drugs Advisory Committee (AMDAC) were largely split, similar questions were raised on both sides of the vote about modest efficacy, especially in light of other available treatments. Very few committee members offered strong "yes" or "no" votes, as most were in the middle. Ultimately, the positive votes felt that despite several questions, the benefits of the drug outweighed the risk.

Of particular concern to the "no" voters was not only that efficacy against hospitalization and death declined from the interim analysis submitted to the FDA (48% relative risk reduction) to the final analysis (30% reduction), but that when examining only the data from the post-interim analysis enrollment, there were fewer placebo patients who were hospitalized or died by day 29 versus patients receiving the intervention (4.7% vs 6.2%, respectively).

Interestingly, even those who voted yes argued that it may only be temporary, given other similar drugs in the pipeline that may have better safety and efficacy profiles. Safety was of chief concern among many committee members. While the committee did not vote on the subject, they discussed how the drug should be handled among pregnant women, given that data from preclinical studies appeared to show embryo-fetal toxicity.

Comment: Once other more potent oral drugs become available, like the Pfizer combination, I do not think this drug will be used. It will be interesting to see what the full FDA decides given efficacy was lowered to 30% and the potential of fetal toxicity.

CDC Says All Adults Should Receive a Booster due to the Emergence of Omicron Variant
The CDC has strengthened its recommendation for Covid-19 booster shots saying all adults who are eligible should receive a booster dose. This means anyone who is aged 18 years or older should get a booster either 6 months after receiving the initial two-dose Pfizer or Moderna or 2 months after J&J.

Comment: Makes sense given current level understanding given the limited information we have on Omicron. I think we will know a lot more in the coming weeks. I personally am still more worried about delta.