Evaluate Vantage

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# Merck’s Covid-19 push narrows further

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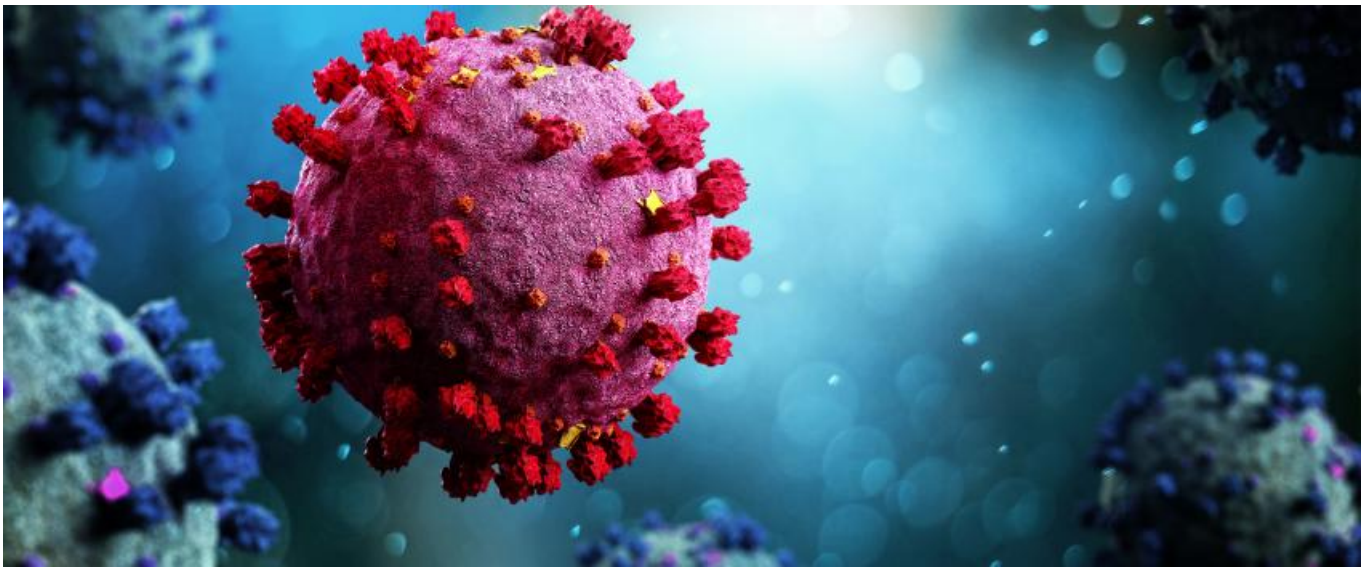

## Merck & Co gives up on MK-7110, and on molnupiravir in hospitalised patients.

Merck & Co had already bowed out of the Covid-19 vaccine arena. Now its efforts at developing a therapy for the virus have taken a step back too.

The company said today that it was discontinuing development of MK-7110, which it gained through its $425m buyout of Oncoimmune, in hospitalised Covid-19 patients. As for its second big hope, the oral antiviral molnupiravir, Merck has scrapped a trial in hospitalised patients; all expectations for the project now rest on a pivotal study in outpatients.

The antiviral pipeline for treating Covid-19 thus now looks even sparser. And the developments are yet another example of how several big names in the vaccine and antiviral space have stumbled, while newcomers have capitalised on opportunities arising from the pandemic.

**Oncoimmune move**

The discontinuation of MK-7110, a recombinant fusion protein previously known as CD24Fc, also raises questions about Merck’s decision to shell out for Oncoimmune in November.

The move had been based on encouraging data from an interim analysis of a phase 3 trial in hospitalised Covid-19 patients; Merck had clearly hoped that this study would be enough for emergency use authorisation. But in February it said the FDA wanted more data.

Given the new clinical trials that would be needed, plus work on manufacturing, Merck noted today that even if things went well MK-7110 would not be available until the first half of 2022. Among other reasons for scrapping MK-7110, the company cited “the availability of a number of medicines for patients hospitalised with Covid-19” by this time. And perhaps the pandemic will be all but over by then.

MK-7110 is also in development for other indications, the most advanced being graft-versus-host disease, so maybe Merck can still recoup some of the cash it has spent.

**Molnupiravir hopes**

In any case, Merck’s only Covid-19 hope is now molnupiravir, which is being developed in collaboration with Ridgeback Biotherapeutics.

And this project’s only shot is in outpatients. Merck today said it had decided to discontinue the phase 2/3

Move-In study in hospitalised patients, after the phase 2 portion had shown that molnupiravir was unlikely to show a benefit.

Maybe this is not surprising: many other agents have struggled to make an impact in this population, and it seems that most therapies need to be given early in the course of disease to have a chance of having an effect.

If antivirals are broadly ineffective in hospitalised Covid-19 patients this could be bad news for the likes of Roche and Pfizer, which both have inpatient trials of their agents ongoing.

Results released by Merck today from the phase 2 portion of the Move-Out outpatient study do appear to suggest that earlier is better. Merck revealed no data, but claimed that molnupiravir's effects were most pronounced in patients who had had symptoms for five days or less.

The company is therefore amending the phase 3 part of Move-Out to focus on this population, and plans to start enrolling into it by late April or early May, with final data due in September/October.

Mizuho analysts still believe that an oral drug that could meaningfully alter the course of mild disease could be a game changer but, with an EUA slated for the second half of this year at the earliest, the group could be running out of time to make an impact in Covid-19.

| Antivirals in development for Covid-19 | | | |
|---|---|---|---|
| **Project** | **Company** | **Setting** | **Note** |
| Veklury (IV) | Gilead | FDA-approved in Covid-19 patients requiring hospitalisation; Gilead discontinued ph3 study in high-risk outpatients (NCT04501952) on 12 Apr | Repurposed Ebola research project |
| NT-300 | Romark | Failed ph3 study on April 14; company to file for EUA based on 85% reduction in progression to severe illness | Reformulation of nitazoxanide |
| Molnupiravir (oral) | Merck & Co/Ridgeback | Ph3 in outpatients (Move-Out, NCT04575597); Merck discontinued ph2/3 trial in hospitalised pts (Move-In; NCT04575584) on 15 Apr | Repurposed flu antiviral |
| AT-527 (oral) | Roche/Atea | Ph2 in hospitalised pts (NCT04396106); ph2 in outpatients (NCT04709835); ph3 planned in outpatients | Repurposed hep C antiviral |
| Ensovibep (IV) | Novartis/Molecular Partners | Ph2 in symptomatic pts (NCT04834856); ph2/3 in ambulatory pts (Empathy, NCT04828161) starting imminently; ph3 in hospitalised pts (Activ-3, NIH-sponsored) planned | Designed for Sars-Cov-2 |
| PF-07304814 (IV) | Pfizer | Ph1 in hospitalised pts (NCT04535167, excludes severely ill or with certain pre-existing conditions) | Repurposed Sars research project |
| MP0423 (IV) | Novartis/Molecular Partners | Preclinical | Designed for Sars-Cov-2; could be better against variants than ensovibep thanks to different targeting mechanisms |
| *Source: Evaluate Pharma & clinicaltrials.gov.* | | | |

*The table in this story has been updated to include Romark's NT-300.*

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