In a placebo-controlled phase 1 trial in 38 healthy volunteers, SAB-301 demonstrated a placebo-like safety profile and, importantly, those who received the cocktail did not develop an antibody response against any of its components, Sullivan says. The final antibody preparation is highly purified to minimize the presence of any bovine material. When fully up and running, the production process is highly efficient. “We’re hyperimmunizing the animals so we develop very high antibody titers to the virus,” says Sullivan. Fully grown animals — which are all clones of the same genotype — produce up to 45 liters per month and antibody yields of up to 25 grams per liter. “This is a system that is very scalable,” Sullivan says. SAB is producing “a few hundred” animals this year. Once they have grown sufficiently, it will be able to start scaling SAB-185 production, assuming it proves to be safe and effective. SAB expects to start trials by early summer.

GigaGen, which is backed by Grifols, is a more recent arrival, and its cell-based recombinant polyclonal immunoglobulin production system is at an earlier stage of development. It involves capturing on a

microfluidics platform the complete B-cell populations of five to ten people who have recovered COVID-19 and mounted a robust immune response to the virus. The associated antibody-encoding genes are then transferred into a mammalian cell line. The resulting polyclonal pool of antibody-producing cells is grown en masse, giving rise to a highly diverse and potent product containing many thousands of polyclonal immunoglobulins. “We’re recreating their entire repertoire,” says GigaGen CEO and cofounder David Johnson. “We don’t make any bet about what the best epitope is — or the best mechanism of action,” he says. “It’s really difficult to know what are the particular factors that led to somebody’s recovery.”

The COVID-19 pandemic has accelerated GigaGen plans to move into clinical trials, but it needs to start producing batches under good manufacturing practice (GMP) conditions before it can file an Investigational New Drug application. “Our biggest bottleneck is finding a manufacturing site,” says Johnson. It hopes to secure a slot during the summer and aims to reach the clinic late this year or early next.

For the vast majority of the many thousands of people who have already died from COVID-19 or have endured severe illness that will have long-term consequences, all of these interventions come too late. There is an inevitable lag between the onset of a pandemic and the ability of the clinical community and pharmaceutical and biotech companies to respond. But the global effort to push back SARS-CoV-2 will need to continue for some time to come.

“People need to recognize when the first wave is done, we’ve probably gotten to only about half of the deaths,” Joyner says. Doctors treating patients have little choice but to use the best interventions available at a given time. “In these sort of situations, the enemy of good is better,” he says. But as we move further into the pandemic, the evidence base supporting the clinical utility of those interventions will steadily improve — and so too, one hopes, will the outcomes. □

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Around the world in a month

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