## <u>United Kingdom Becomes First Country to Approve COVID-19 Vaccine</u>

On December 3<sup>rd</sup>, 2020, the United Kingdom (UK) became the first western country to approve a COVID-19 vaccine. The Pfizer and BioNTech vaccine received approval just 23 days after Phase-III trial results were reported.<sup>1,2</sup> Russia and China had earlier granted approval for a COVID-19 vaccine. Of note, Russia and china have not sought authorization from European Medicine Agency (EMA) for their COVID-19 vaccines.<sup>3</sup> Distribution of the vaccine across the UK is planned to start in as little as one week. Initially, they will receive around 800,000 vaccines to cover health care workers, nursing home staff and residents, and people over age 80. The UK has ordered enough vaccines to vaccinate approximately a third of their population (~40 million doses).<sup>1,2</sup>

As expected, there would be some challenges with rolling out this new vaccine, but the authorities in the UK seem to have a plan. There will be 50 hospital hubs all over the country that will begin offering the vaccine, from 8 a.m. to 8 p.m., seven days a week. Eventually, doctors' offices and pharmacists will be able to operate nearly 1,000 vaccine centers across the UK to vaccinate vulnerable patients. Next, they will filter their way down to the general public by age.<sup>1,2,4</sup>

This news puts even more pressure on the United States (US), although FDA regulators say that more time is needed to make the right decision.<sup>2,4</sup> The FDA and EMA are set to meet this month. The EMA says it could give emergency approval for the vaccine by the end of December. On December 10<sup>th</sup>, the FDA will discuss the emergency use authorization of the vaccine.<sup>1,2</sup>

With the UK taking the leap to vaccinate in this pandemic, there is the expectation that the US would not be left far behind. Pfizer has been providing data to the UK on a rolling basis so that regulators can review it in real time. This method allows for a speedy assessment, allowing them to review data until there is enough evidence supporting a formal authorization. Dr. Anthony Fauci criticized the UK for approving Pfizer's vaccine, stating that the FDA has the gold standard approach for drug approvals. The FDA will examine the data submitted detail by detail, reviewing all safety information thoroughly. Drugmakers and states are getting ready to distribute an approved vaccine as early as mid-December.<sup>5</sup>

## References:

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