How Pfizer Is Preparing Manufacturing for the Next Phase in Fighting Against COVID-19: Oral Treatment Candidate

Pfizer has invested approximately $1 billion at risk in the manufacturing of its potential COVID-19 oral treatment candidate with the goal of making treatment courses available as quickly as possible, pending approval or authorization. Pfizer currently anticipates producing more than 180,000 patient packs by the end of 2021, with up to 120 million packs by the end of 2022.

To achieve this, Pfizer is leveraging four of its key manufacturing locations in Europe and its extensive supplier network to meet the demand for its COVID-19 oral treatment candidate, if approved or authorized.

Freiburg, Germany, Newbridge, Ireland & Ascoli, Italy
Drug Product Manufacturing Tableting and Packaging

Pfizer selected these sites for their technical knowledge and specialized high-volume manufacturing equipment. They will be the primary manufacturing sites for the COVID-19 oral treatment candidate. Upon receipt and approval of the API, Freiburg, Newbridge and Ascoli will begin the production process by mixing, granulating, compressing and coating the tablets, optimizing the entire manufacturing process for the fastest and safest delivery of this treatment. Tablets will then quickly progress to packaging on site to meet the high demands for this critical treatment. Their team of quality experts ensure quality standards are adhered to during all stages of manufacturing and packaging of the product.

If approved or authorized, these facilities have specialized high complexity packaging lines to package this treatment on a large scale, aiming to prepare millions of packs in the first half of 2022, subject to regulatory authorization.

Ringaskiddy, Ireland
Active Pharmaceutical Ingredient (API) Manufacturer

The Ringaskiddy site will manufacture the active pharmaceutical ingredient (API) for the investigational COVID-19 oral treatment candidate. The site has been involved in the extensive research and development process since work first began on the oral treatment candidate, including co-developing the API manufacturing process and scaling manufacturing. In addition, Ringaskiddy is the default API manufacturing site for all new small molecule product launches at Pfizer. As a result, it has extensive experience in helping to ensure rapid planning and processing of new API without compromising its high-quality standards. Once the API is manufactured, and quality tested, it is shipped to the primary production site for tabletting and packaging.

Tackling the pandemic on all fronts – meeting the need for a COVID-19 treatment

Since the start of the pandemic, Pfizer has committed to delivering both treatments and preventative solutions to address COVID-19.

Pfizer believes its COVID-19 oral treatment candidate, if approved or authorized, in addition to our entire EPIC/clinical program, could significantly change the COVID-19 treatment paradigm by potentially reducing illness severity, hospitalization rates and deaths among a broad population of patients.

At Pfizer, we are applying our deep heritage in developing breakthrough therapies and the success from developing and scaling up our manufacturing for the Pfizer-BioNTech COVID-19 vaccine to respond to this global pandemic.

Emergency Use Authorization Statement

PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS CoV-2 viral testing, and who are at high-risk for progression to severe COVID-19, including hospitalization or death.

The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564b(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

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