PULSE

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Pharmacy Benefit Dimensions®

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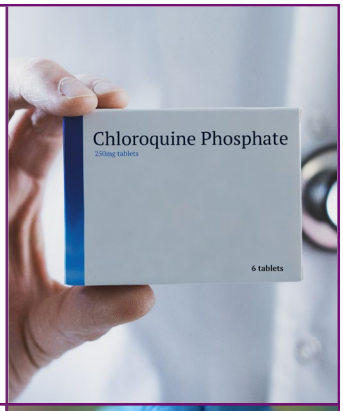
Clinical Updates

Coronavirus (COVID-19) Update: FDA Continues Facilitation of Treatment Development

On March 19, 2020 the U.S. Food and Drug Administration (FDA) published a news release updating the public on their continued efforts to facilitate the advancement of therapies to treat and prevent coronavirus (COVID-19). The update outlines the FDA's ongoing collaboration with government agencies and academic centers to explore several therapies as potential treatments, including chloroquine, remdesivir, sarilumab, as well as various blood products and vaccines. In addition to exploring existing medications for use in COVID-19, the FDA aims to reassure the public that they are working closely with scientific innovators to expedite new treatment developments, leveraging available scientific information about the virus through trials currently underway in other countries such as China, Japan, South Korea and Italy. The update also reiterates that the FDA is diligently monitoring the market to combat false claims surrounding products that are not approved for preventing, treating or diagnosing COVID-19.



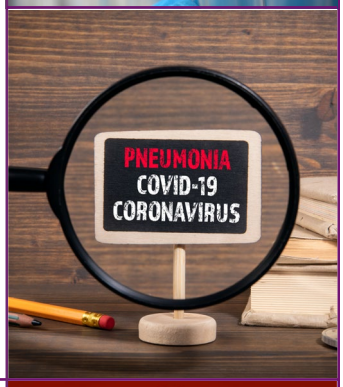
From the Industry

Abbott Laboratories to ship portable, 5-minute coronavirus tests nationwide

On March 27, 2020, Abbott Laboratories announced the FDA issued Emergency Use Authorization (EUA) for the fastest available molecular point-of-care test to detect coronavirus (COVID-19). The test can deliver positive results in as little as 5 minutes and negative results in 13 minutes. The test will run on Abbott's ID NOW platform, a tabletop portable box the size of a small toaster. ID NOW is the most widely used molecular point-of-care testing diagnostic in the U.S., currently used to deliver quick and accurate results for other tests such as strep throat and influenza. Abbott Laboratories plans to deliver 50,000 tests per day starting this week and is working with federal government officials to determine what areas the tests should be sent so they can have the greatest impact.

Clinical trial to evaluate Actemra® in patients with severe COVID-19 pneumonia

On March 19, 2020, Roche announced that they are working with the FDA and the United States Health and Human Services Office of the Assistant Secretary for Preparedness and Response (ASPR) to initiate a phase III trial to evaluate Actemra® (tocilizumab) as a possible treatment option for coronavirus (COVID-19) pneumonia. Actemra® is classified as an interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody and is currently approved in the U.S. to treat several diseases, including rheumatoid arthritis (RA). The announcement has come after the release of updated treatment guidelines from Chinese health authorities, which included a recommendation for the use of Actemra in certain patients with the infection. The clinical trial will evaluate the safety and efficacy of Actemra® infusions in adult patients hospitalized with severe COVID-19 pneumonia when added to standard of care, compared to placebo plus standard of care. The study plans to evaluate clinical status, mortality, mechanical ventilation, and other intensive care unit (ICU) outcomes. The global study is expected to begin enrolling patients in early April with a target of approximately 330 patients.



Recent FDA Approvals

Novel Drug Approval: **Sarclisa® (isatuximab-irfc)**
Intravenous injection for the treatment of multiple myeloma in combination with Pomalyst® (pomalidomide) and dexamethasone in adult patients who have received at least two prior therapies [3/2/2020 – Orphan Drug – SANOFI AVENTIS US]

New Dosage Form: **Durysta™ (bimatoprost)**
Eye implant for the reduction of pressure within the eye in patients with open angle glaucoma or ocular hypertension [3/4/2020 – ALLERGAN]

Novel Drug Approval: **Isturisa® (osilodrostat)**
Oral tablet for the treatment of Cushing's disease in adult patients who are ineligible for or have not been cured by surgery [3/6/2020 – Orphan Drug – NOVARTIS PHARMS CORP]

New Generics Entering the Marketplace

Dymista® (azelastine/fluticasone)
Indication: Seasonal Allergies
Dosage Form/Strength: 137mcg/50mcg Nasal suspension
Average Wholesale Price (AWP): Generic = **$228** | Brand = **$240**

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