

Current Pharma News

1. Nasal spray, developed by Bangladesh, promises to 'kill' coronavirus

Date: January 13, 2021

Source: www.bdnews24.com

Summary: The Bangasafe Oro-Nasal Spray, developed by Bangladesh Reference Institute for Chemical Measurements or BRICM, has proven safe, effective and helpful in reducing the viral load in a small trial, according to the government institute. It reported that a trial on 200 COVID-19 patients at the Dhaka Medical College Hospital was conducted and they will do more clinical trials and get approvals from Bangladesh Medical Research Council and Health Services Division very soon.

2. Globe Biotech gets permission to manufacture Covid-19 vaccine for trial

Date: January 13, 2021

Source: www.dhakatribune.com

Summary: Directorate General of Drug Administration (DGDA) has given permission to Globe Biotech Limited to manufacture their Covid-19 vaccine, Bongavax, for clinical trial. The permission was given on December 28, 2020. Within a week, they will apply at Bangladesh Medical Research Council (BMRC) for ethical permission and hopefully by next month they can go for clinical trial. On December 1, 2020, Globe Biotech, the only Bangladeshi company that has claimed progress in developing a Covid-19 vaccine

3. COVID-19 Survival Declines When Brain Affected: Study

Date: December 28, 2020

Source: www.drugs.com

Summary: Hospitalized COVID-19 patients with brain complications such as stroke and confusion have an increased risk of death, a new study shows.

4. Loss of taste and smell may be most reliable COVID-19 symptoms for digital surveillance

Date: December 24, 2020

Source: www.news-medical.net

Summary: Caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as the coronavirus disease 2019 (COVID19) pandemic has evolved, diagnostic testing capacity expanded and guidelines also changed from testing for just fever and respiratory symptoms to testing for a wider range of symptoms. Several large scale, participatory digital surveillance platforms were also developed worldwide to complement the information obtained from laboratories and some clinical studies.

5. Mental disorders highly prevalent during coronavirus pandemics

Date: December 24, 2020

Source: www.news-medical.net

Summary: Researchers in the United States have conducted an analysis showing the high prevalence of mental disorders across populations impacted by coronavirus pandemics.

6. Researchers find correlation between consistent mask-wearing and improved well-being

Date: December 24, 2020

Source: www.news-medical.net

Summary: Since the emergence of the coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), universal masking has been implemented in many countries. Wearing face masks or coverings can help reduce the risk of being infected with SARS-CoV-2, as they prevent infectious respiratory droplets' entry. At the same time, it prevents droplets from reaching people when the infected sneeze, cough, talk, or breathe.

7. Higher BMI linked to increased risk of SARS-CoV-2 infection

Date: December 24, 2020

Source: www.news-medical.net

Summary: The coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causes severe illness

in high-risk populations. These include the elderly and those with underlying health conditions such as diabetes, hypertension, heart disease and obesity.

8. A common compound in mouthwashes found to inhibit SARS-CoV-2 *in vitro*

Date: December 24, 2020

Source: www.news-medical.net

Summary: Researchers found that cetylpyridinium chloride, found in most mouthwashes, lowers infectivity of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) *in vitro*, likely by inhibiting viral fusion with target cells. With more tests to prove validity, mouthwashes could be a simple, cheap way of curbing transmission.

9. SARS-CoV-2 infection shown to reduce the expression of vitamin D pathway components

Date: December 23, 2020

Source: www.news-medical.net

Summary: A recent computational study from India implicated a dysregulated vitamin D pathway in the pathobiology of the infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) – and opened the door for experimental validation of these observations.

10. Frequent and rapid testing may reduce SARS-CoV-2 transmission in care homes

Date: December 23, 2020

Source: www.news-medical.net

Summary: A team of scientists from the Centers for Disease Control and Prevention, United States, recently conducted a study to evaluate the effectiveness of serial testing and isolation of healthcare personnel in nursing homes in preventing the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative pathogen of coronavirus disease 2019 (COVID-19). The findings reveal that frequent implementation of rapid testing in response to an outbreak is highly effective in reducing COVID-19 spread in nursing homes.

11. SARS-CoV-2 mutations may evade T cell immunity

Date: December 23, 2020

Source: www.news-medical.net

Summary: A potentially disturbing new study published in December 2020 on the *bioRxiv** preprint server suggests that the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that is causing the current coronavirus disease 2019 (COVID-19) pandemic may be undergoing strategic mutations that affect the host immune capacity to recognize and combat the pathogen via T effector cells.

12. Cell-mediated immunity may be more important than neutralizing antibodies in COVID-19 outcome

Date: December 23, 2020

Source: www.news-medical.net

Summary: An interesting new study sheds light on some important differences between asymptomatic and symptomatic patients with coronavirus disease 2019 (COVID-19). The preprint, which appeared on the *medRxiv** preprint server in December 2020, adds important details to the study of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

13. Researchers use fruit fly model to understand COVID-19-related neurological complications

Date: December 23, 2020

Source: www.news-medical.net

Summary: An interesting preprint by researchers from Washington University School of Medicine and the National Cancer Institute, USA, claims to have reproduced disease mechanisms due to coronavirus disease 2019 (COVID-19) in the fruit fly, *Drosophila*, while also providing proof of the efficacy of one drug against these disease processes. If validated, these findings represent a new understanding of how the virus causes neurological symptoms that could help develop more effective therapies.

14. COVID-19 patients retain immunity against the virus for at least 8 months

Date: December 22, 2020

Source: www.news-medical.net

Summary: Australian researchers have revealed - for the first time - that people who have been infected with the COVID-19 virus have immune memory to protect against reinfection for at least eight months.

15. SARS-CoV-2 antibody levels and types differ by disease severity, study finds

Date: December 22, 2020

Source: www.news-medical.net

Summary: Researchers have measured the antibody levels and types in hospitalized coronavirus disease 2019 (COVID-19) patients with different disease severity. Their results suggest gut immune pathways could play a role in reducing virus-based inflammation and recovery.

16. Scientists isolate anti-COVID-19 nanobodies produced by a llama

Date: December 22, 2020

Source: www.news-medical.net

Summary: National Institutes of Health researchers have isolated a set of promising, tiny antibodies, or "nanobodies," against SARS-CoV-2 that were produced by a llama named Cormac. Preliminary results published in *Scientific Reports* suggest that at least one of these nanobodies, called NIH-CoVnb-112, could prevent infections and detect virus particles by grabbing hold of SARS-CoV-2 spike proteins. In addition, the nanobody appeared to work equally well in either liquid or aerosol form, suggesting it could remain effective after inhalation. SARS-CoV-2 is the virus that causes COVID-19.

17. What are the potential benefits of SARS-CoV-2 antigen-based rapid diagnostic tests?

Date: December 22, 2020

Source: www.news-medical.net

Summary: Accurate coronavirus disease 2019 (COVID-19) diagnosis can interrupt transmission, aid clinical management, and help proper allocation of

resources to isolation, contact tracing, and therapy. In many low- and middle-income settings with huge outbreaks, COVID-19 diagnosis efforts using highly sensitive molecular tests have exceeded laboratory capacity. Antigen-detection rapid diagnostic tests (Ag-RDTs) do not need centralized laboratory processing and can be performed in under an hour at a lower cost compared to nucleic acid amplification testing (NAAT). Thus, Ag-RDTs can facilitate higher-volume testing and offer rapid results. However, the lower sensitivity of Ag-RDT has limited their applications in the clinical setting.

18. A hand-held device that measures aerosols could help prevent spread of COVID-19

Date: December 22, 2020

Source: www.news-medical.net

Summary: Researchers have confirmed the efficacy of a portable particle detector at calculating the concentration of aerosols in public spaces. Hand-held devices may be vital in the fight against the COVID-19 pandemic, given the important role that aerosols play in the transmission of the virus.

19. Pregnant women in third trimester unlikely to pass SARS-CoV-2 infection to newborns

Date: December 22, 2020

Source: www.news-medical.net

Summary: A new study demonstrates that women in their third trimester are unlikely to pass a SARS-CoV-2 infection onto their babies. The research also shows that the rates that maternal SARS-CoV-2 antibodies are transferred via the placenta are lower than expected.

20. Researchers have a promising lead on COVID-19 treatment

Date: December 21, 2020

Source: www.news-medical.net

Summary: By taking a lesson from prostate cancer, researchers now have a promising lead on treatment for COVID-19. Two proteins, ACE2 and TMPRSS2, help the coronavirus gain entry and replicate within cells. TMPRSS2 is well-known to Arul Chinnaiyan,

M.D., Ph.D. His lab discovered that TMRSS2 fuses with the ETS gene to drive more than half of all prostate cancers. They also knew that TMRSS2 was regulated by the androgen receptor.

21. COVID-19 contact tracing ineffective without timely testing and isolation, study says

Date: December 21, 2020

Source: www.news-medical.net

Summary: A new study by Canada-based researchers has showed that contact tracing is not effective if testing and isolation are delayed.

22. Study hints that supplements may reduce COVID-19 risk in females

Date: December 11, 2020

Source: www.medicalnewstoday.com

Summary: A recent study found small but significant decreases in the risk of SARS-CoV-2 infection among females who took multivitamins, vitamin D, omega-3 fatty acids, or probiotics. The study has not yet been through the peer review process and appears on the preprint server *MedRxiv*

23. Smartphone-based device could detect SARS-CoV-2

Date: December 10, 2020

Source: www.medicalnewstoday.com

Summary: Scientists are developing a portable device that gives rapid, accurate test results with the help of a regular smartphone camera. By estimating the number of virus particles in samples, the device could also determine an infection's progress.

24. Adapted yellow fever vaccine may protect against COVID-19

Date: December 07, 2020

Source: www.medicalnewstoday.com

Summary: A recent study concludes that a genetically altered yellow fever vaccine is highly effective in preventing SARS-CoV-2 infection in animals. If it passes clinical trials, the new vaccine would have some advantages over other SARS-CoV-2 vaccines.

Information collected and compiled by:

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New Drug Approvals

1. Gemmily (ethinyl estradiol and norethindrone acetate) Capsules 0.02 mg / 1 mg

Company: Chemo Research SL

Date of Approval: November 9, 2020

Treatment for: Ethinyl estradiol and norethindrone is used as contraception to prevent pregnancy.

2. Brinzolamide Ophthalmic Suspension 1%

Company: Watson Laboratories Inc.

Date of Approval: November 27, 2020

Treatment for: Brinzolamide ophthalmic (for the eyes) is used to treat certain types of glaucoma and other causes of high pressure inside the eye.

3. Nitazoxanide Tablets 500 mg

Company: Rising Pharma Holdings Inc.

Date of Approval: November 27, 2020

Treatment for: Nitazoxanide is used to treat diarrhea caused by Giardia or Cryptosporidium.

4. Fosfomycin Tromethamine Granules for Oral Solution 3 grams (base)/single-dose sachet

Company: Xiromed Pharma España, SL

Date of Approval: October 6, 2020

Treatment for: Fosfomycin is an antibiotic that fights infection caused by bacteria. Fosfomycin is used to treat bladder infections.

5. Azelaic Acid Topical Foam 15%

Company: Teva Pharmaceuticals USA, Inc.

Date of Approval: October 7, 2020

Treatment for: Azelaic acid topical (for the skin) is used to treat acne and rosacea.

6. Tavaborole Topical Solution 5%

Company: Perrigo Pharma International DAC

Date of Approval: October 13, 2020 -

Treatment for: Tavaborole topical is used to treat a fungal infection of the toenail called onychomycosis.

7. Pomalidomide Capsules 1 mg, 2 mg, 3 mg and 4 mg

Company: Breckenridge Pharmaceutical, Inc.

Date of Approval: October 30, 2020

Treatment for: Pomalidomide is used to treat multiple myeloma (cancer resulting from a progressive blood disease). Pomalidomide is usually given after at least two other medications have been tried without success.

8. Levothyroxine Sodium Capsules 0.075 mg and 0.15 mg

Company: Teva Pharmaceuticals USA, Inc.

Date of Approval: October 28, 2020

Treatment for: Levothyroxine is used to treat hypothyroidism (low thyroid hormone). This medicine is given when your thyroid does not produce enough of this hormone on its own.

9. Lapatinib Ditosylate Tablets 250 mg (base)

Company: Natco Pharma Limited

Date of Approval: September 29, 2020 -

Treatment for: Lapatinib is used to treat advanced hormone-related breast cancer that has progressed or spread after treatment with other cancer medicines. Lapatinib is used for this condition only if your tumor tests positive for a protein called human epidermal growth factor receptor 2 (HER2). HER2 protein can speed the growth of cancer cells.

10. Ciprofloxacin and Dexamethasone Otic Suspension/Drops 0.3% / 0.1%

Company: Dr. Reddy's Laboratories Ltd.

Date of Approval: August 10, 2020

Treatment for: Ciprofloxacin is an antibiotic that treats infections caused by bacteria. Dexamethasone is a steroid. It reduces the actions of chemicals in the body that cause inflammation. Ciprofloxacin and dexamethasone otic (for the ear) is a combination medicine used to treat infections inside the ear (also

called otitis media), and infections of the ear canal (also called otitis externa).

**11. Dimethyl Fumarate Delayed Release Capsules
120 mg and 240 mg**

Company: Mylan Pharmaceuticals, Inc.

Date of Approval: August 17, 2020

Information collected and compiled by:

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Treatment for: Dimethyl fumarate is used to treat relapsing forms of multiple sclerosis in adults (including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease).

References: www.drugs.com/newdrugs

New Indications & Dosage Forms for Existing Drugs

1. Tagrisso (osimertinib) Tablets

New Indication Approved: December 20, 2020

Date of Original Approval: November 13, 2015

Tagrisso approved in the US for the adjuvant treatment of patients with early-stage EGFR-mutated non-small cell lung cancer. Previously treated EGFR T790M mutation-positive metastatic NSCLC.

2. Xpovio (selinexor) Tablets

New Indication Approved: December 18, 2020

Date of Original Approval: July 3, 2019

Karyopharm Announces FDA approval of Xpovio (selinexor) as a treatment for patients with multiple myeloma after at least one prior therapy.

3. Ocrevus (ocrelizumab) Injection

New Dosage Regimen: December 14, 2020

Date of Original Approval: March 28, 2017

FDA approves Genentech's Ocrevus (ocrelizumab) shorter 2-hour infusion for relapsing and primary progressive multiple sclerosis.

4. Saxenda (liraglutide) Injection

Patient Population Altered: December 4, 2020

Date of Original Approval: December 23, 2014

FDA approves Saxenda (liraglutide) for the treatment of obesity in adolescents aged 12-17.

5. Gavreto (pralsetinib) Capsules

New Indication Approved: December 1, 2020

Date of Original Approval: September 4, 2020

Genentech announces FDA approval of Gavreto (pralsetinib) for people with advanced or metastatic RET-mutant and RET fusion-positive thyroid cancers.

6. Xolair (omalizumab) Subcutaneous Injection

New Indication Approved: December 1, 2020

Date of Original Approval: June 20, 2003

Genentech announces FDA approval of Xolair (omalizumab) for adults with nasal polyps.

7. Hetlioz (tasimelteon) Capsules

New Indication Approved: December 1, 2020

Date of Original Approval: January 31, 2014

FDA approves Hetlioz (tasimelteon) for the treatment of nighttime sleep disturbances in smith-magenis syndrome.

8. Xofluza (baloxavirmarboxil) Tablets and Granules for Oral Suspension

New Indication Approved: November 23, 2020

Date of Original Approval: October 24, 2018

Genentech announces FDA approval of Xofluza for the prevention of influenza following contact with an infected person.

9. Imfinzi (durvalumab) Injection

New Dosage Regimen: November 18, 2020

Date of Original Approval: May 1, 2017

For the treatment of adult patients with locally advanced or metastatic urothelial carcinoma.

10. Vimpat (Lacosamide) Tablets, Injection, Oral Solution

New Indication Approved: November 16, 2020

Date of Original Approval: October 28, 2008

Vimpat (lacosamide) now approved by FDA for primary generalized tonic-clonic seizures and expanded pediatric use for people living with epilepsy.

11. Keytruda (pembrolizumab) for Injection

New Indication Approved: November 13, 2020

Date of Original Approval: September 4, 2014

FDA Approves Merck's Keytruda (pembrolizumab) in combination with chemotherapy for patients with locally recurrent unresectable or metastatic

triple-negative breast cancer whose tumors express PD-L1 (CPS \geq 10).

12. Brilinta (ticagrelor) Tablets

New Indication Approved: November 5, 2020

Date of Original Approval: July 20, 2011

Brilinta approved in the US to reduce the risk of stroke in patients with an acute ischemic stroke or high-risk transient ischemic attack.

13. Sklice (ivermectin) Lotion

Labeling Revision Approved: October 27, 2020

Date of Original Approval: February 7, 2012

FDA approves Sklice (ivermectin) lotion for nonprescription use to treat head lice.

14. Venclexta (venetoclax) Tablets

New Indication Approved: October 16, 2020

Date of Original Approval: April 11, 2016

Venclexta (venetoclax) is an oral B-cell lymphoma-2 (BCL-2) inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

15. Keytruda (pembrolizumab) for Injection

Labeling Revision Approved: October 14, 2020

Date of Original Approval: September 4, 2014

Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal

cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.

16. Wakix (pitolisant) Tablets

New Indication Approved: October 13, 2020

Date of Original Approval: August 14, 2019

Wakix (pitolisant) is a histamine-3 (H₃) receptor antagonist/inverse agonist for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.

17. Ultomiris (ravulizumab-cwvz) Injection

New Formulation Approved: October 9, 2020

Date of Original Approval: December 21, 2018

Ultomiris (ravulizumab-cwvz) is a long-acting C5 complement inhibitor for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

18. Opdivo (nivolumab) Injection

New Indication Approved: October 2, 2020

Date of Original Approval: December 22, 2014

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of melanoma, non-small cell lung cancer, small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma.

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Source: www.drugs.com/new-indications