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 TMPRSS2 fuses with the ETS gene to drive more than half of all prostate cancers. They also knew that TMPRSS2 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.

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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. FosfomycinTromethamine 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

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).

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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 (baloxavir marboxil) 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) 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
New Drug Approvals

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

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

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Source: www.drugs.com/new-indications