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(PHARMACY INSTITUTE)

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PRESENTS

PHARMAINNOVATIONS

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CONTENTS

Messages from the desk of the Editor

It gives us immense joy and satisfaction to introduce the First issue of 2024 of the magazine 'Pharma Innovations'. I hope you enjoy reading the magazine which will be beneficial to enrich your knowledge in Pharmacy, medicines, and health. As always this issue is also an attempt to bring out the knowledge concealed within the students and faculty. Before looking ahead, however, I would like to offer a word of thanks to our readers, our contributors, and our editorial board for their support of the journal and its mission I hope you enjoy reading this issue as much as we have enjoyed making it.

DR. R. MAZUMDER
PROFESSOR AND DEAN
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Messages from the desk of the Associate Editor

On behalf of the editorial board members, it is announced that the First issue of 2024 “Pharma Innovations”. has been published. “Pharma Innovations” is a magazine that sturdily focuses on inspiring the faculty and students to gain knowledge and actively driving the mind toward research in health, medicines, and pharmacy. This unprejudiced attitude toward the scope of the magazine allows the reader to have a divergent and convergent aspect on different topics. Enables budding researchers to think in a rational way to make the scientific pavement.

DR. SWARUPANJALI PADHI
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FACULTY FORUM

A REVIEW OF METALLOANTI-CANCER DRUG

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Since the discovery of cisplatin as an anti-cancer drug and its therapeutic usage, research into cancer treatments has found several prospective medications dependent on metal-containing composites. Metallodrugs occupy an important application in the diagnostics and treatment of various types of cancer and a large number are in the clinical trial phase. Compared to pure organic molecules, these metallodrugs provide a wide range of therapeutic action. Metal in an aqueous solution produces cations and has a strong electron affinity thus indulging in hydrolysis and binds with the neutral or negative biomolecules.

Since the presence of metals in cellular environments is a strictly regulated process, precise drug dosages must be established to get the best possible therapeutic outcome. If the precise dosages of drugs containing metals are not established, an excess or shortfall of metals may result in adverse effects. Platinum-containing medications are frequently used to treat cancers such lung, ovarian, and testicular cancer. Platinum medications are therapeutically helpful in treating a variety of solid tumor types, but their efficacy is limited by toxic side effects and tumor resistance, which often lead to recurrent cancers.

A REVIEW OF METALLOANTI-CANCER DRUG

One of the most distinctive qualities of metal compounds is their ability to bind and inhibit DNA. Certain platinum-based metal compounds, such as carboplatin and cisplatin, can form bonds to DNA molecules. They combine with DNA to generate covalent bonds, which produce DNA adducts and cross-links. These interactions lead to abnormalities in transcription and DNA replication, which ultimately result in cell death. Furthermore, the anti-cancer effects of metal complexes, such as arsenic trioxide (ATO) and copper complexes, are mediated by the production of reactive oxygen species (ROS) through redox processes. ROS have the ability to cause oxidative stress in cancer cells, which can lead to DNA damage, malfunctioning mitochondria, and ultimately, cell death. Acute promyelocytic leukemia is treated with ATO. Similar to this, compounds made of gold and platinum derivatives have shown antiangiogenic properties through blocking the production of VEGF or targeting particular signalling pathways connected to angiogenesis. These substances can stop tumors from growing and spreading by obstructing their blood flow.

Researchers are actively working to overcome these obstacles and optimize the use of metal compounds for more potent and targeted cancer treatments, even though metal compounds have shown promise as anti-cancer agents. However, their development and clinical use frequently face toxicity, resistance, and selectivity challenges.

STUDENTS' FORUM

NOIDA INSTITUTE OF ENGINEERING AND TECHNOLOGY (PHARMACY INSTITUTE)

A REVIEW ON MONOCLONAL ANTIBODIES FOR THERAPEUTIC PURPOSE

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An antibody protein used by the immune system to identify and neutralize foreign objects like bacteria and viruses. Each antibody recognizes a specific antigen unique to its target.

Antigen – A substance that enters the body and starts a process that can cause disease.

History and development of monoclonal antibodies

Paul Ehrlich gave the term " magic bullets" and postulated that if a compound could be made that selectively targets a disease-causing organism then a toxin for that organism could be delivered along with the agent of selectivity.

In the 1970s the b – cell cancer multiple myeloma was known. It was understood that these cancerous b – cells all produced a single type of antibody.

In 1975 Kohler and Milstein provided the most outstanding proof of the clonal selection theory by fusion of normal and malignant cells (Hybridoma technology) for which they received the Nobel prize in 1984.

In 1986 first monoclonal antibody was licensed by the FDA orthoclone OKT3 (meuromonab – CD3) which was approved for use in preventing kidney transplant rejection.

A REVIEW ON MONOCLONAL ANTIBODIES FOR THERAPEUTIC PURPOSE

Monoclonal antibodies are identical immunoglobulins generated from a single B-cell clone. These antibodies recognize unique binding sites on a single antigen.

Steps

1. Immunization of mouse.
2. Screening for antibody production and removal of spleen when level of antibody is high.
3. Fusion of myeloma cells with spleen cells using PEG (Polyethylene glycol).
4. Selection of Hybridoma cells by culturing in HAT medium(HAT)-Hypoxanthine, Aminoptexin, Thymedine.
5. Checking for Hybridoma cells and subculturing them.
6. Cloning of hybridoma cells then storing then utilization as required

Antigen insert → Rat → Spleen cell + myeloma cells → Fused spleen cell → Test to check for antibodies → Pure hybridoma cell antibodies→ Propagation (in-vivo ,in vitro) → Harvest→ Store

A REVIEW ON MONOCLONAL ANTIBODIES FOR THERAPEUTIC PURPOSE

Advantages

Through expensive monclonal antibodies are cheaper to develop than conventional drugs.

Side effects can be treated and reduced by using mice – humans hybrid cells or by using fraction of antibodies. They treat a wide range of conditions

Disadvantages

Time-consuming project.

It is only well developed for limited animals and not for other animals

Hybridoma culture may be subject to contamination.

Applications

MAbs in biochemical analysis – Symptomatic tests based on MAbs are routinely used in radioimmunoassay (RIA) and ELISA.

Use of MAbs in COVID–19 treatment – The FDA issued an emergency use Authorization (EUA) for the investigational monoclonal antibody therapy for the treatment of mild to moderate covid 19 in adults and pediatric patients.

Use of MAbs in the treatment of AIDS- Genetic engineering has been prospering in connecting the FC portion of rat monoclonal antibodies to human CD4 molecules.

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A COMPREHENSIVE STUDY ON **MIXED MICELLES**

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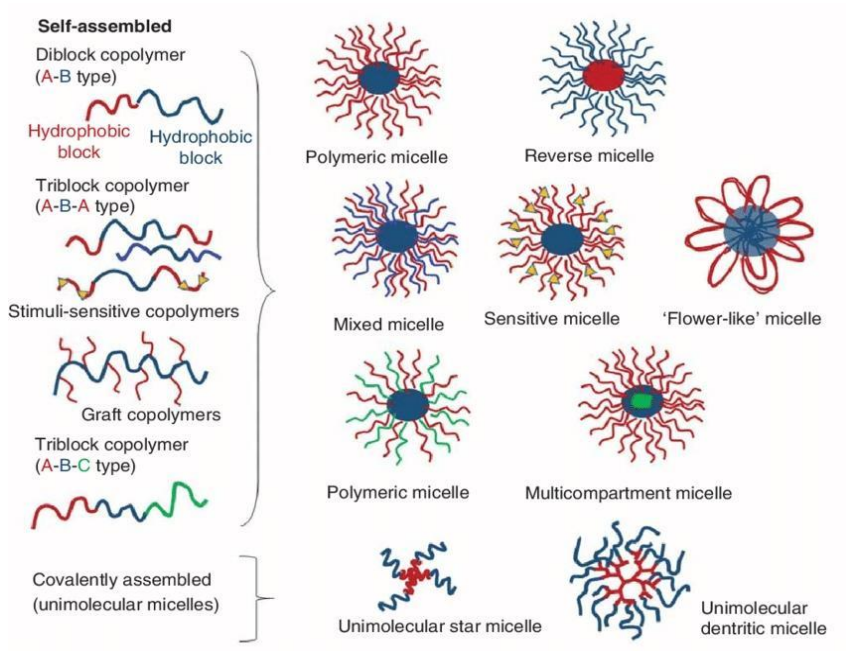
Mixed Micelles

Micelles are microscopic aggregates of amphiphilic molecules, typically surfactants, in a solution. These molecules have both hydrophilic (water-attracting) and hydrophobic (water-repelling) regions. In an aqueous solution, amphiphilic molecules arrange themselves into micelles to minimize exposure of their hydrophobic regions to water. This self-assembly forms spherical structures, with the hydrophilic heads facing outward and the hydrophobic tails sequestered inside. Micelles play crucial roles in various processes, including solubilizing hydrophobic compounds, drug delivery, and biological membrane formation.



Classification of Micelles

A COMPREHENSIVE STUDY ON **MIXED MICELLES**

Micelles Formation

Micelles are spherical supermolecular assemblies of amphiphilic copolymer in which the core can accommodate hydrophobic drugs while the shell is a hydrophilic brush-like corona that makes the micelle water soluble, allowing delivery of the poorly soluble contents.

Micelles are formed in aqueous solution whereby the polar region faces the outside surface of the micelle and the nonpolar region forms the core. Micelles can deliver both hydrophilic and hydrophobic agents. Such structures can deliver macromolecules because these molecules can provide sustained and controlled release of macromolecules, provide chemical and physical stability of the encapsulated molecules, improve drug pharmacokinetics and favorable tissue distribution, and improve drug bioavailability. Formulation of micelle is achieved at above critical micelle concentration.

A COMPREHENSIVE STUDY ON **MIXED MICELLES**

Mixed Micelles

In the realm of pharmaceuticals and beyond, mixed micelles are gaining recognition as versatile carriers with promising applications in drug delivery, cosmetics, and nanotechnology. These nanostructures, formed by the self-assembly of a mixture of amphiphilic molecules, offer unique advantages over traditional drug delivery systems. From enhancing solubility to improving bioavailability and targeting specific tissues, mixed micelles are reshaping the landscape of therapeutic interventions.

Understanding Mixed Micelles

Mixed micelles are composed of a blend of amphiphilic molecules, such as surfactants, phospholipids, or block copolymers, which possess both hydrophilic and hydrophobic domains. When mixed in appropriate ratios, these molecules spontaneously organize into micellar structures in aqueous solutions. Unlike single-component micelles, mixed micelles exhibit a range of physicochemical properties, including size, shape, and surface charge, determined by the composition and concentration of the constituent molecules.

A COMPREHENSIVE STUDY ON **MIXED MICELLES**

Unveiling the Potential of Mixed Micelles: Synergistic Solutions in Drug Delivery

Enhanced Solubility and Bioavailability

One of the primary advantages of mixed micelles lies in their ability to solubilize poorly water-soluble drugs or bioactive compounds. Mixer micelles increase their aqueous solubility by encapsulating hydrophobic molecules within their hydrophobic cores, facilitating their transport through biological fluids and membranes. This property is particularly advantageous for enhancing the bioavailability of lipophilic drugs, which often suffer from poor absorption and low systemic concentrations.

Targeted Drug Delivery

Mixed micelles can be engineered to target specific tissues or cells, offering a tailored approach to drug delivery. By incorporating ligands or targeting moieties on their surfaces, such as antibodies, peptides, or carbohydrates, mixed micelles can selectively bind to receptors or antigens expressed on the surface of target cells. This targeted delivery minimizes off-target effects and reduces systemic toxicity, enhancing the therapeutic index of encapsulated drugs.

A COMPREHENSIVE STUDY ON **MIXED MICELLES**

Synergistic Effects

The combination of different amphiphilic molecules in mixed micelles can lead to synergistic effects, amplifying their therapeutic potential. For example, mixing surfactants with different hydrophobic chains or block copolymers with distinct properties can modulate micellar stability, drug loading capacity, and release kinetics. Furthermore, the co-delivery of multiple drugs within mixed micelles allows for combination therapy, where synergistic or complementary effects can be exploited to achieve superior therapeutic outcomes.

Applications Beyond Drug Delivery

Beyond pharmaceuticals, mixed micelles find applications in various fields, including cosmetics, food science, and nanotechnology. In cosmetics, mixed micelles are utilized to solubilize and deliver active ingredients, improve stability, and enhance skin penetration. In food science, they are employed as emulsifiers, stabilizers, and carriers for encapsulating flavors, colors, and nutrients. In nanotechnology, mixed micelles serve as building blocks for fabricating nanostructures with tailored properties for diverse applications, such as sensors, catalysis, and environmental remediation.

A COMPREHENSIVE STUDY ON MIXED MICELLES

Future Directions

The burgeoning interest in mixed micelles reflects their potential to revolutionize drug delivery and beyond. Future research endeavors aim to further elucidate their physicochemical properties, optimize formulation strategies, and explore novel applications in therapeutics and beyond. As interdisciplinary collaborations flourish and technology advances, mixed micelles are poised to emerge as indispensable tools in the quest for safer, more effective treatments and innovative solutions across diverse domains.

Conclusion

Mixed micelles represent a paradigm shift in drug delivery, offering tailored solutions to the challenges of solubility, bioavailability, and targeted delivery. Their versatility, synergistic effects, and applications beyond pharmaceuticals underscore their significance in modern therapeutics and nanotechnology. As research progresses and applications expand, mixed micelles hold immense promise as transformative carriers, driving innovation and advancement in healthcare and beyond.

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ANTIMICROBIAL RESISTANCE

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Antimicrobial resistance (AMR) is one of the top global problems in health and development sectors. It is estimated that bacterial AMR was directly responsible for 1.27 million global deaths in 2019. The misuse and overuse of antimicrobials in Humans, Animals and Plants are the mainly responsible in the development of drug resistance pathogens.

AMR affects all countries in all regions and at all income levels. its causes and consequences are made by poor or poverty peoples which will mostly affect low & middle economical countries. AMR is responsible for losses of many modern medicines marketing, it makes infections harder to be treated and also affect other medical procedures and treatment such as surgery, cancer chemotherapy and make much riskier.

The world is facing an antibiotic, antimicrobial & access crisis problems, there is an adequate research and development in increasing levels of resistance, and urgent need for additional research and discovery on new and existing vaccines and diagnostics and medicines.

ANTIMICROBIAL RESISTANCE

In addition to death and disability, AMR has significant economic costs the world Bank estimates that AMR could result in US$ 1 trillion in additional healthcare costs by 2050, and US$ 1 trillion to us$3.4 trillion in gross domestic product (GDP) losses per year by 2030. Priorities to cure or reduce AMR in human health include preventing all infections, which may result in the use of antimicrobials and antibiotics, ensuring proper diagnosis and appropriate treatment of infections and complete surveillance on AMR and antimicrobial consumption & use, and also continuous research and development for novel vaccines, treatment/ remedies of AMR and medicines.

Ways to get rid of antimicrobial resistance (AMR)are

i. Don’t take an antimicrobial for a virus.

ii. Don’t save an antimicrobial for the next time you get sick.

iii. Take antibiotics exactly as prescribed. Don’t skip doses. Complete your full course of treatment even if you are feeling better.

iv. Never take an antimicrobial prescribed for someone else or unnecessary.

v. Make them aware others about the side effects and risks associated with the antibiotic they are taking.

vi. Always have fresh fertilizer and pesticide-free products.

vii. Use products that boost your immunity

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PHARMACOVIGILANCE

Pharmacovigilance is a crucial aspect of the pharmaceutical industry that focuses on drug safety and the prevention of adverse effects. It is a scientific discipline that collects, detects, assesses, monitors, and prevents adverse effects or any other drug-related problems. The primary goal of pharmacovigilance is to ensure patient safety by minimizing the risks associated with pharmaceutical products.

The importance of pharmacovigilance has grown significantly in recent years due to the increasing number of new drugs entering the market and the expanding global pharmaceutical market. The process begins with premarketing safety evaluations, which include clinical trials designed to identify potential adverse effects. However, these trials often involve a limited number of patients and may not detect all possible adverse effects, especially rare ones or those that occur over a long period

Post-marketing surveillance is therefore a critical component of pharmacovigilance. It involves the collection and analysis of data from healthcare providers, patients, and other sources to identify adverse effects that were not detected during clinical trials. This information is used to update product labeling, implement risk management strategies, and, if necessary, withdraw a product from the market.

PHARMACOVIGILANCE

Pharmacovigilance also plays a vital role in the detection of drug interactions. With the increasing use of polypharmacy, especially among the elderly, the risk of drug interactions has become a significant concern. Pharmacovigilance systems can help detect these interactions and provide information to healthcare providers to prevent adverse effects.

In addition to its role in patient safety, pharmacovigilance also has economic implications. Adverse drug reactions can lead to hospitalization, prolong hospital stays, and increase healthcare costs. By identifying and preventing adverse effects, pharmacovigilance can help reduce these costs.

Despite its importance, there are several challenges in pharmacovigilance. These include under-reporting of adverse effects, lack of public awareness, and difficulties in causality assessment. To overcome these challenges, efforts are being made to improve reporting systems, increase public awareness, and develop better methods for causality assessment.

In conclusion, pharmacovigilance is a vital component of the pharmaceutical industry that plays a crucial role in ensuring patient safety. Despite the challenges, with the advancements in technology and increased awareness, the field of pharmacovigilance continues to evolve and improve, promising a safer future for patients worldwide.

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REVOLUTIONIZING HEALTHCARE IMPROVEMENTS IN PHARMACEUTICAL INNOVATION

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In recent years, the pharmaceutical industry has witnessed groundbreaking advancements that are reshaping the landscape of healthcare. One notable innovation is the emergence of gene editing therapies, such as CRISPR-Cas9, which enable precise modifications to the genetic code, offering unprecedented potential for treating genetic disorders and diseases at their root cause.

Another significant development is the rise of immunotherapies, which harness the body's immune system to combat diseases like cancer. From checkpoint inhibitors to CAR-T cell therapy, these approaches are providing new hope for patients with previously untreatable conditions, offering targeted and personalized treatment options.

REVOLUTIONIZING HEALTHCARE IMPROVEMENTS IN PHARMACEUTICAL INNOVATION

Biologics represent another frontier in pharmaceutical innovation, with drugs derived from biological sources offering novel treatment modalities for a range of diseases, including autoimmune disorders, cancer, and rare genetic conditions. These therapies, which include monoclonal antibodies and gene therapies, are revolutionizing the treatment landscape by providing highly specific and effective interventions.

Nanomedicine is also transforming drug delivery, leveraging nanotechnology to design precision-targeted therapies that can bypass biological barriers and deliver drugs directly to diseased cells or tissues. By enhancing drug efficacy and minimizing side effects, these nanomedicines are unlocking new possibilities for treating complex diseases.

REVOLUTIONIZING HEALTHCARE IMPROVEMENTS IN PHARMACEUTICAL INNOVATION

Furthermore, digital health technologies are revolutionizing patient care, with innovations such as digital therapeutics, wearable devices, and telemedicine platforms enabling remote monitoring, diagnosis, and treatment. These technologies are improving access to care, enhancing patient outcomes, and driving efficiency throughout the healthcare system.

In parallel, personalized medicine is gaining traction, with advancements in genomics, data analytics, and artificial intelligence enabling tailored treatment approaches based on individual patient characteristics. By considering factors such as genetic makeup, lifestyle, and environmental influences, personalized medicine promises to optimize treatment outcomes and minimize adverse effects.

In conclusion, the pharmaceutical industry is witnessing a paradigm shift driven by innovation across multiple fronts. From gene editing and immunotherapies to biologics, nanomedicine, digital health, and personalized medicine, these advancements are revolutionizing healthcare, offering new hope and possibilities for patients around the world. As these technologies continue to evolve, they hold the promise of transforming the way we prevent, diagnose, and treat diseases, ushering in a new era of personalized and precision medicine.

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PHARMA Info

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OVERVIEW OF THE INDIAN DRUG REGULATORY SYSTEM

(CDSCO/SLA)

Indian Drug

Regulatory System

Regulates drugs, cosmetics and medical devices

Through Drugs and Cosmetics Act, 1940, and Rules thereunder 1945.

THE INDIAN DRUG REGULATORY SYSTEM

Different Ministeries/Departments

- **Ministry of Chemicals and Fertilizers**
  - Dept. of Pharmaceuticals
  - National Pharmaceutical Pricing Authority
- **Ministry of Health**
  - Directorate General of Health Services
  - Central Drugs Standard control organisation
- **Ministry of Environment &Forest**
  - Genetic Engineering Appraisal committee
  - Dept.of biotechnology
- **State Licensing Authority**
  - Manufacturing, Sale and Inspections

THE INDIAN DRUG REGULATORY SYSTEM

THE INDIAN DRUG REGULATORY

Act at two levels

Central level and State level

(CDSCO/SLA).

HIERARCHY

Drug controller General (INDIA

Joint Drugs Controller(India)

Deputy Drugs controller(India)

Assistant Drugs Controller (India)

- Drugs Inspector
- Assistant Drugs Inspector
- Technical Associate Technical Associate
- Supporting Staff

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Patent

Copyright

Plant Breeders right

Types of Intellectual Property Rights in India

Trademark

Geographical Indication

Trade secrets

PBR

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List of new drug candidate approved by FDA (June 2024)

Drug Name	Active Ingredient	Approval Date	FDA approved use
Zelsuvmi	berdazimer	1/5/2024	To treat molluscum contagiosum
Exblifep	cefepime, enmetazobactam	2/22/2024	To treat complicated urinary tract infections
Letybo	letibotulinumtoxinA-wlbg	2/29/2024	To temporarily improve the appearance of moderate-to-severe glabellar lines
Tevimbra	tislelizumab-jsgr	3/13/2024	To treat unresectable or metastatic esophageal squamous cell carcinoma
Rezdiffra	resmetirom	3/14/2024	To treat noncirrhotic non-alcoholic steatohepatitis with moderate to advanced liver scarring
Tryvio	aprocitentan	3/19/2024	To treat hypertension
Duvyzat	givinostat	3/21/2024	To treat Duchenne muscular dystrophy in individuals aged 6 years and older
Winrevair	sotatercept-csrk	3/26/2024	To treat pulmonary arterial hypertension
Vafseo	vadadustat	3/27/2024	To treat anemia due to chronic kidney disease
Voydeya	danicopan	3/29/2024	To treat extravascular hemolysis with paroxysmal nocturnal hemoglobinuria

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Drug Name	Active Ingredient	Approval Date	FDA approved use
Zevtera	ceftobiprole medocaril sodium	4/3/2024	To treat certain bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia
Lumisight	pegulicianine	4/17/2024	To use as an optical imaging agent for the detection of cancerous tissue
Anktiva	nogapendekin alfa inbakicept-pmln	4/22/2024	To treat bladder cance
Ojemda	tovorafenib	4/23/2024	To treat relapsed or refractory pediatric low-grade gliom
Xolremdi	mavorixafor	4/26/2024	To treat WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis)
Imdelltra	tarlatamab-dlle	5/16/2024	To treat extensive stage small cell lung cancer
. Rytelo	imetelstat	6/6/2024	To treat low- to intermediate-1 risk myelodysplastic syndromes
Iqirvo	elafibranor	6/10/2024	To treat primary biliary cholangitis in combination with ursodeoxycholic acid
Sofdra	sofpironium	6/18/2024	To treat primary axillary hyperhidrosis

Drug Name	Active Ingredient	Approval Date	FDA approved use
Piasky	crovalimab-akkz	6/20/2024	To treat paroxysmal nocturnal hemoglobinuria
Ohtuvayre	ensifentrine	6/26/2024	To treat chronic obstructive pulmonary disease

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“See you in the Next Edition”
Stay Safe, Stay healthy,
and
Keep Learning

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