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PHARMACEUTICAL ADVANCES IN NEPHROLOGY

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Introduction:

The U.S. Food and Drug Administration (FDA) has granted an expanded indication for furosemide injection (Furoscix; scPharmaceuticals, Inc.), marking a significant advancement in the management of edema in adult patients with chronic kidney disease (CKD), including those with nephrotic syndrome. This development, anticipated to be available by April 2025, builds upon the existing approval for heart failure-related congestion and introduces a novel subcutaneous loop diuretic option for CKD patients (Stock Titan, 2025).

I. Expanded Clinical Utility in CKD:

Novel Subcutaneous Administration:

- The expanded indication extends the utility of the Furoscix On-Body Infusor, enabling at-home, subcutaneous administration of furosemide for CKD-related edema (GlobeNewswire, 2024).

- This offers a patient-centric alternative to traditional intravenous (IV) therapy, potentially reducing hospitalizations and improving patient quality of life.

Targeted Treatment of Edema in Diverse CKD Presentations:

- The approval encompasses edema management in a broad CKD patient population, including those with nephrotic syndrome, addressing a significant clinical need (Stock Titan, 2025).
- This expansion recognizes the challenges of fluid overload in CKD and provides a standardized approach to diuretic therapy.

Pharmacokinetic and Pharmacodynamic Equivalence:

- The approval was supported by demonstrating pharmacokinetic and pharmacodynamic bridging to the existing 10 mg/mL listed drug, negating the need for extensive new clinical trials (GlobeNewswire, 2024).
- This highlights the efficacy and safety profile established in previous studies, allowing for a swift expansion of the drugs indication.

II. Clinical and Pharmacological Considerations:

Established Efficacy in Heart Failure:

- The existing approval for NYHA class 2 and 3 heart failure establishes the efficacy of subcutaneous furosemide in achieving IV-equivalent diuresis (scPharmaceuticals, 2022).
- Clinical studies have demonstrated high bioavailability (approximately 99.6%) and comparable urine output to IV administration (scPharmaceuticals, 2022).

Contraindications and Safety Profile:

- The treatment remains contraindicated in patients with anuria, hepatic cirrhosis with ascites, and hypersensitivity to furosemide or medical adhesives (GlobeNewswire, 2024).
- It is not intended for emergency situations or acute pulmonary edema, emphasizing the importance of appropriate patient selection (GlobeNewswire, 2024).

Future Developments: Auto-Injector Formulation:

- The development of SCP-111, a low-volume, pH-neutral formulation of furosemide for auto-injector administration, is underway (scPharmaceuticals, 2024).
- This aims to provide greater flexibility in subcutaneous administration, complementing the On-Body Infusor and enhancing patient convenience (scPharmaceuticals, 2024).

Label Expansion Initiatives:

- scPharmaceuticals is also pursuing label expansion for NYHA class 4 heart failure, indicating a commitment to broadening the therapeutic scope of furosemide injection (scPharmaceuticals, 2024).
- This proactive approach highlights the potential for this therapy to address a wider range of fluid overload conditions (scPharmaceuticals, 2024).

III. Implications and Future Directions:

Impact on CKD Patient Management:

- The expanded indication has the potential to significantly improve the management of fluid overload in CKD, a common and

debilitating complication (Stock Titan, 2025).

- The at-home administration option may reduce the burden of frequent clinic visits and hospitalizations (Stock Titan, 2025).

Strategic Growth and Public Health Significance:

- This approval represents a key growth initiative for scPharmaceuticals, addressing the significant prevalence of CKD in the United States (Stock Titan, 2025).
- The availability of a reliable subcutaneous diuretic option may contribute to improved patient outcomes and reduced healthcare costs (Stock Titan, 2025).

Ongoing Research and Development:

- The ongoing pharmacokinetic studies of the furosemide auto-injector formulation underscore the commitment to innovation and patient-centered care (scPharmaceuticals, 2024).
- Future research should focus on long-term outcomes and comparative effectiveness studies to further refine the use of subcutaneous furosemide in CKD (scPharmaceuticals, 2024).

Conclusion:

The FDA's approval of the expanded indication for furosemide injection represents a significant advancement in the management of edema in CKD. This development, coupled with ongoing research into alternative administration methods, underscores the evolving landscape of diuretic therapy and its potential to improve the lives of patients with chronic kidney disease (Stock Titan, 2025).

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UNDERSTANDING POLYCYSTIC OVARY SYNDROME (PCOS) WITH HYPERTHYROIDISM

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Introduction

Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder affecting women of reproductive age. When accompanied by hyperthyroidism, managing hormonal imbalances becomes more complex. This newsletter aims to provide insights into the relationship between PCOS and hyperthyroidism, their impact on health, and effective management strategies.

Understanding the Connection

PCOS is characterized by hormonal imbalances, irregular menstrual cycles, ovarian cysts, and metabolic issues. Hyperthyroidism, on the other hand, results from an overactive thyroid gland, leading to an excess production of thyroid hormones. Studies suggest that thyroid disorders can influence ovarian function and exacerbate symptoms of PCOS, including weight fluctuations, fertility challenges, and metabolic disturbances (Smith et al., 2021).

A study by Jones & Patel (2022) indicates that women with PCOS often present with altered thyroid hormone levels, which can worsen insulin resistance and impact reproductive health (Jones & Patel, 2022).

Health Implications

The coexistence of PCOS and hyperthyroidism may lead to:

- **Increased Metabolic Disorders:** Insulin resistance and an increased risk of type 2 diabetes.
- **Menstrual Irregularity:** Hyperthyroidism may amplify menstrual disturbances common in PCOS.
- **Fertility Challenges:** Both conditions impact ovulation and pregnancy outcomes (Williams et al., 2023).
- **Cardiovascular Risks:** Elevated thyroid hormones can exacerbate dyslipidemia and hypertension associated with PCOS (Brown & Lee, 2021).

Management Strategies

1. **Medical Treatment:**

- **Thyroid Regulation:** Anti-thyroid medications or beta-blockers may be prescribed for hyperthyroidism.
- **PCOS-Specific Therapies:** Metformin and hormonal therapy can help regulate insulin resistance and menstrual cycles.

2. **Lifestyle Modifications:**

- A balanced diet rich in fiber, lean proteins, and healthy fats can help manage weight and hormonal imbalances.
- Regular exercise enhances insulin sensitivity and overall metabolic health.

3. **Regular Monitoring:**

- Routine hormonal assessments ensure early detection and management of complications (Nguyen & Thompson, 2024).

Conclusion

PCOS and hyperthyroidism share overlapping symptoms, making diagnosis and management crucial for women's health. A comprehensive approach involving medical treatment, lifestyle adjustments, and regular monitoring can significantly improve patient outcomes.

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BEYOND TRASTUZUMAB: NEW TREATMENT OPTIONS FOR HER2-POSITIVE BREAST CANCER

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Breast cancer remains one of the most prevalent cancers affecting women globally, with HER2-positive subtype accounting for approximately 20% of cases. HER2 (human epidermal growth factor receptor 2) overexpression leads to aggressive tumor growth and poorer prognosis if left untreated. Fortunately, the advent of targeted therapies like trastuzumab has significantly improved outcomes for HER2-positive breast cancer patients. However, despite its efficacy, some patients develop resistance or experience treatment failure over time, necessitating the exploration of alternative therapeutic options.

The Role of Trastuzumab and Its Limitations

Trastuzumab, a monoclonal antibody targeting the HER2 receptor, has been a cornerstone in the treatment of HER2-positive breast cancer since its approval in the late 1990s. By blocking HER2 signaling pathways, trastuzumab inhibits tumor growth and enhances the efficacy of chemotherapy in both early and metastatic settings. Despite its success, a considerable number of patients eventually relapse due to acquired resistance or intrinsic insensitivity to

a considerable number of patients eventually relapse due to acquired resistance or intrinsic insensitivity to trastuzumab, highlighting the need for novel treatment strategies.

Emerging Therapeutic Approaches

Recent advancements in HER2-targeted therapies offer promising alternatives beyond trastuzumab:

1. **Second-Generation: HER2-Targeted Agents**: Drugs like pertuzumab, which targets a different HER2 dimerization domain, have shown synergistic effects in combination with trastuzumab and chemotherapy. Pertuzumab received FDA approval based on clinical trials demonstrating improved progression-free and overall survival rates.
2. **ADCs (Antibody-Drug Conjugates)**: ADCs such as trastuzumab emtansine (T-DM1) combine the specificity of trastuzumab with a cytotoxic payload, delivering chemotherapy directly to HER2-positive cancer cells while minimizing systemic toxicity. T-DM1 has demonstrated efficacy in patients progressing on trastuzumab-based therapies.
3. **Small Molecule Inhibitors**: Tyrosine kinase inhibitors like lapatinib and neratinib block HER2 signaling pathways intracellularly. Neratinib, for instance, has shown promise in adjuvant settings, reducing the risk of recurrence when used after adjuvant trastuzumab-based therapy.
4. **Immunotherapy**: Checkpoint inhibitors, such as pembrolizumab, in combination with trastuzumab have shown potential in enhancing anti-tumor immune responses in HER2-positive breast cancer, particularly in tumors with high PD-L1 expression.

Future Directions and Challenges

The landscape of HER2-positive breast cancer treatment continues to evolve with ongoing research into novel agents and therapeutic combinations. Challenges such as resistance mechanisms, biomarker identification for patient selection, and managing treatment-related toxicities remain critical areas of investigation.

Conclusion

While trastuzumab remains a cornerstone in HER2-positive breast cancer treatment, emerging therapies are expanding the therapeutic arsenal. From second-generation HER2-targeted agents to innovative ADCs and immunotherapy combinations, these treatments offer hope for improved outcomes and survival rates. Continued research and clinical trials will be essential in further defining the role of these therapies and optimizing their use in clinical practice.

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SPOTLIGHT ON GLP-1S FOR DIABETES AND WEIGHT LOSS MANAGEMENT

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Welcome to our comprehensive exploration of GLP-1 receptor agonists (GLP-1s), a class of medications at the forefront of diabetes management and weight loss strategies. In this newsletter, we will delve deeply into the mechanisms, clinical efficacy, safety profiles, and emerging research surrounding GLP-1s.

Introduction to GLP-1 Receptor Agonists:

Glucagon-like peptide-1 (GLP-1) receptor agonists are a group of medications designed to mimic the action of the endogenous hormone GLP-1. This hormone plays a crucial role in regulating glucose metabolism and satiety. By activating GLP-1 receptors, these agonists enhance insulin secretion in response to meals, suppress glucagon release (thereby reducing hepatic glucose production), actions result in improved glycemic control, reduced blood glucose variability, and enhanced satiety, which can lead to weight loss.

Mechanisms of Action:

The mechanisms through which GLP-1 receptor agonists exert their effects are multifaceted and involve interactions at several levels of glucose homeostasis. Primarily, GLP-1 receptor agonists bind to and activate GLP-1 receptors on pancreatic beta cells. It leads to potentiation of glucose-stimulated insulin secretion, which helps lower postprandial glucose levels without increasing the risk of hypoglycemia. Furthermore, GLP-1s inhibit glucagon secretion from alpha cells, which reduces hepatic glucose output, and they also slow gastric emptying, contributing to a feeling of satiety and aiding in weight loss efforts.

Clinical Efficacy of GLP-1 Receptor Agonists:

Numerous clinical trials have demonstrated the efficacy of GLP-1 receptor agonists in improving both glycemic control and weight management in patients with type 2 diabetes. For example, landmark trials such as the LEADER trial (Reference 1) and the SUSTAIN trials (Reference 2) have shown significant reductions in HbA1c levels, improved fasting and postprandial glucose control, and substantial weight loss among participants treated with GLP-1 agonists compared to placebo or other antidiabetic agents. In the LEADER trial, which involved over 9,000 patients, liraglutide was shown to significantly reduce the risk of major cardiovascular events, including cardiovascular benefits beyond glycemic control. The SUSTAIN trials evaluated semaglutide and demonstrated

weight loss compared to other GLP-1 receptor agonists and placebo.

Safety Profiles and Adverse Effects:

While generally well-tolerated, GLP-1 receptor agonists are associated with some potential adverse effects. Common side effects include nausea, vomiting, diarrhea, and periodically, transient pancreatitis. These gastrointestinal symptoms often diminish over time as patients acclimate to the medication. Additionally, concerns have been raised about the potential for pancreatitis thyroid C-cell hyperplasia, and neoplasia, which have been monitored in preclinical studies and some post-marketing surveillance data. However, the overall safety profile of GLP-1 receptor agonists remains favorable, especially considering their benefits in glycemic control and weight reduction. Comprehensive reviews and meta-analyses (Reference 3) consistently report a low incidence of severe adverse events, reinforcing the clinical utility of these medications in appropriate patient populations.

Emerging Research and Future Directions:

The field of GLP-1 receptor agonists continues to evolve with ongoing research focusing on several fronts. New formulations and delivery methods are being analyzed to improve patient adherence and satisfaction. Combination therapies involving GLP-1s with other antidiabetic agents, such as SGLT-2 inhibitors or DPP-4 inhibitors, are being investigated to achieve synergistic effects on glycemic control and weight management (Reference 4).

Moreover, recent studies have extended beyond traditional diabetes care to explore the potential benefits of GLP-1 receptor agonists in cardiovascular risk reduction and non-alcoholic fatty liver disease (NAFLD). The REWIND trial (Reference 5), for instance, demonstrated

Conclusion:

In conclusion, GLP-1 receptor agonists represent a pivotal advancement in the management of type 2 diabetes and obesity. Their multifaceted mechanisms of action, coupled with demonstrated efficacy in improving glycemic control, promoting weight loss, and potentially reducing cardiovascular risk, underscore their importance in clinical practice. As research starts again to expand our understanding of these agents, we anticipate further refinements in treatment strategies and broader applications in metabolic and cardiovascular health.

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ROLE OF ARTIFICIAL INTELLIGENCE (AI) IN ADVERSE DRUG REACTION (ADR)

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Adverse drug reactions (ADRs) are major challenges in drug discovery, threatening patient safety and dramatically increasing healthcare expenditures. Since ADRs are not as visible as infectious diseases, the potential consequences are considerable. Early detection of ADRs is an essential indicator of a drug's viability and safety profile. The application of these modern computational methods allows for the rapid, thorough, and precise prediction of probable ADRs even before the drug's practical synthesis as well as preclinical and clinical trials, resulting in more efficient and safer medications with a lesser chance of drug's withdrawal. The following steps are involved in ADR management.

Early Detection and Prediction of ADRs:

- AI-powered algorithms can analyze large datasets from electronic health records, spontaneous reporting systems, and real-world data sources to detect signals and patterns indicative of potential ADRs.
- Machine learning models can predict the likelihood of ADRs occurring, even for rare or delayed-onset reactions, enabling proactive risk management.

Improved Risk Assessment and Communication:

- AI can assist in the assessment of ADR severity, causality, and risk factors, supporting better-informed decision-making and risk mitigation strategies.
- AI-generated insights can be used to enhance communication about drug safety to healthcare providers, patients, and regulatory bodies.

Optimization of Pharmacovigilance Processes:

- AI can streamline and automate various pharmacovigilance tasks, such as case processing, data validation, and trend analysis, improving efficiency and reducing costs.
- The integration of AI into pharmacovigilance systems can free up resources for more complex tasks, such as signal investigation and risk management.

In summary, the role of AI in ADR management is transformative, enabling more proactive, efficient, and accurate identification, evaluation, and communication of drug safety issues, ultimately enhancing patient safety and the overall pharmacovigilance process.

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DEPARTMENTAL ACTIVITIES

6TH NATIONAL CONFERENCE AT MANGALURU

The Indian Pharmaceutical Association, Mangaluru Local Branch, in association with Srinivas College of Pharmacy, Mangaluru, organized the ***6th National Conference*** *on "Innovative Practices in Clinical Training and Patient Safety" from May 16 to May 18, 2024. Our Pharm.D Interns Ms. Megala and Ms. Prathiba, presented their research findings at the conference. Additionally, our students Ms. A. Afreen, Ms. K. Megala, Ms. I. Prathiba and Mr. B. Yogeash participated in the quiz competition and qualified for the final round, secured the fourth place. The management, Principal, Department Heads, faculty and students of The Erode College of Pharmacy, Erode, congratulate the oral participants and quiz winners.*

ONE DAY INDUSTRIAL VISIT AT SPINOS

The Department of Pharmacy Practice at the Erode College of Pharmacy organized a ***One Day Industrial Visit*** *to Spinos Life Science and Research Private Limited, located in Coimbatore. A contingent of 45 students from the D.Pharm II Year, accompanied by Dr. C. Kannan (Associate Professor), Dr. A. Kavinraja (Assistant Professor) and Mrs. K. Priya (Assistant Professor), participated in this event on May 04, 2024. The dedicated team at Spinos Life Science and Research provided valuable insights into the realms of clinical research, encompassing data collection, analysis, and ethical considerations. Dr. R. Sambathkumar, our Principal, extended encouragement for this field visit, which was organized by the Department of Pharmacy Practice. We extend our sincere appreciation to Abiraamasundari R (Managing Director), Seenivasan P (General Manager), Robert Benjamin C (Business Development Executive), and Dr. Kuriakose Joy (Medical Writer) of Spinos Life Science and Research Private Limited, Coimbatore, as well as to our Management, for graciously affording our students this wonderful learning opportunity.*

World Hypertension Day

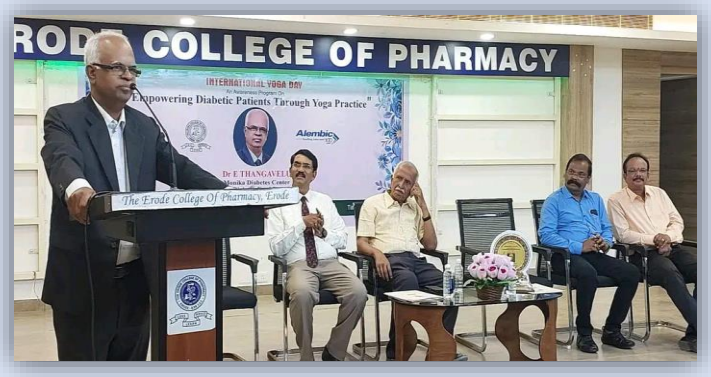
On observance of World Hypertension Day 2024, The Tamil Nadu Dr.M.G.R Medical University, Chennai and The Erode College of Pharmacy, Erode set up a Camp on 'Blood Pressure Screening for All'' on June 11, 2024 from 10 a.m. in the College Campus. Organized by Department of Pharmacy Practice and NSS. During the Camp the Pharm.D fourth year students participated as volunteers for screening and data entering. Nearly 200 people including Teaching, Non-teaching staff(s) and students were screened for blood pressure and random blood glucose level.

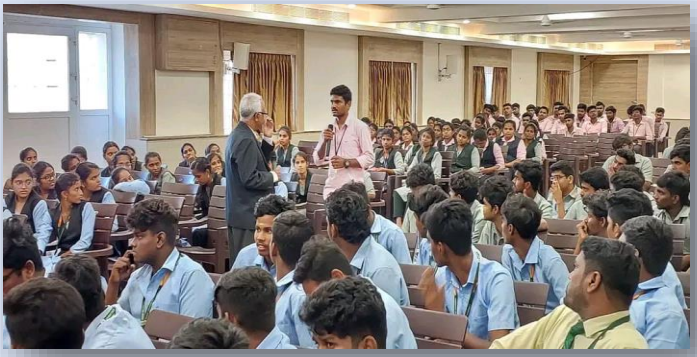
ONE DAY WORKSHOP

*The Erode College of Pharmacy, Erode, organized a one-day workshop on "**Maximizing Potential: The Role of Scientists in Building a Career in IPR."** The session was conducted by **Dr. Umesh Banakar**, President of Banakar Consulting Services, USA. The workshop aimed to provide insights into **intellectual property rights (IPR)** and career opportunities for scientists in this field. Around **25 faculty members and 210 students** actively participated, engaging in discussions on patents, trademarks, and the importance of IPR in pharmaceutical sciences. The event helped students understand how IPR can shape their careers and contribute to scientific advancements.*

International Yoga Day

The Erode College of Pharmacy, Erode, organized an "International Yoga Day" Awareness Program on "Empowering Diabetic Patients through Yoga Practice" on June 21, 2024, at 3:00 PM. Dr. E. Thangavelu, a diabetology expert from Monika Diabetic Center, delivered a special lecture on the prevention and treatment of diabetes, raising awareness among students and staff. The event emphasized the role of yoga in diabetes management. More than 300 students and 50 staff members actively participated, gaining valuable insights into healthy living and disease prevention through yoga and lifestyle modifications.





International Yoga Day Awareness Program

The Erode College of Pharmacy, Erode, organized an International Yoga Day awareness program on June 21, 2024, at 2:00 PM. More than 50 girl students, along with the Physical Director, actively participated in the session. The event emphasized the benefits of daily yoga practice for a healthy lifestyle. A special lecture on the importance of yoga was delivered by the yoga master, highlighting its role in physical and mental well-being. The session aimed to inspire students to incorporate yoga into their daily routine for a healthier and stress-free life.