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ONCOLOGY REVIEW | RESEARCH ADVANCES | NEW TREATMENTS | CANCER PREVENTION



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Meet the team!

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Dr. Sajeve Thomas

Dr. Sajeve Thomas, a certified medical oncologist and internal medicine specialist affiliated with the Orlando Health Cancer Institute, brings forth a wealth of expertise spanning more than ten years.

His clinical emphasis lies in the management of melanoma, sarcoma, and gastrointestinal disorders. Serving as a key investigator at the cancer center, he spearheads diverse clinical trials, investigating avant-garde treatment modalities, including targeted therapy, immunotherapy, intratumoral therapy, and intricate cellular therapies.



Dr. Daniel Landau

Dr. Daniel Landau, a renowned hematologist/oncologist certified by the board, possesses extensive expertise garnered from his tenure at the Orlando Health Cancer Institute and the Medical University of South Carolina. He is a prominent figure in the realms of genitourinary oncology and hematology.

Distinguished for his significant impact, Dr. Landau assumes the role of Director of Telemedicine Services, championing the incorporation of advanced technology in oncology. This initiative not only underscores his commitment to patient care but also aims to elevate the overall patient experience through the implementation of cutting-edge system designs.

Letter from the *Author*



*MedOncMD:
Where
information
meets inspiration,
and together, we
empower the
cancer
community to
face the
challenges with
strength and
hope*

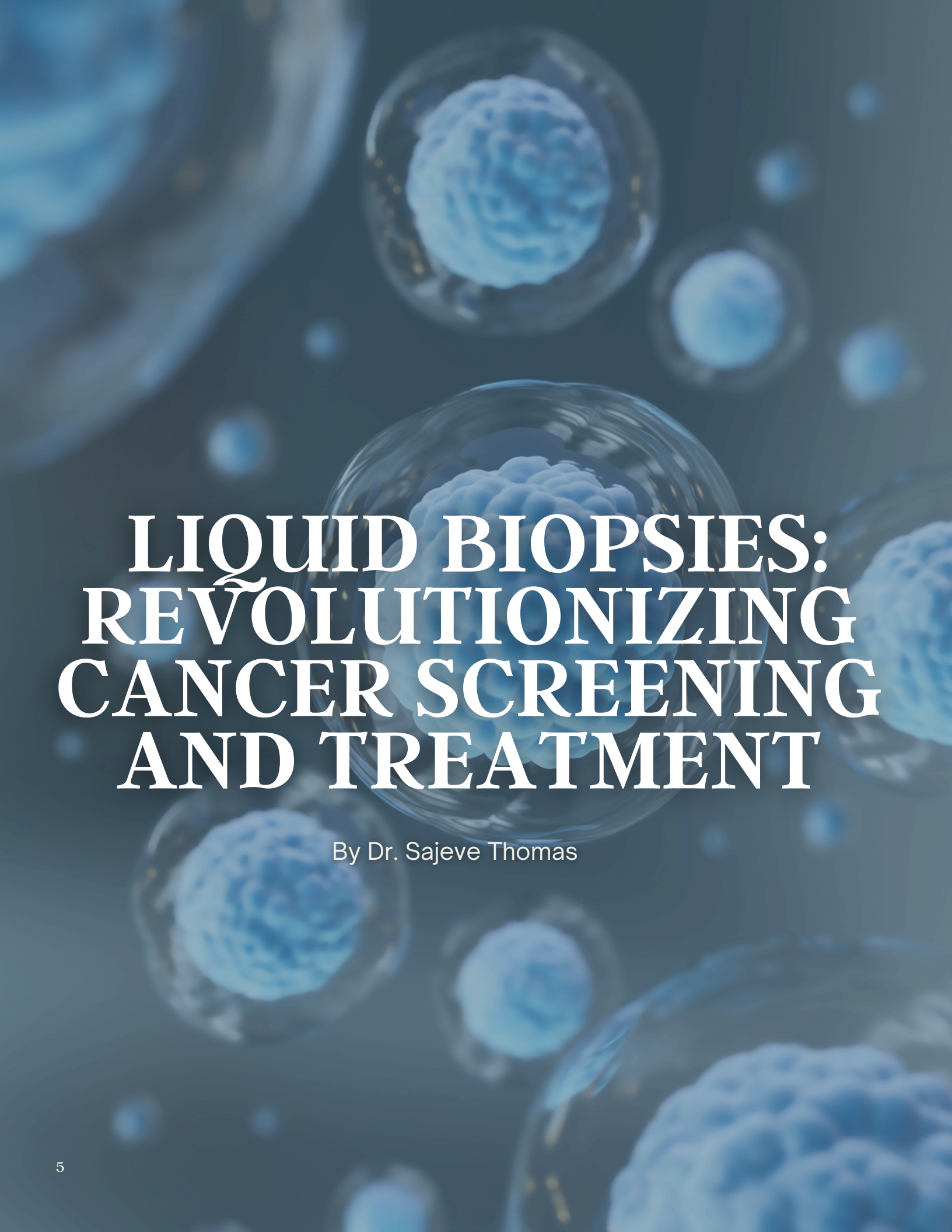
Welcome to the third edition of MedOncMD, your trusted source for the latest and indispensable information tailored for cancer patients, caregivers, and healthcare providers. As we embark on this edition, our commitment to bridging the informational gap in oncology consultations remains unwavering. With a wealth of experience spanning over 12 years in the field of medical oncology, we empathize with the challenges that both patients and their families face in their cancer journey. MedOncMD is meticulously crafted to equip you with the knowledge needed to navigate the complex terrain of cancer care.

Our enduring mission is to empower patients, caregivers, and healthcare providers with the invaluable gift of knowledge.

This edition delves into critical topics such as the forefront of immunotherapy, the strides in personalized medicine, the nuances of survivorship care, and the paramount importance of mental health support during cancer treatment.

Join us on this continuous journey as we navigate the ever-evolving landscape of oncology together. We are committed to providing reliable information and sharing uplifting stories that instill hope and resilience.

At MedOncMD, our passion is deeply rooted in making a meaningful difference in the lives of cancer patients and their families. We stand ready to be your steadfast ally in the fight against cancer.

A microscopic view of several cancer cells, showing their irregular, bumpy nuclei and thin, translucent membranes. The cells are scattered across the frame, with some in sharp focus and others blurred in the background. The overall color palette is a range of blues, from light sky blue to deep navy blue.

LIQUID BIOPSIES: REVOLUTIONIZING CANCER SCREENING AND TREATMENT

By Dr. Sajeve Thomas

Gone are the days of relying solely on invasive procedures like tissue biopsies for cancer diagnosis

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Cancer screening has undergone a remarkable transformation, with technological strides leading to more effective and less invasive methods. In this article, we delve into the integration of liquid biopsies as a groundbreaking approach to early cancer detection, heralding a new era of precision medicine.

Gone are the days of relying solely on invasive procedures like tissue biopsies for cancer diagnosis. The advent of liquid biopsies marks a paradigm shift, offering a minimally invasive alternative

that leverages blood samples to detect genetic mutations and abnormalities associated with various cancers.

Liquid biopsies shine in identifying genetic alterations linked to cancer by analyzing circulating tumor DNA (ctDNA) in the bloodstream. This approach provides a comprehensive genetic profile of the tumor, enabling oncologists to tailor treatment plans to the specific genetic makeup of an individual's cancer. This not only aids in early detection but also opens the door to personalized treatment strategies,

optimizing outcomes and minimizing side effects.

However, as we embrace the promise of liquid biopsies, challenges persist. Sensitivity and specificity are crucial factors that require further research to refine the accuracy of these tests. Additionally, addressing regulatory considerations and accessibility issues is paramount for ensuring widespread adoption. The integration of liquid biopsies into cancer screening signifies a significant step towards more patient-friendly and effective diagnostic approaches.

Oncology *Nursing*

Oncology nurses emerge as staunch advocates for their patients, ensuring that each patient's voice is heard, needs are met, and concerns are communicated effectively to the broader medical team

By Dr. Sajeve Thomas



Oncology nurses play a pivotal role in coordinating comprehensive cancer care, ensuring seamless communication among various specialists and healthcare services

Oncology Nursing: Illuminating the Heroes in Cancer Care

In the realm of cancer care, this article shines a spotlight on the often-overlooked heroes – oncology nurses. Dedicated and hardworking, these caregivers go above and beyond traditional nursing duties, playing multifaceted roles in the intricate journey of cancer patients.

1. Advocacy Beyond Care: Oncology nurses emerge as staunch advocates for their patients. Their commitment ensures that each patient's voice is heard, needs are met, and concerns are communicated effectively to the broader medical team. Their advocacy extends beyond hospital walls, guiding patients through the complexities of healthcare systems.

2. Educators and Compassionate Counselors: Education is pivotal in oncology nursing. Nurses educate patients and families about the disease, treatment options, and self-care strategies. Providing emotional support, they serve as a pillar for patients and families navigating the psychological impacts of cancer diagnosis and treatment.

3. Seamless Care Coordinators: Oncology nurses play a pivotal role in coordinating comprehensive cancer care. From scheduling treatment cycles to managing side effects, they ensure seamless communication among various specialists and healthcare services.

4. Masters of Symptom Management: Oncology nurses excel in managing the myriad symptoms and side effects associated with cancer and its treatment. With skillful assessment and appropriate interventions, they adapt care plans to meet the evolving needs of patients.

5. Clinical Experts in Oncology: In the ever-evolving landscape of cancer care, oncology nursing demands specialized knowledge and skills. From cancer biology to the latest treatments and technologies, these nurses are equipped to handle the complexities of the field, adapting to advancements such as immunotherapy, targeted therapy, and hormonal therapy.

As we celebrate the dedicated oncology nurses, let's reflect on the roles they play – educators, advocates, and caregivers. Their compassion coupled with clinical expertise makes them indispensable in the cancer care continuum. Beyond bedside care, they contribute to advancements in cancer research, offer palliative support, and stand as pillars of strength for patients and their families. In acknowledging their contributions, we not only celebrate their dedication but also recognize their pivotal role in transforming the landscape of cancer care.

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Enzalutamide

for Non-Metastatic Prostate Cancer

By Dr. Daniel Landau



In a groundbreaking move, the Food and Drug Administration (FDA) has approved enzalutamide (Xtandi, Astellas Pharma US, Inc.) for non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence. This momentous decision breathes new hope into the lives of patients at high risk for metastasis.

The Road to Approval: EMBARK Trial Insights

The approval stems from the EMBARK clinical trial (NCT02319837), where enzalutamide demonstrated its potential among 1068 patients with nmCSPC and high-risk biochemical recurrence. The trial, utilizing a randomized 1:1:1 design, assessed enzalutamide in combination with leuprolide, enzalutamide monotherapy, and a placebo with leuprolide.

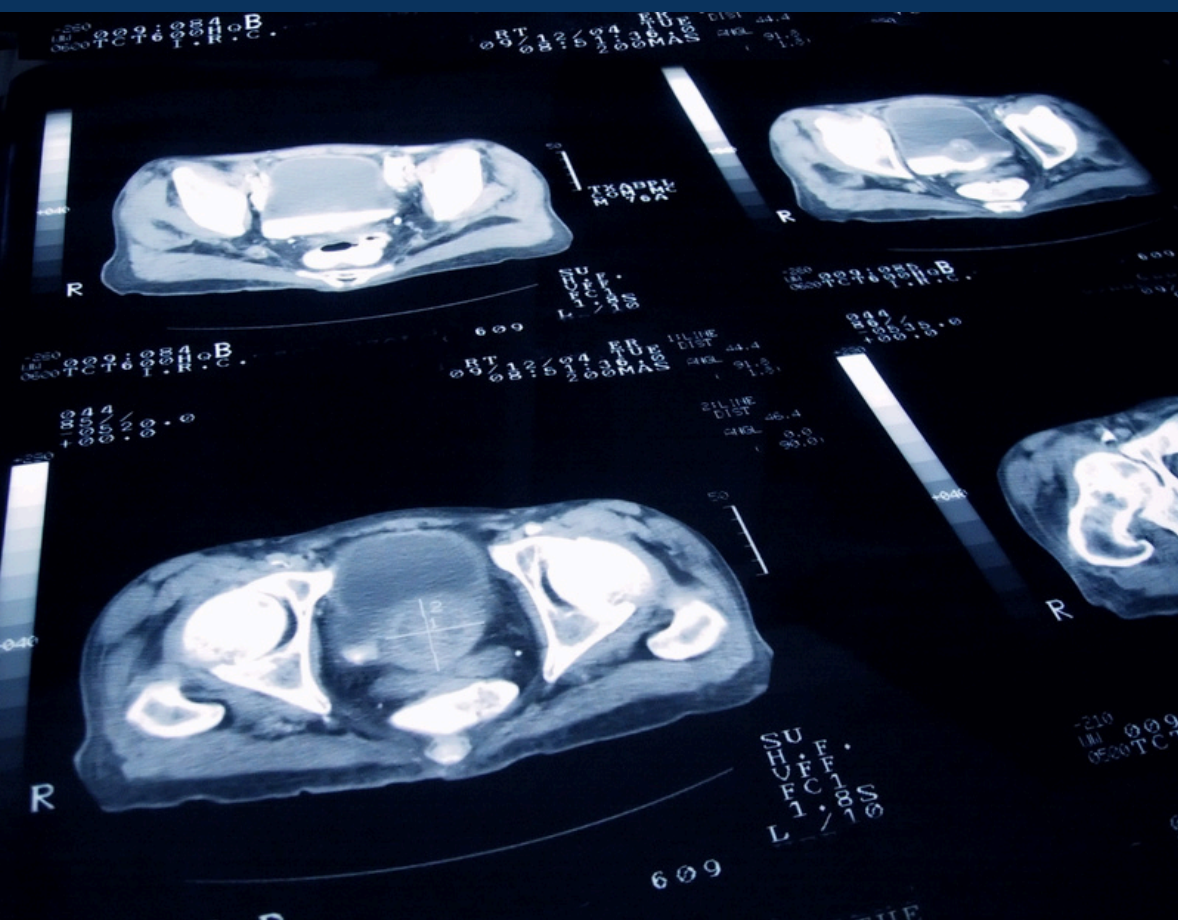
Metastasis-free survival (MFS) was the primary measure of success, evaluated through blinded independent central review. Enzalutamide, as monotherapy or in combination with leuprolide, significantly improved MFS compared to the placebo with leuprolide. The hazard ratios and p-values underscore the efficacy of enzalutamide in delaying disease progression.

Patients undergoing enzalutamide treatment experienced common adverse reactions like hot flushes, musculoskeletal pain, fatigue, and hemorrhage. Understanding these side effects is crucial for patients, families, and healthcare providers to ensure a balanced approach to treatment.

For those embarking on enzalutamide treatment, the recommended dose is 160 mg administered orally once daily, with or without food. The flexibility of administration and the option to suspend treatment based on PSA levels offer personalized care to patients.

The review process utilized the Real-Time Oncology Review (RTOR) pilot program, streamlining data submission. Remarkably, the FDA approved the application five weeks ahead of the goal date, showcasing the commitment to expediting access to promising treatments

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Enzalutamide, as monotherapy or in combination with leuprolide, significantly improved MFS compared to the placebo with leuprolide, underscoring its efficacy in delaying disease progression

Navegating Information

A NURSE NAVIGATOR'S APPROACH

in Oncology Care

By Ashlee Jones



A cancer diagnosis triggers a multitude of questions for patients, ranging from the reasons behind the diagnosis to concerns about the spread of the disease, potential outcomes, and the possibility of a cure

In the complex landscape of oncology, Ashlee Jones, our esteemed nurse navigator specializing in melanoma and sarcoma, stands as a beacon of support. Recognized by our entire team, including nurses, pharmacists, staff, research professionals, and physicians, Ashlee plays a pivotal role in simplifying the journey for patients newly diagnosed with cancer. Facing the challenges of an unfamiliar diagnosis, an array of initial tests, specialist appointments, and insurance concerns can be overwhelming, particularly in large, multi-institutional hospital settings. Our navigators, led by Ashlee, guide patients seamlessly from the initial clinic visit to the commencement of their first treatment.

A cancer diagnosis triggers a multitude of questions for patients, ranging from the reasons behind the diagnosis to concerns about the spread of the disease, potential outcomes, and the possibility of a cure. The answers to these questions often inundate patients with a deluge of new information, compounded by advice from friends and family, and information gleaned from internet searches. The result is information overload, heightening anxiety and complicating decision-making for patients.

The care team, comprising physicians, nurses, and support staff, serves as the primary source of information for oncology patients.

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It is crucial to present this information in a manner that enhances patient understanding without overwhelming them.

While all patients require basic information such as diagnosis, stage, and treatment options, the amount of information each patient can comprehend may vary significantly.

Helpful strategies for delivering information to patients include allowing ample time for questions during appointments, providing post-appointment resources like nurse navigators for further inquiries, recapping crucial points of the conversation, providing written materials, and circling back in future appointments or follow-ups to ensure ongoing understanding.

Eflornithine Breakthrough

FDA Approves Milestone Pediatric Oncology Therapy

for High-Risk Neuroblastoma

By Dr. Sajeve Thomas



In a watershed moment, the Food and Drug Administration (FDA) granted approval to eflornithine (IWILFIN, USWM, LLC) on December 13, 2023, ushering in a new era in pediatric oncology. This approval marks a historic breakthrough as the first-ever FDA endorsement for a therapy tailored to reduce the risk of relapse in pediatric patients grappling with high-risk neuroblastoma (HRNB).

Understanding the Efficacy of Eflornithine: Imagine eflornithine as a beacon of hope, navigating uncharted waters in the fight against HRNB.

The FDA's approval followed a meticulous evaluation of eflornithine's effectiveness in a trial that compared outcomes from Study 3b (investigational arm) and Study ANBL0032 (clinical trial-derived external control arm). Think of this as a comparison between two ships at sea, determining which one sails safer and stronger.

Key Efficacy Measures and Patient Impact: In Study 3b (NCT02395666), involving 105 HRNB patients, eflornithine showcased its prowess in a sea of uncertainty.

The primary focus was on event-free survival (EFS) - a measure of smooth sailing through disease progression, relapse, secondary cancer, or any cause of death. Picture EFS as a compass guiding the ship, with eflornithine demonstrating a notable hazard ratio in steering clear of treacherous waters.

Navigating the Seas of Safety and Adverse Reactions: Picture eflornithine as a sturdy ship with a manageable safety profile, weathering common adverse reactions like otitis media, diarrhea, and cough.

These challenges are akin to navigating unpredictable waves, yet eflornithine stands resilient, fostering a sense of security in its passengers.

Charting the Course for Pediatric Hope: The journey doesn't end with FDA approval; it's a call to action for healthcare professionals to join the voyage. Prescribing information serves as the map, detailing the recommended dosage based on body surface area. The Real-Time Oncology Review (RTOR) program acts as a navigation system, expediting data submission, with priority review, breakthrough designation, and orphan drug designation as the wind in the sails.



This approval marks a historic breakthrough as the first-ever FDA endorsement for a therapy tailored to reduce the risk of relapse in pediatric patients grappling with high-risk neuroblastoma (HRNB)

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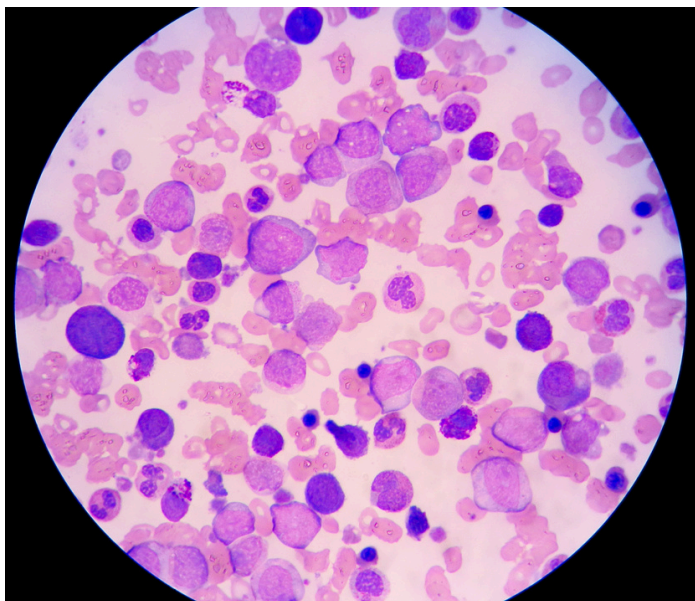
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Pirtobrutinib Accelerates Hope: FDA Approves Breakthrough CLL/SLL Treatment

By Dr. Daniel Landau



This approval stands as a lighthouse for adults navigating the turbulent seas of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after enduring two prior lines of therapy, resembling a resilient ship charting its course through uncharted waters



On December 1, 2023, a ray of hope emerged as the FDA granted accelerated approval to pirtobrutinib (Jaypirca, Eli Lilly and Company). This approval stands as a lighthouse for adults navigating the turbulent seas of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after enduring two prior lines of therapy, resembling a resilient ship charting its course through uncharted waters.

The BRUIN Trial: A Resilient Crew Facing Challenges: Imagine the BRUIN trial (NCT03740529) as a global expedition, where 108 courageous patients with CLL or SLL formed a resilient crew. These patients, having weathered at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor, embarked on a journey of discovery. Facing challenges akin to unpredictable currents, 77% of participants discontinued the last BTK inhibitor due to refractory or progressive disease.

Pirtobrutinib's Promise: A Guiding Beacon in the Dark: In the vast ocean of efficacy, pirtobrutinib emerged as a guiding beacon. Evaluated by an independent review committee using the 2018 iwCLL criteria, it showcased an impressive overall response rate (ORR) of 72%, akin to a beacon cutting through the darkness. The median duration of response (DOR) reaching 12.2 months symbolizes a period of stability, akin to a lighthouse providing stability to those navigating turbulent seas.

avigating Adverse Seas: Safety Profile and Challenges: Embarking on pirtobrutinib's journey comes with its share of challenges—fatigue, bruising, cough, musculoskeletal pain, and COVID-19. These are the turbulent seas that patients must navigate, akin to the unpredictable waves faced by a sturdy ship. Serious infections, reported in 32% of patients, and fatal infections in 10%, serve as reminders of the potential storms, emphasizing the need for vigilant navigation.

Embarking on pirtobrutinib's journey comes with its share of challenges—fatigue, bruising, cough, musculoskeletal pain, and COVID-19. These are the turbulent seas that patients must navigate, akin to the unpredictable waves faced by a sturdy ship



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