Ibrance Fda Approval History

Ibrance FDA Approval History

Ibrance, known generically as palbociclib, is a targeted therapy that has made significant strides in the treatment of breast cancer, particularly for hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) breast cancers. Developed by Pfizer, Ibrance received its FDA approval in February 2015, marking a pivotal moment in oncology treatments. This article explores the FDA approval history of Ibrance, detailing its development, clinical trials, and the impact it has had on breast cancer treatment.

Introduction to Ibrance

Ibrance is classified as a cyclin-dependent kinase (CDK) 4/6 inhibitor. It functions by interrupting the cell cycle of cancer cells, preventing them from proliferating. This action is particularly beneficial in HR+ breast cancer, where estrogen drives tumor growth. By inhibiting CDK4 and CDK6, Ibrance effectively halts the progression of these cancerous cells, often in conjunction with endocrine therapy.

Development Timeline

The journey of Ibrance from conception to approval is a testament to the rigorous process of drug development.

Early Research and Development

- 2000s: Initial research into CDK inhibitors began in the early 2000s, focusing on their potential to treat various cancers.
- 2010-2013: Pfizer developed palbociclib, conducting preclinical studies that demonstrated its effectiveness in inhibiting tumor growth in HR+ breast cancer models.

Clinical Trials

The pathway to FDA approval involved several pivotal clinical trials:

1. PALOMA-1 Trial:
- Phase: Early-phase (Phase 2).
- Aim: To evaluate the safety and efficacy of Ibrance in combination with letrozole (an aromatase inhibitor) in patients with HR+ HER2- breast cancer.
- Results: The trial showed a significant improvement in progression-free survival (PFS) compared to letrozole alone.

2. PALOMA-2 Trial:
- Phase: Randomized Phase 2.
- Aim: To confirm the findings of PALOMA-1 with a larger patient cohort.
- Results: The combination of Ibrance and letrozole demonstrated a PFS of 20.2 months compared to 10.2 months for letrozole alone, reinforcing the drug's efficacy.

3. PALOMA-3 Trial:
- Phase: Phase 3.
- Aim: To evaluate the efficacy of Ibrance in patients with HR+ HER2- breast cancer who had previously received endocrine therapy.
- Results: This trial demonstrated that Ibrance significantly extended PFS compared to placebo when combined with letrozole or an aromatase inhibitor.

FDA Approval Process

Ibrance's application for FDA approval was bolstered by the positive results from these clinical trials.

Submission for Approval

- Application Date: Pfizer submitted a New Drug Application (NDA) for palbociclib in September 2014.
- FDA Review: The FDA granted priority review designation due to the drug's potential to meet an unmet medical need in a serious condition.

Approval Announcement

On February 3, 2015, the FDA approved Ibrance for use in combination with letrozole as an initial endocrine-based therapy for patients with HR+ HER2- advanced breast cancer. This marked a significant milestone, as it was the first CDK 4/6 inhibitor approved for breast cancer treatment.

Subsequent Approvals and Indications

Following its initial approval, Ibrance underwent further evaluations and received additional indications:

Expanded Indications

- Combination with Other Therapies: Subsequent studies demonstrated Ibrance's efficacy in combination with various endocrine therapies, leading to its approval for use with additional medications.
- PALOMA-3 Results: The results from this trial not only supported its initial indication but also led to approval for use in patients who had previously received endocrine therapy.

Real-World Evidence and Post-Marketing Studies

Post-marketing studies and real-world evidence have continued to validate the effectiveness and safety profile of Ibrance in broader patient populations. These studies have provided insights into the drug's long-term impact and helped refine treatment protocols.

Impact on Breast Cancer Treatment

The approval of Ibrance has had a profound impact on the management of HR+ HER2- breast cancer:

Improved Patient Outcomes

- Increased PFS: Clinical trials consistently showed that Ibrance, combined with endocrine therapy, significantly increased progression-free survival compared to endocrine therapy alone.
- Quality of Life: Patients treated with Ibrance have reported improved quality of life markers, as the drug allows for longer control of the disease with manageable side effects.

Shift in Treatment Paradigms

The introduction of Ibrance has shifted treatment paradigms for HR+ breast cancer. It has encouraged the integration of targeted therapies with traditional hormonal treatments, leading to:

1. Personalized Treatment Plans: Oncologists can customize treatment regimens based on individual patient characteristics.
2. Increased Use of CDK 4/6 Inhibitors: Ibrance set a precedent for the development of other CDK inhibitors, expanding options for patients.

Challenges and Considerations

Despite its success, Ibrance is not without challenges:

Side Effects

Common side effects associated with Ibrance include:

- Neutropenia (low white blood cell counts)
- Fatigue
- Nausea
- Diarrhea
- Liver enzyme abnormalities

Patients require close monitoring to manage these side effects effectively.

Cost and Accessibility

The cost of Ibrance can be a barrier for many patients. Although insurance coverage can mitigate expenses, the high price point raises concerns about accessibility. Ongoing discussions regarding drug pricing in the U.S. healthcare system continue to be a critical consideration for patients and

healthcare providers alike.

Conclusion

The FDA approval history of Ibrance represents a significant milestone in the fight against breast cancer. Since its approval in 2015, Ibrance has transformed treatment paradigms, leading to improved patient outcomes and quality of life for those battling HR+ HER2- breast cancer. As ongoing research continues to explore its efficacy in various combinations and settings, Ibrance remains a cornerstone in the management of this prevalent disease. Future advancements in this area hold promise for even more effective and personalized treatment options for patients.

Frequently Asked Questions

When did the FDA first approve Ibrance?

Ibrance (palbociclib) was first approved by the FDA on February 3, 2015.

For what type of cancer was Ibrance originally approved?

Ibrance was originally approved for the treatment of HR-positive, HER2-negative breast cancer.

Has the FDA approved any additional indications for Ibrance since its initial approval?

Yes, the FDA has approved Ibrance for use in combination with letrozole as an initial endocrine-based therapy for HR-positive, HER2-negative breast cancer.

What is the significance of Ibrance's approval for the treatment of breast cancer?

Ibrance was one of the first CDK4/6 inhibitors approved, marking a significant advancement in targeted therapy for breast cancer, providing a new option for patients with HR-positive tumors.

Are there any notable clinical trials associated with Ibrance's FDA approval?

Yes, the approval of Ibrance was supported by the PALOMA-1 and PALOMA-3 clinical trials, which demonstrated its efficacy in combination with aromatase inhibitors.

Ibrance Fda Approval History

16 Best Fine Dining Restaurants in Sydney 2025
Jan 17, 2024 · Indulge in the best fine dining restaurants in Sydney! Discover top fine dining Sydney spots for exquisite cuisine, stunning views, and unforgettable experiences.

Best restaurants Sydney 2025: Gourmet Traveller's ultimate hitlist
Apr 23, 2025 · And for out-of-towners, we recommend Quay for fine-dining finesse with views of the harbour and Sydney Opera House. Whether you're a Sydney local routinely chasing the hottest new ticket in town or visiting the Harbour City for this year's thrilling instalment of Vivid Sydney, you'll want to book a table at these best Sydney restaurants ...

10 Best Fine Dining In Sydney Restaurants 2025 Guide
Dec 31, 2024 · 10 Best Fine Dining In Sydney Restaurants 2025 Guide Looking for the best fine dining in Sydney restaurants? Whether you're looking for somewhere to eat in Sydney to celebrate a special occasion or wondering where to eat for a corporate dinner, look no further.

THE 10 BEST Fine Dining Restaurants in Sydney (UPDATED 2025)
Best Fine Dining Restaurants in Sydney, New South Wales: Find Tripadvisor traveler reviews of THE BEST Sydney Fine Dining Restaurants and search by price, location, and more.

18 Best Luxury Restaurants in Sydney To Visit in 2025
BENNELONG RESTAURANT WITH ITS VIBRANT MULTICULTURAL population, Sydney is a hub for delicious eateries — from casual to fine dining, it's safe to say we are thoroughly spoiled for choice.

The Best Restaurants In Sydney Worth Booking In 2025 - Urban ...
Jul 1, 2025 · This is your guide to Sydney's best restaurants in July 2025, curated by our expert food editors and food-obsessed content creators.

54 of the best restaurants in Sydney for 2025 - Australian Traveller
Jul 17, 2025 · From hole-in-the-wall hotspots to fine dining gems, here are the Australian Traveller editors' picks of some of the best Sydney restaurants.

21 of the best fine dining restaurants in Sydney
May 23, 2025 · Discover the best fine dining restaurants in Sydney. Plan a special meal at Quay, Bennelong, Hubert, Ester, Mimi's, Icebergs and more.

The best new restaurants opening in Sydney in 2025 - RUSSH
Jul 21, 2025 · From Mediterranean-inspired havens, to a traditional Greek local, these are the restaurants opening in Sydney in 2025.

8 Best Michelin Star Restaurants Sydney Options [2025]
Apr 30, 2024 · LuMi Bar and Dining is a fine dining restaurant that has perfected its craft in creating fresh, modern Italian food with a Japanese twist. This Michelin star restaurants Sydney, which has

sweeping views of King Street Wharf, is renowned for its flawless presentation and culinary arts finesse.

15+ Best Restaurants In Sydney (2025 Edition) | Nox
Jan 1, 2025 · Craving amazing eats in Sydney? Dive into our 2024 guide to the top Sydney restaurants. From fine dining sensations to must-try local spots, your ultimate food journey starts here!

Sydney’s 10 Best New Restaurants 2025 (So Far) - Broadsheet
Jun 24, 2025 · MID-YEAR WRAP Sydney’s Best New Restaurants of 2025 (So Far) A good-times dining room in Surry Hills joins a charcoal grill with a perpetual crowd, an outstanding lasagne in the suburbs and a spot for punchy Bengali plates from a Firedoor alum.

クレジットカードの請求明細の**BB-MSFTEVETOKYO**という **...**
Jan 8, 2025 · クレジットカードの請求明細のBB-MSFT EVE TOKYOという詳細について質問です。どこからの請求でしょうか? 詐欺ですか? MicrosohtのOne Driveの容量を拡張するため …

カードでマイクロソフトから**14900**円の支払いがありました **...**
Jun 1, 2024 · カードでマイクロソフトから14900円の支払いがありました。ネットで見てみると、どうやら金額的にMicrosoft365の支払いだという事は分かりました。確かに、最近、試し …

*MSFT * E0800RAUZE MSBILL.INFO IRL - Microsoft Community*
Apr 14, 2024 · Hello,On my credit card statement, I read the following charge that I do not recognize: MSFT * E0800RAUZE MSBILL.INFO IRL EUR 123.85Then, if I go into the …

なぜマイクロソフトの略が*MSFT*なんですか? *- Yahoo!*知恵袋
Aug 5, 2024 · MSFTはNASDAQのティッカーで、4文字でわかりやすく、重複がないことが要求されます。 MSFTが上場した時に適当な4文字をマイクロソフトが自分で考えたときにそれ …

ペイディを利用していたのですが、身に覚えのない請求が**4**件 **...**
Oct 20, 2024 · 「MSFT JAPAN CO., LTD」と「Microsoft*Xbox」から4つとも16,500円の請求です。マイクロソフトのアカウントを確認したのですが、やはり注文履歴にはなく、明日マ …

Cannot find subscription - "MSFT"Billed on Credit Card
Jul 11, 2021 · I am being billed on my credit card monthly with a transaction code "MSFT". The microsoft billing information claims that microsoft billion show up as "microsoft" fully spelled out.

Unknown Device on Microsoft ACPI-Compliant System found in ...
Jul 25, 2023 · Dear AllI have found "Unknown Device on Microsoft ACPI-Compliant System found in my new computer". I have downloaded all latest driver from the ASUS and installed them, …

Unknown bills from MSFT - Microsoft Community
Jan 6, 2022 · I was checking an account that I don't view regularly and have mostly for subscriptions and quick payments.I noticed a charge of about 66 GBP I did not recognise with …

クレジットの明細を見ていると半年ほど前からMSFTというところ ...
Nov 15, 2022 · クレジットの明細を見ていると半年ほど前からMSFTというところから毎月身に覚えのない1496円が引かれており調べてみてマイクロソフトアカウントからサブスクリプ …

Unauthorised transaction MSFT * E0800CBSV7 Singapore
CA CatD3 Created on November 3, 2020 Unauthorised transaction MSFT * E0800CBSV7 Singapore

Explore the Ibrance FDA approval history

Back to Home