Pharmaceutical Research Summary: palbociclib

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Search Sources: EMA EPAR, EMA-PSBG, FDA Approvals, FDA-PSBG

Research Results

palbociclib – Regulatory Dossier

EPAR (EMA)

• [Ibrance: EPAR – Public assessment report](https://www.ema.europa.eu/en/documents/assessment-report/ibrance-epar-public-assessment-report_en.pdf) – EMA/CHMP, 2016-09-15
• Key points: Palbociclib (Ibrance) indicated for HR-positive, HER2-negative advanced or metastatic breast cancer in combination with endocrine therapy. Marketing Authorisation granted on 2016-11-09.

EMA-PSBG

• **Result:** No product-specific bioequivalence guidance found for palbociclib

FDA Approvals

• NDA 207103 – approval date (2015-02-03)
• Dosage form/strength: Capsules, 75 mg/100 mg/125 mg
• Review path: Accelerated approval
• Key letters:
• [Approval Letter](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/207103Orig1s000ltr.pdf)
• NDA 208295 – approval date (2019-04-04)
• Dosage form/strength: Tablets, 75 mg/100 mg/125 mg
• Review path: Original approval (standard review)
• Key letters:
• [Approval Letter](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/208295Orig1s000ltr.pdf)

FDA Review Package
• **Clinical Pharmacology Biopharmaceutics Review(s):**
• [Clinical Pharmacology and Biopharmaceutics Review for NDA 207103](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207103Orig1s000ClinPharmR.pdf) – 2015-02-03

FDA-PSBG
• **Result:** Guidance found
• Draft:
• [Palbociclib Capsules: Draft Guidance for Industry](https://www.fda.gov/media/144772/download) – 2020-10
• [Palbociclib Tablets: Draft Guidance for Industry](https://www.fda.gov/media/144773/download) – 2020-10

Clinical Trials

NCT	Phase	Primary Endpoint	Outcome Summary
NCT01740427	III	Progression-Free Survival (PFS)	Met primary endpoint. Significantly prolonged PFS (PALOMA-2).
NCT01942135	III	Progression-Free Survival (PFS)	Met primary endpoint. Demonstrated benefit in combination therapy.
NCT00721409	II	Progression-Free Survival (PFS)	Improved PFS leading to initial accelerated approval (PALOMA-1).

Summary of Key Regulatory Information
• First EMA approval: 2016-11-09
• First FDA approval: 2015-02-03
• Current EMA status: authorised
• Current FDA status: approved
• Orphan designations: none
• Safety/risk-management highlights: RMP in EU; labeling includes monitoring for neutropenia

Source URLs
• https://www.ema.europa.eu/en/medicines/human/EPAR/ibrance
• https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance
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• https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/208295Orig1s000ltr.pdf
• https://clinicaltrials.gov/