

OPTIMAL Trial – ASCO 2025



Paclitaxel oral (DHP107) vs. IV en cáncer de mama HER2- negativo

2025 ASCO[®]
ANNUAL MEETING

Phase III of Oral Paclitaxel (DHP107) vs. Intravenous Paclitaxel in HER2-Negative Recurrent or Metastatic Breast Cancer (mBC): Primary Analysis of Multinational OPTIMAL Trial

Sung-Bae Kim,^{1*} Binghe Xu^{2*}, Hye Hyun Jeong¹, Tao Sun³, Qingyuan Zhang⁴, Sanja Kostic⁵, Xiaojia Wang⁶, Zhongsheng Tong⁷, Shusen Wang⁸, Jingfen Wang⁹, Wei Li¹⁰, Keun Seok Lee¹¹, Yong Wha Moon¹², Myoung Joo Kang¹³, Xichun Hu¹⁴, Tae Yong Kim¹⁵, Dušan Milenković¹⁶, Jae Hong Seo¹⁷, Jee Hung Kim¹⁸, Jieun Lee¹⁹, Joohyuk Sohn²⁰

¹Asan Medical Center, University of Ulsan College of Medicine, Korea; ²Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, China; ³Liaoning Cancer Hospital, China; ⁴Harbin Medical University Cancer Hospital, China; ⁵University of Belgrade, Faculty of Medicine, Clinical Hospital Center Bežanijska Kosa, Serbia; ⁶Zhejiang Cancer Hospital, China; ⁷Tianjin Cancer Hospital, China; ⁸Sun Yat-sen University Cancer Center, Sun Yat-sen University, China; ⁹Linyi Cancer Hospital, China; ¹⁰First Affiliated Hospital of Jilin University, China; ¹¹National Cancer Center, Korea; ¹²CHA Bundang Medical Center, CHA University, Korea; ¹³Inje University Haeundae Paik Hospital, Inje University College of Medicine, Korea; ¹⁴Fudan University Shanghai Cancer Center and Shanghai Medical College, Fudan University, China; ¹⁵Seoul National University Hospital, Korea; ¹⁶Clinical Center MB, Faculty of Medicine, Serbia; ¹⁷Korea University Guro Hospital, Korea; ¹⁸Gangnam Severance Hospital, Yonsei University College of Medicine, Korea; ¹⁹Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Korea; ²⁰Severance Hospital, Yonsei University College of Medicine, Korea.

*Sung-Bae Kim and Binghe Xu contribute equally

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PRESENTED BY: Sung-Bae Kim, MD, PhD

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KNOWLEDGE CONQUERS CANCER

- Paclitaxel IV requiere solventes → reacciones adversas y visitas hospitalarias.
- DHP107 (Liporaxel®): formulación oral sin solventes.
- Objetivo: demostrar no inferioridad en SLP vs. IV.

Contexto

Diseño del Estudio

- Ensayo fase III, abierto, multinacional, aleatorizado.
- 402 pacientes con cáncer de mama HER2-recurrente/metastásico.
- DHP107 oral vs. paclitaxel IV.
- **Objetivo primario:** supervivencia libre de progresión (SLP valorada por el investigador).
- **Objetivos secundarios:** SLP (valorada centralmente) SG, ORR, calidad de vida.

Resultados principales

- SLP mediana: 10,02 meses (oral) vs. 8,54 meses (IV). (HR 0,869; (95% CI, 0,707-1,068).
- SG mediana: 32,62 vs 31,80 (HR: 0,967; (95% CI, 0,762-1,22) .
- Tasa Respuesta objetiva 43,32% vs 38,78% y Tasa Control de la enfermedad 89,17% vs 84,41%.
- Tiempo hasta el fracaso del tratamiento mediana 7,62 vs 7,43.

Conclusions

- This study demonstrated non-inferiority of DHP107 versus IV paclitaxel in terms of progression-free survival.
- Overall survival, objective response rate, disease control rate, time to treatment failure, and QoL are comparable between DHP 107 and IV paclitaxel.
- DHP107 exhibited a clinically manageable safety profile with lower incidences of peripheral neuropathy, hypersensitivity reactions, and infusion-related reactions.

DHP107 is an effective, convenient alternative to IV paclitaxel for patients with HER2-negative mBC, supporting its potential role in routine clinical practice.

Key Takeaway Points/Conclusions

Oral paclitaxel, DHP107, demonstrated comparable efficacy to IV paclitaxel with tolerable and manageable toxicity in chemotherapy-naïve, HER2-negative mBC.

DHP107 is an effective, convenient alternative to IV paclitaxel for patients with HER2-negative mBC, supporting its potential role in routine clinical practice.

