

**ABSTRACT**

**IG-001:Genexol-PM®**

IG-001 (Genexol-PM™) is a Cremophor-free, polymeric micellar formulation of Paclitaxel. IG-001 is in a phase I/II study for the treatment of breast cancer and has been approved in South Korea for the treatment of metastatic breast cancer (MBC) in 2012. The study design of IG-001 is described below.

**Phase 3: multicenter, randomized comparison of the safety and efficacy of weekly TOSCON® Paclitaxel (100 mg) vs. weekly Paclitaxel injection (80 mg) in the treatment of metastatic breast cancer (MBC)**

**Objective:**

- To compare the objective response rates (ORR) as assessed by RECIST in patients with MBC treated with TOSCON® Paclitaxel or Paclitaxel injection

**Endpoints:**

- Complete response (CR) or partial response (PR) rate
- Time to progression (TTP)
- Overall survival (OS)
- Progression-free survival (PFS)
- Quality of life (QoL)

**Study Design:**

- TOSCON® Paclitaxel (100 mg/m²)
- Paclitaxel injection (80 mg/m²)

**Key Points:**

- TOSCON® Paclitaxel is a novel formulation of Paclitaxel that can be administered as an intravenous bolus, allowing for a shorter infusion time compared to the traditional 240-minute infusion
- The study demonstrated a superior safety profile with TOSCON® Paclitaxel, with fewer adverse events and a shorter hospital stay
- TOSCON® Paclitaxel has shown promising results in the treatment of MBC, with a high response rate and prolonged progression-free survival

**CONCLUSIONS:**

- TOSCON® Paclitaxel is a promising new formulation of Paclitaxel for the treatment of MBC
- Further clinical trials are needed to confirm these findings and explore the potential of TOSCON® Paclitaxel in a broader range of cancer indications