About the GENESIS Trial
The GENESIS trial (NCT03246529) is a 2-part, Phase-3, randomized, double-blind, placebo-controlled, multicenter study.1

**Primary Objective:**
- The primary objective of Part 2 was to evaluate if one dose of motixafortide plus filgrastim (G-CSF) compared to placebo plus filgrastim, for the mobilization of hematopoietic stem cells (HSC) in patients with multiple myeloma

**Patient Population:**
- A total of 122 multiple myeloma patients from 18 sites in 5 countries were enrolled and randomized to receive motixafortide plus filgrastim or placebo plus filgrastim.

**Study Design:**
- **Part 1** was a single center, open-label study involving 12 patients treated with motixafortide in a single apheresis session.
- **Part 2** was a double-blind, placebo-controlled, multicenter study involving 110 patients treated with motixafortide in a single apheresis session.

**Local Laboratory Data Analyzed:**
- Local laboratory data were used for sensitivity analysis. Data are descriptive, leading to the use of local laboratory data for all patients in the APHEXDA plus filgrastim arm versus 9.5% in the placebo arm (as measured by local laboratory data).

**Additional GENESIS Data:**
- 86.3% of patients harvested at least 6 million stem cells after one dose and one apheresis session in the APHEXDA treatment arm.1

**SAFETY**
- Injection site reactions (73%) including pain (53%), erythema (27%), and pruritus (24%) have been reported with APHEXDA.
- Other adverse reactions include:
  - **Hypersensitivity:** Anaphylactic shock and other serious hypersensitivity reactions have been reported.
  - **Immune-mediated:** Injection site reactions, pancreatitis, hypokalemia, and hyperkalemia have been observed.
  - **Drug-related:** Hypotension, hypotension-related, and vasovagal syncope have been reported.
- **Embryo-fetal Toxicity:** Based on its mechanism of action, APHEXDA can cause fetal harm. Advise pregnant women of the potential risk to the fetus and advise use of effective contraception during treatment and for 8 days after the final dose.
- **Lactation:** There are no data on the presence of motixafortide in human milk, the effects on the breastfed child, or the effects on milk production.

**INDICATION**
- APHEXDA is indicated for the mobilization of hematopoietic stem cells (HSC) in patients with multiple myeloma in advance of an autologous transplantation.

**INDICATION AND IMPORTANT SAFETY INFORMATION**
- Please see the Prescribing Information and the full Prescribing Information before prescribing APHEXDA.

**References:**