Background: The HERMIONE study was conducted to assess, in HER2-positive early breast cancer, the safety profile of subcutaneous formulation of trastuzumab (SC T) in real life in France.

Methods: This prospective, multicenter, noninterventional study included 511 patients planned to be treated in both neoadjuvant and adjuvant settings with a follow-up (FU) of 12 months maximum. The safety analyses concerned 305 patients, either naive (40.4%) or non-naive (59.6%) of intravenous trastuzumab (IV T). According to routine practice, patients received concomitant locoregional radiotherapy (68.7%), endocrine therapy (59.9%) and chemotherapy (37.8%). Primary endpoint was the description of systemic and local Adverse Events (AEs) of SC T assessed by NCI-CTCAE. Congestive Heart Failure (CHF), hepatobiliary toxicity and suspected transmission of an infectious agent by SC T were AEs of Special Interest (AESIs). Secondary endpoints included description of patients, disease characteristics and modalities of SC T administration. Quality of life (QoL) was assessed by QLQ-C30.

Results: Patients were included in 101 sites between January and November 2015. The median age was 58 years. Over the FU period, AEs occurred in 422 patients (83.6%): 92 AEs (3.8%) were grade ≥ 3, 76 (3.1%) were serious, 87 (3.6%) were AESIs and 336 (13.7%) were related to SC T. Most frequent AEs (>10% of patients) were asthenia, arthralgia, radiation skin injury, myalgia, hot flush and diarrhea. Main grade ≥3 events were radiation skin injury (1.8% of patients) and febrile neutropenia (1.4%). Serious AEs (SAEs) included febrile neutropenia (9.2% of SAEs) and pulmonary embolism (6.6%). Main AESI was CHF in 11.5% of patients and was related to SC T only in 4.5%. Injection site pain was the main SC T Related AE (9.1% of patients). Few AEs (1.4%) led to permanent SC T discontinuation. Only 1 death assessed as not related to SC T (pulmonary thromboembolism) was reported. QoL analyses showed no deterioration of global health status.

Conclusions: The Hermione study showed that the safety of SC T (HERCEPTIN®) in a real-life setting is consistent with the known profile, without new safety concerns or QoL deterioration.

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A retrospective study was conducted to compare cardiac toxicity profile of adjuvant fixed-dose subcutaneous T and weight-based intravenous T, according to anthropometric data which takes into account more than simply weight.

**Results:**

- Amongst ER negative patients, the pCR rate was greatest in the TCHP group (75% TCHP vs 37% FEC-THP).
- Despite the small subgroup most likely to achieve pCR were ER negative patients treated with TCHP.
- Across all regimens, pCR rates were greatest in ER negative patients, regardless of regimen. The pCR rate was 81% amongst D regimens.

**Conclusions:**

- Pertuzumab-containing regimens improved pCR rates (ypT0ypN0) compared with Herceptin plus chemotherapy in the neoadjuvant setting.
- The highest pCR rate was seen in dual targeting regardless of ER or nodal status.

**Disclosure:**

All authors have declared no conflicts of interest.

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**Disclosure:**

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