

Tanvex biopharma announced today (08/24/2017) the successful completion of the phase III clinical trial for TX01, a proposed biosimilar of US-licensed Neupogen (filgrastim). The trial results are as follows.

1. Subjects: healthy volunteers
2. Actual subject number: 319
3. Location of the trial: US and Canada
4. Clinical trial design and results

The trials are composed of three studies, all conducted in a random and double blind fashion to compare TX01 and US-licensed Neupogen in terms of PK/PD bioequivalence, safety and immunogenicity.

Study 1:

- A. Study design: Single dose, randomized and double blind, cross over study, to compare TX01 and reference product Neupogen in terms of pharmacokinetics, pharmacodynamics (primary endpoints), immunogenicity and safety (secondary endpoints). The main PK parameters are Area under the serum concentration curve (AUC) and the maximum serum concentration (C_{max}). The main PD parameters are the maximum absolute neutrophil count (ANC), E_{max}, and the area under the ANC curve (AUEC). 49 healthy subjects were included in this study.
- B. Study results: All PK and PD parameters met the bioequivalence criteria (the 90% confidence interval of the ratio of the mean of TX01 vs. Neupogen lies completely within 80-125%). Safety wise, TX01 have similar adverse events known to be associated with Neupogen in terms of type, seriousness and rates. No anti drug antibodies were found in this study. Therefore, TX01 and Neupogen demonstrated similarity in terms of safety and immunogenicity. The pre-specified study endpoints are met.

Study 2:

- A. Study design: Multiple dose, randomized and double blind, cross over study, to compare TX01 and reference product Neupogen in terms of pharmacodynamics (primary endpoint), immunogenicity and safety (secondary endpoints). The main PD parameters are based on the CD34 positive cell counts. 50 healthy subjects were included in this study.

- B. Study results: PD parameters met the bioequivalence criteria (the 90% confidence interval of the ratio of the mean of TX01 vs. Neupogen lies completely within 80-125%). Safety wise, TX01 have similar adverse events known to be associated with Neupogen in terms of type, seriousness and rates. Anti drug antibodies were found in a few subjects in this study. However, the antibody showed low titers, were transient and not neutralizing, and did not appear to impact PD or safety. Therefore, TX01 and Neupogen demonstrated similarity in terms of safety and immunogenicity. The pre-specified study endpoints are met.

Study 3:

- A. Study design: Multiple dose, randomized and double blind, parallel study, to compare TX01 and reference product Neupogen in terms of immunogenicity (primary endpoint), and safety (secondary endpoint). For immunogenicity, the rate of antidrug antibody, titer, persistence and neutralizing ability are characterized and compared. 220 healthy subjects were included in this study.
- B. Study results: Anti drug antibodies were found in a few subjects in this study. However, the antibody showed low titers, were transient and not neutralizing. The upper bound of the 1-sided 95% confidence interval of the anti drug antibody rate difference between TX01 and Neupogen is lower than the pre-determined non-inferiority margin of 10%. Safety wise, TX01 have similar adverse events known to be associated with Neupogen in terms of type, seriousness and rates. Therefore, TX01 and Neupogen demonstrated similarity in terms of immunogenicity and safety. The pre-specified study endpoints are met.