Article Title: LBEC0101, a Proposed Etanercept Biosimilar: Pharmacokinetics, Immunogenicity, and Tolerability Profiles Compared with a Reference Biologic Product in Healthy Male Subjects

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Fig 1. Comparison of individual pharmacokinetic parameters Cmax and AUCinf of etanercept based on ADA status after a single 25-mg etanercept subcutaneous administration (Left: LBEC0101, Right: Enbrel®).

(a) (b)
Fig 2. Mean changes of major laboratories over time after a single 25-mg etanercept subcutaneous administration (Solid circle: LBEC0101, Solid triangle: Enbrel®).

Dash line: normal range (albumin: 3.5-5.0 g/dL, ALT: 0-40 IU/L, AST: 0-40 IU/L, serum creatinine: 0.7-1.4 mg/dL, hs-CRP: 0-0.5 mg/dL)

The error bar (downward: LBEC0101, upward: Enbrel®) denotes the standard deviations.
Fig 2. Mean changes of major laboratories over time after a single 25-mg etanercept subcutaneous administration (Solid circle: LBEC0101, Solid triangle: Enbrel®).

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The error bar (downward: LBEC0101, upward: Enbrel®) denotes the standard deviations.
Fig 3. Relationship between body mass index (BMI) and the natural log-transformed maximum concentration (ln (Cmax), Left) or area under-the-concentration-time curve from time 0 to infinity (ln (AUCinf), Right) after a single 25-mg etanercept subcutaneous administration (Solid square: LBEC0101, Open circle: Enbrel®). A linear regression line is overlaid. r²: determination coefficient.
Fig 4 Relationship between weight and the natural logarithm of maximum concentration ($\ln(C_{\text{max}})$, Left) or the natural logarithm of area under-the-concentration-time curve from time 0 to infinity ($\ln(AUC_{\text{inf}})$, Right) after a single 25-mg etanercept subcutaneous administration (Solid square: LBEC0101, Open circle: Enbrel®)

A linear regression line is overlaid. $r^2$: determination coefficient

$$\ln(C_{\text{max}}) = 3.23 - 0.04 \times \text{weight}, \; r^2 = 0.3585 \text{ in LBEC0101}$$

$$\ln(C_{\text{max}}) = 2.94 - 0.04 \times \text{weight}, \; r^2 = 0.3209 \text{ in Enbrel®}$$

$$\ln(AUC_{\text{inf}}) = 8.26 - 0.04 \times \text{weight}, \; r^2 = 0.3700 \text{ in LBEC0101}$$

$$\ln(AUC_{\text{inf}}) = 7.83 - 0.03 \times \text{weight}, \; r^2 = 0.3589 \text{ in Enbrel®}$$