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Mechanism of Action (MOA): Reflecting bioassays for biosimilar drug development

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The demand for biosimilars and bioassays for biosimilars are increasing as the patent cliff approaches for many blockbuster biologics drugs. Recently, the expanded approval of Actemra (Tocilizumab) to treat CAR-T (Chimeric antigen receptor T) cell-induced cytokine release syndrome (CRS) demonstrated the role of anti-IL-6 blocking drugs as critical for the treatment of serious diseases such as cancer and autoimmune diseases. To address this need we have developed a suite of luciferase reporter-based bioassays to support the development and potency determination of biosimilar drugs targeting cytokines such as IL-2, IL-6, IL-12, IL-15, IL-12/23, IL-17, VEGF, RANKL, Epo, IFNs, etc. The availability of quantitative functional bioassays in thaw-and-use format provides the benefit of convenience, reproducibility, and transferability. We demonstrate these assays are able to measure relative potency for antibody biologics and detect potency changes for stressed antibody samples. In summary, the reporter-based bioassay portfolio for biosimilars provides a valuable tool for antibody screening, development, stability testing, and potency determination in manufacture of biosimilars and biobetters.

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