IS02-1 **Effect of Added Alkalizer and Surfactant on Dissolution and Absorption of a Novel CGRP Inhibitor**

○Allen C TEMPLETON[1], Dina ZHANG[1], Michael H KRESS[1]
[1]Pharmaceutical Sciences & Clinical Supply, Merck Research Laboratories

As an integral part of drug product development, it is essential that factors such as stability, bioavailability, and processability are thoroughly evaluated. The magnitude of a specific challenge is correlated to the product's position in the development continuum. Fortunately, most formulation challenges of material impact to the composition and process have been resolved as a part of careful early investigations and scale-up evaluations. We discuss a case of the need to bridge the bioperformance of two formulations of Talcagepant. The case study can be dissected into the following sections: 1. Formulation redesign necessitated by multiple stability challenges. 2. Rapid screening, optimization and selection of a replacement formulation. 3. Successful design and execution of formulation bioequivalency studies with the replacement formulation. Since development is inter-dependent across many areas, decisions needed to be made prior to the availability of a complete dataset, resulting in risk. This case study will also highlight risk assessment strategies that impacted the approach to the optimization of the replacement formulation and conduct of the bioequivalency studies.