

Registration Enabling Seamless Phase 1/2 Oncology Trial Design

Jun Dong

Amgen Biopharmaceutical R&D (Shanghai) Co., Ltd.

E-mail: jund@amgen.com

Abstract: In recent years, cases have shown the possibility of regulatory (accelerated or conditional) approval with phase 2 data for oncology products, when the treatment effect is clinically meaningful and relatively large. This is also consistent with China CDE's policy for conditional approval where the drug meets urgent clinical needs. In this presentation, an example design is shown, where the phase 1 dose exploration, phase 1b dose expansion and phase 2 are seamlessly integrated. In the single arm phase 2 portion, the investigational product is compared with external control for efficacy evaluation. Conditional approval is then sought after with a phase 3 confirmatory trial. Other adaptive component can be incorporated as well to further accelerate the clinical development process.