Case Study 6

Case Study 6: Using competitor's product in a Phase 2 trial offsets the need to conduct one of the required Phase 3 trials

Challenge: Reduced spend and accelerated approval – how engaging Camargo with its in-depth understanding of the 505(b)(2) pathway pays for itself multiple times over.

Background: Traditional NDA drug development requires at least two Phase 3 clinical studies and this requirement exists for both 505(b)(1) and 505(b)(2) NDAs. However, this requirement can be met for 505(b)(2) NDAs in several ways. In some cases, literature may provide robust support to eliminate the need entirely for sponsor-conducted trials. Where two trials are needed, but the need for safety information is not critical, a combination of a Phase 2 and Phase 3 may be possible. In short, knowledge of each FDA therapeutic drug divisions' practices and how previous drugs have been approved can lead to fewer studies with reduced scope and cost with shorter timelines.

Solution: The existing competitive products to the client's product provide symptom relief, but do not treat the disease. By leveraging this knowledge and experience gained from more than 800 FDA meetings, Camargo was able to gain FDA agreement to use one of the competitor products in a Phase 2 trial which was then used to offset the need to conduct one of the required Phase 3 trials. Further, the Phase 3 trial was reduced in scope (fewer patients).

Outcome: A cost of $10MM was avoided as well as 18 months gained on market approval, enabling earlier entry into an expected >$300MM/year market.