Drug Delivery Technology

New Gold-Standard of Treatment

A biotech company targeted a new oncology indication with an improved delivery technology of an already-approved drug. Because the active pharmaceutical ingredient had been previously approved and the public domain has information to access in lieu of conducting new clinical trials, the biotech knew its intended drug indication needed to be approved via the U.S. FDA 505(b)(2) regulatory pathway.

Intending to tap in-house drug development experience, the biotech began nonclinical trials, but found it had trouble addressing multiple issues with the FDA. Because there is no standard approach to achieving a 505(b)(2) NDA, the client realized it needed help gaining approval – their in-house expertise was not enough to develop the drug without causing permanent damage to their program from the regulatory perspective.

When the client approached Camargo to help sort out the misunderstandings, Camargo leveraged its frequent exposure and long-standing relationship with the division in the FDA, developed a strategy which would enable an efficient path through approval, and compiled evidence advocating the safety and efficacy of the drug.

With the added benefit of utilizing Camargo's standard cross-functional teams, the biotech's program gained careful examination from each angle of the drug development program, with the goal of program optimization.

Camargo's cross-functional team corrected and rewrote the deficient modules, including 2.4, 2.6, 2.7, and 4. The team crafted the nonclinical data into a meaningful story, covering essential pharmacokinetics, toxicology, nonclinical testing strategy, pharmacodynamics, and toxicokinetics, as well as compiling relevant nonclinical study reports.

Properly assembled, not only did the studies show outstanding results, but also revealed the patients' unprecedented success with the drug, resulting in remission and longer lives.

Once presented as a high-value, viable, and realistic drug product with imminent regulatory success, a parent company acquired the originating biotech company for a substantial sum. The drug gained approval, and has the potential to become a new "gold standard" treatment in oncology.

Camargo celebrates the successes of our client partners, especially when a drug has a significant impact in helping patients in need.