phase, Catalent conducted a series of tests to determine the molecule's physicochemical properties and its chemical compatibility with different excipients, the molecule's solubility and its developability classification system (DCS), solid-state characterization, and stability. At the enhance phase, Catalent evaluated three enabling technologies in parallel, based on the data from the "assess" phase. These included lipid-based formulation, amorphous solid dispersion, and particle size engineering. In 12 weeks, Catalent provided prototypes employing all three technologies for use in an animal PK study, and delivered a full report with recommendations and all data, which included two weeks' stability testing data.

Trio tested all the prototypes in the animal study, and the data showed the bioavailability of all prototypes for TML-2 was greatly increased, says Dr. Woodrow. Among these prototypes, micronization (particle size engineering) showed the most substantial bioavailability enhancement (4 times).

At the early stages of the development process, which spans from drug candidate selection to Phase 1 clinical studies, Catalent offers a continuum of solutions, including druggability, preformulation, toxicity enabling formulation, formulation screening, and fast clinical supplies to Phase 1. When incorporated, these solutions accompany a molecule to proof-of-concept in-man studies. "This continuum leverages differentiated enabling technologies, often targeted at addressing complex bioavailability challenges that go way beyond simple exposure issues, and ensure successful dose escalation in single ascending dose studies," says Mr. Meissonnier.

At later stages of product development, Catalent leverages a toolkit of differentiated technologies to ensure appropriate matching to complex release profiles. This toolkit of technologies addresses complex extended-release profiles, as well as the growing demand in targeted release delivery.

Savings in development time are important. But with regulators making evermore stringent demands for broader, increasingly global clinical trials, working with a company that can offer strategies and methods to accelerate a product's journey through the trial process to marketing authorization and commercial manufacture, is critical, says Mr. Meissonnier. "This holistic view of development to commercialization can maximize the time a product enjoys patent protection, and reduce how long it takes for it to recoup its development costs."

CordenPharma: Focusing on Small-Molecule Oncolytics

Cancer remains the second leading cause of death and represents the largest category of new medicines. A range of new mechanisms is expected to drive innovation and growth for the CDMOs that have the right expertise and capabilities in this area, says Jason Bertola, Director, Global Highly Potent & Oncology Platform, CordenPharma International. "Greater understanding of cancer progression has led to the development of increasingly targeted approaches, which mean not only increased safety and efficacy for the patients but also increased manufacturing requirements and need for containment and engineering controls," he says. "For example, antibody drug conjugates (ADCs) offer better safety profiles for patients, but manufacturers must be able to produce and handle cytotoxic drugs that are significantly more potent than their chemotherapeutic predecessors."

Manufacturing at CordenPharma Plankstadt (Germany).

Despite significant focus on biologics, small molecules still represent more than half of the total market. For instance, tyrosine kinase inhibitors and poly ADP-ribose polymerase inhibitors are among the small-molecule targeted therapies. These products are also driving the need for oral solid dose highly potent manufacturing. Some estimates predict oral oncolytics to be 25%-30%[2] of the market, double the figures from 10 years ago.

CordenPharma's service offering targets the oral formulation development and manufacturing of oncolytics. "Recent investments have expanded our capabilities to develop and supply clinical trial materials and small-scale manufacturing. Engineering controls are in place to allow the safe handling of compounds in development and manufacturing," he says.

HERMES PHARMA: Ensuring Quality Right From the Start

Quality has always been a key priority for the pharmaceutical industry, however, over the last year CDMOs like HERMES PHARMA have observed an increased em-