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WHITEPAPER

Novel uses for oral solid doses driving lifecycle management strategies

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Abstract

With few potentially epic drugs in the pharma pipeline right now, drug companies are seeking options to meet the needs of patients and increase revenue in the oral solid dosage (OSD) arena. Current strategies include exploring fixed dose combinations, reformatted injectables, and most intriguing, drugs that carry digital, ingestible sensors that can send information directly to a physician. Currently there is only one.

Portfolio expansion implementing lifecycle management strategies is less expensive than developing a new drug from scratch, as safety and efficacy have been previously established. In this whitepaper, Thermo Fisher Scientific shares ideas and opportunities that brand managers looking to expand their portfolios in a cost-effective manner—while helping patients—will find helpful.

Introduction

With few potential blockbuster drugs in the pharma pipeline right now, drug companies are increasingly looking at other options to meet the needs of patients and increase revenue in the oral solid dosage (OSD) arena. Current areas of exploration include novel drug combinations, oral delivery of large molecules that were available only as injectables, and perhaps most interesting, drugs that carry digital, ingestible sensors that can send information directly to a physician.

"The new drug pipeline is shrinking," says Anil Kane, PhD, Global Head of Technical and Scientific Affairs at Thermo Fisher Scientific, a leading contract development and manufacturing organization. "So many companies are looking to expand their product portfolio from their existing molecules. They are looking into many different lifecycle management strategies."

Fixed dose combinations

The most common strategy today, says Kane, is to expand into "fixed dose combinations." This typically entails combining two existing molecules, resulting in a formulation that has a synergistic effect, a better safety profile, fewer side effects, or a better release profile. Some of these combinations offer a novel "multiple release" profile where, for example, one drug is formulated to be released in the stomach, where there is maximum absorption and clinical efficiency, while the other is designed to be released only in the lower GI tract. Or one portion might be released immediately, while the other is released over time.

Reformatted injectables

Another new trend, he says, is reformulating large molecules that were previously used only as injectables, so they can be taken orally. With a new dosage form, the molecule can be protected from gastric acid, allowing patients to take it in pill form. Most people prefer pills over injections, so the new form could lead to better patient compliance.

Patient compliance issues, in fact, are driving much of the new formulation work, says Kane. "There is a lot of data showing that drugs are not effective, not because they don't work, but because they are not taken as they are prescribed." Drug companies are thus trying to find ways to make their drugs more appealing to patients to increase compliance. Reducing side effects, making a drug available as an oral dose, lowering the total number of pills a patient has to take each day—all can potentially lead to better patient compliance.

Currently, it is possible to formulate some drugs so they are released over 48 hours. "But can we reduce the pill burden even further?" Kane asks. "Can we develop a once-a-week or once-a-month oral solid dose formulation?" That option is now being explored.

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Digitized drugs

The third new trend is digitized drugs. "We are definitely seeing an increased interest in digitized medicines," again in relation to patient compliance, says Kane. These drugs contain ingestible sensors that, once inside the body, can send a signal to a skin patch, indicating that the dose was indeed taken, the identification number of the individual pill, and other data. The skin patch can also record the patient's biometrics, such as posture, pulse rate and blood pressure, and all of the information can be uploaded to a smartphone app and shared with the patient's physician or others. Digital sensors can also be used to track drug supply chains, to foil counterfeiters, and to avoid misuse.

"With these sensors, we'll be able to see if drugs are getting to the correct patients, or if they are being diverted and sold on the street."

Such technology could be particularly useful in the formulation of narcotics and opioid drugs, which are all too often sold illegally. Tagging unit dosage forms such as tablets and capsules with ingestible circuits with unique identifiers—bar codes, lot number, manufacturer—can help tracking medication (beyond serialization) in the supply chain, thereby avoiding counterfeit.

Currently, only one drug with an ingestible sensor has been approved by the Food and Drug Administration: Abilify MyCite® (aripiprazole tablets with sensor). But Kane predicts that pharma companies will develop many more applications of digitized medicines in coming years.

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Expanding an existing portfolio with lifecycle management strategies does involve some expense, but it's not nearly as expensive as developing an entirely new drug. "You don't have to start from scratch," says Kane. "The safety and efficacy of the existing drug have already been established. That forms a strong foundation for exploring potential benefits with other formulations.

"At Thermo Fisher Scientific, we know the opportunities we can leverage from these and other trends. We are happy to share these ideas with brand managers, to explore ways to expand their portfolios in a cost-effective manner that will help patients."

About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 55 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. We give pharma and biotech companies of all sizes instant access to a global network of facilities and technical experts across the Americas, Europe, Asia and Australia. Our global leadership is built on a reputation for scientific and technical excellence. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. As a leading pharma services provider, we deliver unrivaled quality, reliability and compliance. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

Anil Kane, PhD, MBA

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Dr. Kane has more than 25 years of experience in the science and business of taking molecules through the entire drug development process. His extensive knowledge spans early stage development to scale-up and commercial manufacturing, and includes technical transfers between global sites and drug life cycle management. Dr. Kane received his Bachelors, Masters and Ph.D. degrees from the Bombay College of Pharmacy, University of Bombay, India, and served as a post-doctoral fellow at the School of Pharmacy, University of Cincinnati, Ohio. He has also earned an executive MBA from Richard Ivey School of Business, University of Western Ontario, Canada. Dr. Kane is a member of various international pharmaceutical professional organizations, and is often asked to speak about scientific topics on formulation, technology other technical aspects, QbD, etc at major industry events. He has also published many articles in International journals and delivered many talks at meetings and conferences cross the globe.

In his current role, Dr. Kane leads a team of "Subject Matter Experts" to support our clients in developing sound formulation and process development strategies and closely works with the scientific teams at Thermo Fisher Scientific's global sites for execution, provides leadership in the complete development of novel lead compounds and line extensions. He is also responsible for evaluating drug delivery technologies to support the business. Dr. Kane has been an invited speaker at many global conferences, workshops, seminars and training programs and has published several articles, interviews and white papers across the world including North American, European, Japanese and Korean publications.

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Published 04/21

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