Medicines360 IS DRIVEN TO EMPOWER WOMEN

Trending now: *New nonprofit pharma company changing access to medicine.*

SAN FRANCISCO-BASED Medicines360.org is a nonprofit pharma company that is doing things differently from traditional pharma companies. Its mission is to help remove barriers and improve access to healthcare in the public sector.

Dedicated to women's health, Medicines360 is changing access through a new, ground-breaking model, including a structure to reinvest earnings into further technological innovation and distribution of contraceptives to women who want them. Medicines360 is driven to empower women, regardless of socioeconomic status, age, weight, or race, to take charge of their healthcare and have choices.


Pamela Weir

The company developed Liletta, an intrauterine device (IUD), now FDA approved, based on the largest ever hormonal IUD pivotal study in the United States.

To expand access, Medicines360 has partnered with Actavis. Proceeds from the commercial Liletta sales will be used to provide the IUD at an affordable price to public sector clinics. Millions of women in need of birth control and without health insurance are now able to afford and choose an IUD.

Chief Operating Officer Pamela Weir says Actavis has an incredible women's health salesforce in the private sector.

Ms. Weir is a 25-year pharma veteran, most recently serving as VP of marketing at King Pharmaceuticals and Nycomed — now part of Pfizer — and Takeda Pharmaceutical.

YourEncore Assembles Top-Level Experts for Regulatory Practice

YourEncore, which helps life-sciences, consumer products, and food companies solve complex product development and regulatory challenges, is bringing together a group of high profile pharmaceutical, consumer packaged goods (CPG), and Food & Drug Administration executives and opinion leaders to launch a regulatory practice.

The YourEncore regulatory practice is comprised of experts who have deep experience running regulatory departments for the world's largest pharmaceutical companies.

In addition, experts will include former senior FDA officials and policy thought leaders, with expertise spanning the entirety of drug development.

Members of the YourEncore regulatory practice include: Don Ashbrook, Ph.D., a 30-year pharmaceutical industry veteran with experience in international drug, device, and biotech development, is CEO of Triligent International, which focuses on compliance issues management; Brian Daniels, M.D., former senior VP, global development and medical affairs for Bristol-Myers Squibb with extensive drug development experience; Joe Lamendola, Ph.D., former VP, regulatory affairs for Bristol-Myers Squibb and Schering-Plough Research Institute; Neal Matheson, former chief technology office, global R&D at Unilever, is currently is an advisor to multiple start ups; Bob Meyer, M.D., director of the Virginia Center for Regulatory and Translational Science at the University of Virginia School of Medicine, who previously served as chair of PhRMA's regulatory affairs committee, VP of global regulatory strategy at Merck, and director of drug evaluation for the FDA; Peter Pitts, president of the Center for Medicine in the Public Interest and chief regulatory officer at Adherent Health Strategies, who is also the former associate commissioner for external relations at the FDA; and Don Therasse, M.D., a 16-year veteran of Eli Lilly & Co., where he served as VP, global patient safety.

The regulatory practice is led by Tim Franson, M.D., YourEncore's chief medical officer. Dr. Franson also is the president of the U.S. Pharmacopeial Convention.

What's New on the Shelves

New Book Helps Drug Makers Make More Informed Predictions in an Unpredictable Market

How will sales for a blockbuster drug erode once a comparable (but cheaper) alternative hits the market? To what extent will increased competition impact orphan drugs in the pipeline?

Pharmaceutical companies constantly try to predict — or forecast — answers to these and similar questions; answers that affect crucial business decisions today. Financial groups make R&D investments based on anticipated sales for a new drug. Marketing teams forecast success ratios of various tactics when planning a go-to-market strategy. Members of the C-suite look to forecasts to provide accurate direction in product portfolio decisions.

But while forecasting quantifies revenue potential and drives a number of tactical and strategic decisions at pharmacos, almost everyone struggles to make accurate, fact-based predictions.

In response to this impasse, global forecasting expert Arthur G. Cook writes about the inherent issues with legacy forecasting practices and ingenious solutions to overcome them in, Forecasting for the Pharmaceutical Industry: Models for New Product and In-Market Forecasting and How to Use Them.

Forecasting for the Pharmaceutical Industry is available on Amazon.com. For more details, visit http://bit.ly/1OBLiWp.

PointCross Life Sciences and InterpretOmics partner for Clinical and Genomic Biomarker Management for Drug Development

PointCross Life Sciences has announced a strategic partnership with InterpretOmics to provide an in-

tegrated big data and globally accessible environment for genomic interpretation and analysis of all biomarkers collected in the context of clinical trials and nonclinical studies. This platform serves the needs of precise or multitargeted drug candidates, stratified patient selection and ex-post analysis of efficacy and disease progression-free survival.

"The tidal shift to biology and genomics driven drug development and the need for precise, targeted clinical trials for reducing costs and improving efficacy for targeted patients has already happened," says Dr. Shree Nath, VP, PointCross Life Sciences. "The integration of our RDIS platform with iOmics allows us to address critical industry needs with a visionary integration capable of exploiting diverse data types to identify important safety and efficacy signals."

TransCelerate BioPharma Launches Two New Global Initiatives

TransCelerate BioPharma has established two new global initiatives to accelerate and enhance clinical trials. Both initiatives — Placebo/Standard of Care Data Sharing and Electronic Labels for Clinical Trials (e-Labels) — are made possible through the collaboration of participating member companies. They aim to create solutions that will have a direct impact on patients, sponsors, and investigative sites.

The Placebo/Standard of Care Data Sharing Initiative has the potential to create a framework for data sharing that offers the potential to reduce the patient population needed to be enrolled in a clinical trial, as it intends to allow for the leverage of data from previous studies respecting boundaries of informed consent.


Craig Lipset

It would thereby decrease the time spent on cumulative trial execution, and assist in acceleration of new therapies to patients.

It also offers the potential for more rapid understanding of safety signals to better manage patient safety during clinical trials, as well as identify statistical techniques that may deliver more accurate study design and statistical power calculations.

The e-Labels Initiative supports TransCelerate member companies in establishing an innovative information channel: electronic labels (e-Labels). This initiative will work to enhance label utility for patients, provide more consistent labeling approaches for sites, and offer the potential to reduce clinical labeling timelines and provide cost efficiencies for sponsors.

The Initiative, in collaboration with regulatory agencies, will develop guidance to facilitate implementation of e-Labeling.

Craig Lipset, head of clinical innovation at Pfizer, and executive sponsor of the TransCelerate e-Labels Initiative, says this effort aims to make product information more accessible to patients and to permit deeper engagement during the clinical trial process.

Membership in TransCelerate is open to pharmaceutical and biotechnology companies with research and development operations.

Executive offices are located in Philadelphia, PA. For more information, visit transceleratebiopharmainc.com.

Kadmon Launches Gene Therapy Unit

Kadmon Corp. has launched Kadmon Gene Therapy Holdings, Limited (KGT), a new, independently managed subsidiary focused on the development of novel gene therapy treatments for a range of inherited and acquired disorders. The company will initially focus on developing therapies for ocular diseases, including rare inherited blindness, and xerostomia following radiation treatment for head and neck cancer.

KGT anticipates having four gene therapy products in clinical studies in 2016. PV

Global Updates…

Clinipace Worldwide Expands European Operations with Acquisition of Accovion

Clinipace Worldwide, a global digital contract research organization (dCRO), has completed the merger with Accovion, a European full-service CRO with headquarters in Frankfurt, Germany.

Accovion provides the entire range of clinical services to the pharmaceutical, biotechnology, and medical device industries. Bringing these organizations together strengthens Clinipace Worldwide's operational and therapeutic expertise in Europe, with strong back-end and front-end services, and expands the company's footprint to additional countries including Russia, Italy, Czech Republic, Romania, Poland, Spain, France, and Ukraine.

Dr. Andree Beckerling, the CEO of Accovion, has day-to-day operating responsibility for all of the European offices, including existing Clinipace staff and locations.

Incyte to Establish European Headquarters in Geneva, Switzerland

Incyte has established the new headquarters of Incyte Europe in Geneva, Switzerland. The company intends to use Incyte Europe as the base from which it will conduct its European clinical development operations, and expects to occupy the 9,000-square-foot facility by mid-2015.

"The establishment of Incyte Europe in Geneva is a natural step in our company's evolution," says Hervé Hoppenot, president and CEO of Incyte. "Incyte has a broad and growing pipeline of proprietary, wholly owned products, and we expect that this new facility in the center of Europe will enable us to create the infrastructure needed to support our global drug development programs, and to bring additional, potentially life-changing medicines to patients with cancer."

Pfizer Acquires Minority in Dutch Company

Pfizer has acquired a minority equity interest in AM-Pharma, a recombinant human alkaline phosphatase for inflammatory diseases, and secured an exclusive option to acquire the remaining equity in the company. The option becomes exercisable upon completion of a Phase II trial of recAP in the treatment of acute kidney injury (AKI) related to sepsis. There are no drugs currently approved for this condition and the only treatment option is dialysis and supportive care. Results from the current Phase II trial for recAP are expected in the second half of 2016.

Pfizer has made an upfront payment of $87.5 million for the minority equity interest and exclusive option, with additional potential payments of up to $512.5 million.