Week of September 29, 2014

In This Issue:

1. Home Search Central Interface.

1. Home/Search Central Interface

If you have been paying attention you will have noticed the change in the PharmaCircle Home/Search Central interface. We have most recently moved from a rainbow color scheme to one that is more monochromatic. Thanks for your patience and your input into the redesign process.

For those of you who miss the earlier interface with all of the modules on a single screen the option remains to access them by clicking on the All Modules panel for users with individual login credentials. This is now the default panel for those of you with a single corporate login interface. Both user groups still have the option to see selected subsets of the modules by clicking the panels on the left side of the Home/Search Central screen.

2. Kurt's News Picks - PDF Format

In response to a reader request we will be including a PDF version of Kurt's news from the past week. Some of you may find this an easier way to scan the news and identify items of interest. The link will be provided in the Kurt's Drug Delivery & Formulation Highlights section of the newsletter.

A reminder that the PharmaCircle Enhanced Links will take you to the same article but with links to additional PharmaCircle subscriber content related to the news item, often company and product information.

Upcoming Drug Delivery & Formulation Conferences

For a complete list go to the PharmaCircle Meetings Page

October 2014

Partnerships Drug Delivery
October 14-15, Massachusetts

November 2014

AAPS Annual Meeting
November 2-6, California

Abuse Deterrent Formulations
November 17-18, Washington DC

January 2015

Drug Delivery Partnerships
January 28-30, Florida
3. Kurt's Drug Delivery & Formulation Highlights (PDF Link)

From the Week of of September 22, 2014

Product Approvals

Alimera Sciences Receives FDA Approval For ILUVIEN®, The First Long-Term Treatment For Diabetic Macular Edema (9/26) PharmaCircle Enhanced Link

Ligand Earns Milestone Payment Triggered by EU Approval of Merck's Captisol-enabled NOXAFIL® (posaconazole) Concentrate for Solution for Infusion (9/26) PharmaCircle Enhanced Link

Boehringer Ingelheim Announces FDA Approval of Spiriva® Respimat® (tiotropium bromide) Inhalation Spray for the Maintenance Treatment of COPD (9/25) PharmaCircle Enhanced Link

AbbVie's HUMIRA® (adalimumab) Receives U.S. FDA Approval for the Treatment of Pediatric Patients with Moderately to Severely Active Crohn's Disease (9/25) PharmaCircle Enhanced Link

Noven Receives FDA Approval of a New Indication with a New Dose for Minivelle® (Estradiol Transdermal System) (9/24) PharmaCircle Enhanced Link

Dr. Reddy's Announces Approval and Launch of LEVALBUTEROL INHALATION SOLUTION, USP FOR ORAL INHALATION ONLY (9/24) PharmaCircle Enhanced Link

Celgene Announces the Swissmedic Approval of ABRAXANE® for Treatment of Both Metastatic Pancreatic and Breast Cancers (9/23) PharmaCircle Enhanced Link

Product Filings

Positive CHMP Opinion for MOVENTIG (naloxegol) (9/26) PharmaCircle Enhanced Link

Novartis drug Signifor® LAR recommended by CHMP for EU approval to treat patients with rare hormonal disorder acromegaly (9/26) PharmaCircle Enhanced Link

AcelRx Pharmaceuticals Provides Regulatory Update on Zalviso™ (9/26) PharmaCircle Enhanced Link

Medunik Canada announces Health Canada Priority Review of PHEBURANE© indicated for the treatment of Urea Cycle Disorders (UCD) (9/24) PharmaCircle Enhanced Link

FDA Receives Paragraph IV Notice Letter for KUVAN(R) (sapropterin dihydrochloride) Tablets (9/24) PharmaCircle Enhanced Link
Product Deals

Nicox completes the acquisitions of Doliage and of the Carragelose® anti-viral eye drop program (9/26) PharmaCircle Enhanced Link

Sumitomo Dainippon Pharma and SanBio Conclude Joint Development and License Agreement for North America With Respect to SB623, a Therapy for Stroke (9/26) PharmaCircle Enhanced Link

PharmaEngine and Merrimack Amend MM-398 License Agreement (9/26) PharmaCircle Enhanced Link

IGI Laboratories, Inc. Acquires Eighteen Former Products From AstraZeneca (9/25) PharmaCircle Enhanced Link

The Medicines Patent Pool Adds New Sub-Licensing Agreements to Improve Access to Novel ARVs in Developing Countries (9/25) PharmaCircle Enhanced Link

Genzyme Collaborates on Gene Therapy for Rare Disease that Causes Childhood Blindness (9/24) PharmaCircle Enhanced Link

Baxter and Merrimack Pharmaceuticals Enter into Exclusive Ex-U.S. Licensing Agreement to Develop and Commercialize Novel Cancer Compound MM-398 (9/24) PharmaCircle Enhanced Link

NovaDel Announces the Sale of Its ZolpiMist® New Drug Application, License and Intellectual Property to Amherst Pharmaceuticals, LLC (9/22) PharmaCircle Enhanced Link

Technology Deals

None for week

Drug Delivery Patent News

Actavis Confirms Generic Butrans® Patent Challenge (9/25) PharmaCircle Enhanced Link

Regulus Announces Notice of Allowance from U.S. Patent Office Related to microRNA-103/107 Program in Metabolic Disorders (9/24) PharmaCircle Enhanced Link

iCeutica Receives Key Patent for SoluMatrix Fine Particle Technology Platform (9/23) PharmaCircle Enhanced Link

Technology News

People News

Columbia Laboratories Announces Appointment of New Chief Financial Officer (9/24) PharmaCircle Enhanced Link

Financial/Company News

Shire Reaches Final Agreement with U.S. Government (9/24) PharmaCircle Enhanced Link

Foamix Pharmaceuticals Ltd. Announces Closing of Initial Public Offering (9/23) PharmaCircle Enhanced Link

Echo Therapeutics Suspends Operations To Conserve Liquidity (9/23) PharmaCircle Enhanced Link

Nanobiotix expands operations into the USA as part of its international development strategy (9/22) PharmaCircle Enhanced Link

Acquisitions

Allergan Issues Statement Regarding Recent Valeant Correspondence (9/25) PharmaCircle Enhanced Link

Product News

Pain Therapeutics Expands Pipeline With FENROCK(TM), an Abuse-Deterrent Pain Patch (9/23) PharmaCircle Enhanced Link

Prosensa extends the re-dosing of drisapersen in Europe in patients with Duchenne muscular dystrophy (9/26) PharmaCircle Enhanced Link

Sagent Pharmaceuticals Announces the Launch of GLYDO(TM) (Lidocaine HCI Jelly USP, 2%) (9/26) PharmaCircle Enhanced Link

Bausch + Lomb and Nicox's Glaucoma Candidate VESNEO® (latanoprostene bunod) Meets Primary Endpoint in Phase 3 Studies (9/25) PharmaCircle Enhanced Link

Braeburn Pharmaceuticals' Probuphine® Study Hits Enrollment Milestone (9/25) PharmaCircle Enhanced Link

Inovio Pharmaceuticals Ebola Vaccine Moving into Human Trial with GeneOne Life Science (9/24) PharmaCircle Enhanced Link

Lipocine Announces Positive Top-Line Results in Its Phase 3 Study of LPCN 1021 for Oral Testosterone Replacement Therapy (9/24) PharmaCircle Enhanced Link

Gilead's Investigational Tenofovir Alafenamide (TAF)-Based Single Tablet HIV Regimen Meets 48-Week Primary Objective in Two Phase 3 Studies (9/24) PharmaCircle Enhanced Link

Brickell Announces Positive Preliminary Results of a Pilot Clinical Study of BBI-4000 for the Treatment of Hyperhidrosis (9/24)
Alnylam Initiates DISCOVERY, a Screening Study Examining the Prevalence of Transthyretin (TTR) Mutations in Patients Suspected of Having Cardiac Amyloidosis (9/24) PharmaCircle Enhanced Link

Egalet Announces Update on Clinical Development Plan for Abuse-Deterrent Morphine Egalet-001 (9/23) PharmaCircle Enhanced Link

OPKO’s Second Rayaldee Phase 3 Trial Meets Primary Endpoints (9/23) PharmaCircle Enhanced Link

Diclegis® for Morning Sickness Now Available Through California and Nebraska Fee-For-Service Medicaid Programs (9/23) PharmaCircle Enhanced Link

Oxabact® granted EMA Orphan Drug Designation for treatment of SBS (9/23) PharmaCircle Enhanced Link

Portage Announces New Consultants for its PPL-003 Development Programs (9/23) PharmaCircle Enhanced Link

Tekmira Joins International Consortium to Conduct Clinical Trials of Ebola Virus Therapeutics in West Africa (9/23) PharmaCircle Enhanced Link

KemPharm Receives Health Canada Approval to Begin KP201 Clinical Trials in Canada (9/23) PharmaCircle Enhanced Link

Novaliq GmbH reports positive results from CyclASol® (Cyclosporin A solution) eye drops repeated and ascending dose Phase 1 study (9/23) PharmaCircle Enhanced Link

Nuvilex's Partner, Austrianova, Publishes Scientific Review Article Emphasizing Use of Cell-in-a-Box(R) for Treatment of Diabetes (9/22) PharmaCircle Enhanced Link


CytRx Announces Presentation of Aldoxorubicin Global Phase 3 Soft Tissue Sarcomas and Global Phase 2b Small Cell Lung Cancer Trial Designs at ESMO 2014 Congress (9/22) PharmaCircle Enhanced Link

Neuralstem ALS Investigator Presents Long-Term Follow Up Phase I Data (9/22) PharmaCircle Enhanced Link

Hemispherx Announces Primate Research Showing Alferon® LDO Protection from Pulmonary Damage Associated with Infection by Highly Pathogenic Influenza Virus (9/22) PharmaCircle Enhanced Link

DBV Technologies Announces Primary Endpoint Met in VIPES, Viaskin® Peanut’s Phase IIb Clinical Trial in Peanut Allergy (9/22) PharmaCircle Enhanced Link

Anacor Pharmaceuticals Announces Commercial Launch of KERYDIN (tavaborole) Topical Solution, 5% in the United States (9/22) PharmaCircle Enhanced Link
Mylan Pharmaceuticals recalling nitroglycerin spray due to defective pump (9/20) PharmaCircle Enhanced Link

Founded in 2003, PharmaCircle is a leading provider of authoritative content and expert analysis on the pharmaceutical, biotechnology, medical device and animal health industries. PharmaCircle’s flagship platform provides a comprehensive view on all aspects of the pharmaceutical business with in-depth, global coverage of research, development, regulatory, clinical, and commercial activities. Most multinational pharmaceutical companies as well as numerous commercial and emerging stage biopharmaceutical companies and suppliers rely on PharmaCircle for a full service solution for seamless content integration, layered analytics and data-driven tactical support, enabling them to uncover new opportunities and make informed business decisions.

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