Are Scientists Closing In on Treatments for Schizophrenia’s Most Elusive Symptoms?
By Bill Myers

Researchers, buoyed by a spike in promising clinical trials and tools, believe they may be close to unraveling new ways to treat some of the most insidious yet elusive effects of schizophrenia.

Scientists have long divided schizophrenia according to its so-called positive and negative symptoms. “Positive” signs are the most obvious and familiar—the hallucinations and delusions. The “negative” ones are more subtle — and harder to treat. They’re things like apathy, the inability to feel any emotion and disorganized thinking — symptoms that tend to hide in plain sight.

Decades of research into treatments, especially for the mental disorder’s “negative” effects, have turned up empty, leaving scientists discouraged and patients out of options. But now, for the first time in years, many longtime researchers say it looks like the tide may be turning.

“There’s been this slow but steady effort, on the part of the whole industry, both to redouble our efforts to find new treatments but also, perhaps, a little renaissance, if you will, in our thinking about how to evaluate negative symptoms,” says Mark Opler, chief research officer at MedAvante-ProPhase.

“The cautious optimism springs out of these small signs of hope.”

There are currently 177 active trials worldwide on potential targets or therapies

see Schizophrenia on page 4

WHO: Focus on Biosimilar Differences
By Bill Myers

Clinical trials of biosimilars should focus on how they differ from the drugs they copy rather than on creating a whole new safety or efficacy study, the World Health Organization says.

The group says it’s considering new standards for biosimilars because the industry has exploded since it last updated its rules nearly a decade ago.

WHO, in proposed guidelines posted on its website last week, suggests that “clinical development can be abbreviated” as long as sponsors can prove a biosimilar drug’s molecular structure and effect on patients mimic that of the original product.

Comparing the molecular structures and patient immune responses may allow sponsors to skip separate safety or efficacy trials and extrapolate results for regulators. But more complex products, such as monoclonal antibodies (made by identical immune cells that are clones of a unique parent cell), might require more extensive analysis before any data can be generalized, WHO says.

Some countries strictly control the biosimilar industry while others have little to no oversight. So the health agency says it’s also time to revisit the rules to come up with a uniform set of regulations. It notes, for instance, that the FDA has tougher standards for approval of biosimilars than the European Union, which lacks the authority to determine

see Biosimilar Differences on page 5

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August 6, 2018

Industry Briefs…2-3

Drug & Device Pipeline News…7

Nineteen drugs and devices have entered a new trial phase this week.

Trial Results…8

CenterWatch reports on results for four drugs.

JobWatch…9

Job listings, networking events and educational programs.
FDA Signs Off on Treatment for Rare Adrenal Gland Tumors

The FDA has approved the injectable drug Azedra for rare cancers of the adrenal glands — the first ever non-surgical therapy OK’d for these tumors. Azedra (iobenguane I131) is a radiotherapy drug that attacks tumors with a high, specifically targeted dose. It’s designed to treat adults and children (12 and older) with inoperable locally advanced or metastatic cancers called pheochromocytoma and paraganglioma. Pheochromocytoma forms inside and paraganglioma grows outside the adrenal gland(s). Both tumor types release hormones that can cause symptoms including high blood pressure, rapid heartbeat and anxiety.

University of Pennsylvania researchers gave 68 patients in a trial at least one therapeutic dose of Azedra. The results: 25 percent who received at least one dose and 32 percent of those who received two doses saw their blood pressure drop enough to cut their hypertension meds in half. “This is a true breakthrough. Until today, there were no anti-tumor therapies available for patients with these tumors who were not candidates for surgery,” said principal investigator Daniel Pryma, an associate professor of Radiology and Radiation Oncology. “This therapy not only controls the tumors but also the debilitating symptoms caused by their excess hormone production, meaning it provides dual benefit to patients,” added Pryma, also chief of Penn’s Nuclear Medicine and Clinical Molecular Imaging. Reported side effects include low white blood cell and platelet counts, fatigue and anemia. The FDA gave Azedra an Orphan Drug designation, Fast Track status and Breakthrough Therapy designation, giving the 35 ALS patients (in their ongoing 2a trial) 50 mg of ibudilast twice a day for 36 weeks. They’ll monitor participants’ physical function and scan brain activity to see if the drug helps slow disease progression. The trial is being led by Nazem Atassi, associate director of Massachusetts General Hospital’s Neurological Clinical Research Institute.

Antioxidant May Help Prevent Hearing Loss in Kids in Chemo

The antioxidant sodium thiosulfate may help prevent hearing loss in children being treated with the chemotherapy drug cisplatin, researchers have found. Drugs such as cisplatin have offered near-miraculous as cisplatin have offered near-miraculous treatment for Parkinson’s disease. Induced pluripotent stem cells (iPS) are derived from skin or blood cells and induced back into an embryonic-like pluripotent state that can divide into more stem cells or become any type of cell in the body, leading to a potentially unlimited source of any type of human cell needed for therapeutic purposes. They’re considered promising for regenerative research because they can become different human cells and, also, avoid controversy surrounding stem cells from human embryos. Researchers plan to transplant iPS cells into the brains of Parkinson’s patients in the hope they will help repair or replace damaged nerve cells. This is the first trial of its kind to use iPS cells. Scientists say they’re cautiously optimistic after testing the process in monkeys, who showed improvement and didn’t develop brain tumors — a much-feared potential side effect.

ALS Trial: Enrollment Complete

Researchers have attained full enrollment in a trial testing whether the anti-inflammatory drug ibudilast can help protect patients from the ravages of ALS. MediciNova wants to see if ibudilast can help prevent microglia — immune-triggering cells in the brain and spinal cord — from targeting healthy nerve cells as Amyotrophic Lateral Sclerosis progresses. ALS, also known as Lou Gehrig’s disease (after the baseball legend who died from the condition), is a progressive neurodegenerative disorder. There’s no known cure and patients typically die within five years of diagnosis. Researchers plan to give the 35 ALS patients (in their ongoing 2a trial) 50 mg of ibudilast twice a day for 36 weeks. They’ll monitor participants’ physical function and scan brain activity to see if the drug helps slow disease progression. The trial is being led by Nazem Atassi, associate director of Massachusetts General Hospital’s Neurological Clinical Research Institute.

Japan Greenlights Parkinson’s Trial Using Adult Stem Cells

In the first trial of its kind, Kyoto University scientists have won approval from Japanese regulators to test adult stem cells as a possible treatment for Parkinson’s disease. Induced pluripotent stem cells (iPS) are derived from skin or blood cells and induced back into an embryonic-like pluripotent state that can divide into more stem cells or become any type of cell in the body, leading to a potentially unlimited source of any type of human cell needed for therapeutic purposes. They’re considered promising for regenerative research because they can become different human cells and, also, avoid controversy surrounding stem cells from human embryos. Researchers plan to transplant iPS cells into the brains of Parkinson’s patients in the hope they will help repair or replace damaged nerve cells. This is the first trial of its kind to use iPS cells. Scientists say they’re cautiously optimistic after testing the process in monkeys, who showed improvement and didn’t develop brain tumors — a much-feared potential side effect.
New Low Blood Sugar Marker
Researchers at Louisiana State University say they may have found a new way to determine whether someone is suffering from dangerously low blood sugar. They believe that analyzing the way brains use acetate may be an indication of hypoglycemia-associated autonomic failure (HAAF), a potentially deadly condition in diabetics whose blood sugar levels crash so often they stop experiencing symptoms. The body often looks for alternate sources of energy like acetate when it doesn’t have enough glucose or sugar. So researchers wondered if spikes in acetate levels might be triggered by or correspond with low blood sugar. In a small trial, LSU researchers had six healthy men check into the hospital for continuous glucose monitoring over four days. They then had participants fast for 72 hours — offering them only water — before rescaning their acetate levels. The results showed fasting reduced their blood-sugar levels and also increased their acetate concentrations. Those with higher baseline acetate concentrations suffered from longer periods of hypoglycemia, the team found. Researchers hope their findings will bring trial participants who took Alunbrig showed “a statistically significant” improvement in progression-free survival rates. Alunbrig is awaiting FDA approval as a frontline treatment for lung cancer.

Team Finds Ebola Antibodies
A team of Vanderbilt University researchers say they’ve identified two antibodies that appear to neutralize three different strains of the deadly Ebola virus. Ebola kills about half the people it infects, according to the World Health Organization (WHO). Researchers report in the July 17 issue of the journal Immunity that they isolated the antibodies EBOV-515 and EBOV-520 in blood plasma samples from 17 survivors. Researchers said the findings are a “promising” step in the search for a vaccine against the disease, which claimed at least 11,000 lives between 2014 and 2016 in West Africa. That was the largest and most complex Ebola outbreak since the virus was first discovered in 1976, according to WHO.

Lung Cancer Drug Shows Promise
Alunbrig may help extend patient life spans, according to early results from Phase III trials of the lung cancer drug, Takeda’s Alunbrig (brigatinib) is a small-molecule targeted cancer therapy designed as a tumor inhibitor. Researchers are testing the drug to see if it can improve progression-free survival in lung cancer patients better than Merck’s Keytruba (crizotinib), another targeted therapy. About half the participants in the ALTAL 1L trials were given 180 mg of Alunbrig once a day; the rest were given 250 mg of crizotinib twice daily. According to results released last week, cancer patients better than Merck’s Keytruba.
for schizophrenia's negative symptoms, according to the FDA. That's the most in recent memory, Opler says — and certainly in the four years since Roche announced that its once-promising drug bitopertin — a glycine uptake inhibitor then being considered as an adjunct to antipsychotics for the treatment of persistent negative and poorly controlled positive symptoms — flunked its Phase III trials.

After bitopertin’s failure, trials for drugs to ease negative symptoms seemed to go into eclipse, Opler says. But two years later, researchers led by Sonia Dollfus of Centre Hospitalier Universitaire de Caen in France published the results of a study based on analysis of negative symptoms from an unlikely source: the patients themselves.

The team created the Self-evaluation of Negative Symptoms (SNS) survey, which made sure that questionnaires were specific enough for research — that negative symptoms aren't exclusive to schizophrenia. People with other conditions like Alzheimer's and Parkinson's disease as well as those recovering from a stroke also often report feeling apathetic or un-motivated.

And it may be that the dearth of successful trials since clozapine hit the market will help yet by giving the industry “a better sense of what doesn’t work,” MedAvante’s Opler says.

“It’s too soon to tell yet whether this is the beginning of another renaissance,” he adds. “But I don’t think it’s an accident that we’re suddenly seeing so much creativity in assessments and so much creativity in the search for new molecules.”

244 European patients were hospitalized and taken off antipsychotic and psychotropic drugs before being given either a placebo or MIN-101 daily for 12 weeks. The findings, published in the American Journal of Psychiatry: The ones who took the drug showed “statistically significant improvement.” Minerva is now recruiting for a Phase III MIN-101 trial, according to the FDA.

In an ironic twist, part of the recent optimism comes from a seemingly vexing insight — that negative symptoms aren't exclusive to schizophrenia. People with other conditions like Alzheimer's and Parkinson's disease as well as those recovering from a stroke also often report feeling apathetic or un-motivated.

That suggests scientists may be looking at “a behavioral syndrome,” British researchers Masud Husain and Jonathan Roiser say in the most recent issue of Nature. Drug tests on mice and rats “have revealed the complexity of neurotransmitter involvement in motivated behavior,” they write. “This seems an area ripe for investigation, given the clear clinical need and close correspondence between behavioral tests developed for human and animal models.”

And it may be that the dearth of successful trials since clozapine hit the market will help yet by giving the industry “a better sense of what doesn’t work,” MedAvante’s Opler says.

“There’s been this slow but steady effort, on the part of the whole industry, to redouble our efforts to find new treatments.”

— Mark Opler, chief research officer, MedAvante-Prophase
**Biosimilar Differences** (continued from page 1)

whether a biosimilar is interchangeable with the drug it’s patterned after.

The global patchwork — especially in developing countries — has allowed many biosimilars that “do not now meet current WHO regulatory expectations” to come to market, the 36-page draft guidance warns. “Very little is known about the safety and efficacy of these individual products.”

WHO regulations already require sponsors to test new biotherapies to make sure patient immune systems won’t reject them in clinical trials. The proposed guidelines say the same rules should apply to biosimilars. That means sponsors would have to show that their knock-offs’ molecular makeup or amino acid sequences are almost identical to those of the originals. The group also recommends testing trial participants for anti-drug antibodies triggered by the original and copied versions — and investigating any differences even if the biosimilar stokes fewer anti-drug antibodies.

An FDA spokesperson said the agency is reviewing the proposals and would provide feedback. But the U.S. already has similar regs in place so the most likely scenario is that these guidelines would help force the rest of the world to play catch up.

The FDA has approved 17 biosimilars over the past decade, five of them last year. Read the WHO’s draft guidance here: www.fdanews.com/08-01-18-WHO.pdf.

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**Europe Hits Pause Button on Clinical Data As Brexit Stirs Staff Upheaval**

*By Bill Myers*

European regulators have stopped accepting and publishing clinical trials data, blaming the uncertainty of Brexit for staff cutbacks that the agency claims has disrupted its ability to function properly.

Officials at the European Medicines Agency (EMA) announced the decision last week but say it’s only temporary. The UK’s decision to leave the European Union has forced the EMA to move its headquarters from London to Amsterdam by March, which has caused “significant staff loss,” the regulator said in announcing the pause.

Last year, the EMA estimated it had around 700 employees. It predicted that the move from London to Amsterdam would cost about 200 jobs.

“The temporary cuts in activities are required because it has become clear that the agency will lose more staff than initially anticipated,” the EMA said. “Staff who will not relocate to Amsterdam have already started to leave the agency and this trend is expected to accelerate.”

Dutch labor law also means that the EMA will have to shed some 135 short-term contractors in the move. Overall, the agency said it expects to lose about 30 percent of its staff by March.

The agency did not provide further specifics on the number or types of jobs lost or the timeline for its temporary measures. The cutbacks do not appear to affect clinical trials themselves but European regulators have stressed the importance of data transparency.

The EMA also wants to put some of its international efforts on hold, noting that for now it will focus on “urgent” drug safety guidelines and limit travel to “Brexit-related interactions.”

Even before last week’s announcement, European regulators had been sounding alarms about Brexit. Last month, the EMA released the results of a survey of drugmakers that found hundreds would have to rearrange at least part of their inspection or database operations because European law no long covers them in the UK.

A thin majority of voters supported a referendum pulling the UK out of the European Union in 2016. The following March, British Prime Minister Theresa May sent formal notice to the EU that her government was leaving, giving both sides a year to settle on terms of the divorce.

The EMA Brexit may disrupt drug approvals and safety inspections for two to three years after Brexit takes effect.
Celebrating 50 Years of Pioneering, Together.

It isn’t in our nature to seek the limelight or to sing our own praises. But when you turn 50, well, that’s something pretty special. We don’t want to celebrate alone though, because we know the real power comes from pioneering together. To all of those who share our passion for protecting people and are inspired by science and medical discovery, a heart felt thank you for joining us on our first 50 years of pioneering together!
## Drug & Device Pipeline News

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clover Biopharmaceuticals, Inc.</td>
<td>SCB-808</td>
<td>rheumatoid arthritis (RA) and other autoimmune diseases</td>
<td>Phase I trial initiated</td>
<td>cloverbiopharma.com</td>
</tr>
<tr>
<td>Arcus Biosciences, Inc.</td>
<td>AB154</td>
<td>anti-TIGIT antibody</td>
<td>Phase I trial initiated</td>
<td>arcusbio.com</td>
</tr>
<tr>
<td>CeraPedics</td>
<td>P-15L Peptide Enhanced Bone Graft</td>
<td>transforaminal lumbar interbody fusion (TLIF) surgery</td>
<td>Phase I trial initiated enrolling 364 subjects</td>
<td>cerapedics.com</td>
</tr>
<tr>
<td>BioLineRx Ltd.</td>
<td>AGI-134</td>
<td>patient-specific tumor neoantigens</td>
<td>Phase I/IIa trial initiated</td>
<td>biolinerx.com</td>
</tr>
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<td>Avelas BioSciences, Inc.</td>
<td>AVB-620</td>
<td>primary, non-recurrent breast cancer undergoing surgery</td>
<td>Period II, Phase II trial initiated enrolling 31 subjects</td>
<td>avelasbio.com</td>
</tr>
<tr>
<td>Biohaven Pharmaceutical Holding Company, Ltd.</td>
<td>trigriluzole (BHV-4157)</td>
<td>mild-to-moderate Alzheimer's disease (AD)</td>
<td>Phase II/III trial initiated enrolling 292 subjects</td>
<td>biohavenpharma.com</td>
</tr>
<tr>
<td>Kala Pharmaceuticals, Inc.</td>
<td>KPI-121 0.25%</td>
<td>dry eye disease</td>
<td>Phase III trial initiated enrolling 900 subjects</td>
<td>kalarx.com</td>
</tr>
<tr>
<td>GE Healthcare and Lantheus Holdings, Inc.</td>
<td>Flurpiridax</td>
<td>coronary artery disease</td>
<td>Phase III trial initiated enrolling 650 subjects</td>
<td>gehealthcare.com lantheus.com</td>
</tr>
<tr>
<td>Progenics Pharmaceuticals</td>
<td>Azedra</td>
<td>adult and pediatric subjects 12 years and older with iodobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy</td>
<td>NDA approval granted by the FDA</td>
<td>progenics.com</td>
</tr>
<tr>
<td>United Therapeutics Corporation</td>
<td>Remodulin</td>
<td>pulmonary arterial hypertension (PAH)</td>
<td>NDA approval granted by the FDA</td>
<td>unither.com</td>
</tr>
<tr>
<td>Sensus Healthcare, Inc.</td>
<td>SRT-100+</td>
<td>non-melanoma skin cancer and keloids</td>
<td>510(k) clearance granted by the FDA</td>
<td>sensushealthcare.com</td>
</tr>
<tr>
<td>Modulated Imaging</td>
<td>Clarifi Imaging System</td>
<td>peripheral vascular diseases, diabetic foot ulcers, burns, skin flaps and chronic wounds</td>
<td>510(k) clearance granted by the FDA</td>
<td>modulatedimaging.com</td>
</tr>
<tr>
<td>Daiichi Sankyo Company, Ltd.</td>
<td>quizartinib</td>
<td>relapsed/refractory FLT3-ITD acute myeloid leukemia (AML)</td>
<td>Breakthrough Therapy Designation granted by the FDA</td>
<td>daiichisankyo.com</td>
</tr>
<tr>
<td>Armagen Inc.</td>
<td>GT-184</td>
<td>Mucopolysaccharidosis type IIIA (also known as Sanfilippo Syndrome A or MPS IIIA)</td>
<td>Orphan Drug Designation granted by the FDA</td>
<td>armagen.com</td>
</tr>
<tr>
<td>Endomag</td>
<td>Magtrace</td>
<td>breast cancer</td>
<td>PMA granted by the FDA</td>
<td>endomagnetics.com</td>
</tr>
<tr>
<td>Hologic, Inc.</td>
<td>Panther Fusion GBS assay</td>
<td>Group B Streptococcus (GBS)</td>
<td>Clearance granted by the FDA</td>
<td>hologic.com</td>
</tr>
<tr>
<td>Shionogi &amp; Co., Ltd.</td>
<td>Mulpleta (lusutrombopag)</td>
<td>thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure</td>
<td>Approval granted by the FDA</td>
<td>shionogi.co.jp/en/</td>
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<tr>
<td>Roche</td>
<td>cobas</td>
<td>cervical cancer</td>
<td>Approval granted by the FDA</td>
<td>roche.com</td>
</tr>
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<td>Indivior PLC</td>
<td>PERSERIS</td>
<td>schizophrenia</td>
<td>Approval granted by the FDA</td>
<td>indivior.com</td>
</tr>
</tbody>
</table>

For news on trial results, FDA approvals and drugs in development, Join the LinkedIn Drug Research Updates group!
Promising Crohn’s Therapy
RedHill Biopharma announced positive top-line safety and efficacy results from the first Phase III study with RHB-104 for Crohn’s disease (the MAP US study). The study successfully met its primary and key secondary endpoints. Top-line results in the intent-to-treat (ITT) population demonstrated superiority of RHB-104 over placebo in achieving remission at week 26, defined as Crohn’s Disease Active Index (CDAI) value of less than 150, the primary endpoint of the study. The proportion of patients meeting the primary endpoint was significantly greater in the RHB-104 group compared to placebo (37 percent vs. 23 percent, p=0.013). The study also successfully met key secondary endpoints, demonstrating consistent benefit to Crohn’s disease patients treated with RHB-104. The MAP US randomized, double-blind, placebo-controlled first Phase III study of RHB-104 included 331 subjects with moderately to severely active Crohn’s disease in the U.S., Canada, Europe, Australia, New Zealand and Israel. Subjects were randomized 1:1 to receive RHB-104 or placebo in addition to baseline background medication including of 5-ASAs, corticosteroids, immunomodulators or anti-TNFα agents. RHB-104 was found to be generally safe and well tolerated. Top-line results demonstrated that the active and placebo treatment groups experienced similarly low rates of serious adverse events and treatment emergent adverse events, indicating a positive safety profile for RHB-104.

Positive Dupuytren’s Trial
180 Therapeutics LP announced positive results from a Phase IIa clinical trial of the anti-TNF monoclonal antibody, adalimumab, in patients suffering from Dupuytren’s disease. The randomized, dose response, placebo-controlled Phase IIa trial involved 28 patients with Dupuytren’s disease who were scheduled to receive elective surgery to remove diseased tissue from their hands. They received either a placebo or a single injection of the anti-TNF drug, adalimumab, at various dose levels, two weeks before scheduled surgery. The tissue removed during surgery was then analyzed in the laboratory. Adalimumab, at a dose of 40mg, reduced expression of the fibrotic markers, α-smooth muscle actin (α-SMA) and type I procollagen proteins, at two weeks post injection, suggesting anti-TNF therapy may help treat early Dupuytren’s disease by blocking activity of disease-causing myofibroblast cells. The dose-ranging study found that injection of the anti-TNF drug into Dupuytren’s disease nodules reduced key cellular fibrosis markers. The treatment was found to be well-tolerated.

First Patient Dosing in STRIDE 3
Kala Pharmaceuticals announced that the first patient has been dosed in STRIDE 3 (Short Term Relief in Dry Eye), its Phase III trial of KPI-121 0.25% for the short-term treatment of dry eye disease. The STRIDE 3 trial is a multicenter, randomized, double-blind, placebo controlled, parallel-arm study comparing KPI-121 0.25% to placebo, each dosed four times a day (QID) for 14 days, in approximately 900 patients with dry eye disease. Subjects who meet initial screening and inclusion/exclusion criteria undergo a two-week run-in period with placebo. Subjects who continue to meet inclusion/exclusion criteria after the run-in are randomized to either KPI-121 0.25% or placebo. The primary endpoint, Day 15 ocular discomfort severity, is based upon a patient diary in which ocular discomfort is recorded daily over the entire course of the trial using a visual analog grading scale. KPI-121 0.25% achieved statistical significance for the primary sign endpoint of conjunctival hyperemia at Day 15 in the intent to treat (ITT) population in both Phase III trials. KPI-121 0.25% was well-tolerated in both Phase III trials with elevation in intra-ocular pressure, a known side effect with topical corticosteroids, similar to placebo.

NVAMD Trial Encouraging
RXi Pharmaceuticals Corporation announced positive results with RXI-109 in a Phase I/II clinical trial. RXI-109-1501 is an open-label, multi-dose, dose escalation study with three dose cohorts, enrolled sequentially, evaluating the safety and tolerability of RXI-109 injections in the eye of subjects with advanced neovascular age-related macular degeneration (NVAMD) or ‘wet’ age-related macular degeneration, and accompanying subretinal fibrosis. During this study, the clinical effect of these injections was evaluated as a secondary endpoint. Nine subjects were enrolled, three in each of the following dosage groups: Cohort 1 (low dose), Cohort 2 (intermediate dose), Cohort 3 (high dose). Each subject received a total of four doses of RXI-109 at one-month intervals. RXI-109 was administered by intravitreal injection in one eye only. The dosing period (three months) was followed by a four-month observation period. In total, 25 AEs were reported, 13 in Cohort 1, seven in Cohort 2 and five in Cohort 3. The severity of all these AEs was either mild or moderate: 18 of these AEs were considered mild and the other seven AEs were considered moderate. The primary objective of this study was to evaluate the safety and tolerability of ocular injections with RXI-109. The primary objective was met as shown by the absence of dose-limiting and serious toxicities, and only mild to moderate procedure related adverse events. None of the adverse events were drug-related. In addition, comprehensive ocular examinations showed no indications of inflammation or other tolerability issues related to the treatment, indicating RXI-109 was safe and well tolerated by patients in the three dosage groups.
Twice monthly, CWWeekly provides featured listings of clinical research job openings, upcoming industry conferences and educational programs from JobWatch, CenterWatch’s online recruitment website for both clinical research employers and professionals.

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- **Bioinformatics Scientist**
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  TRiNDS, LLC
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  Covance
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- **Senior Clinical Data Manager**
  Brighttech International
  Somerset, NJ
- **Manager, Clinical Trials**
  Ferring Pharmaceuticals, Inc.
  Parsippany, NJ
- **Project Assistant - Clinical Trials**
  Pharmatech Inc.
  Denver, CO

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### Academic Programs

- **Boston College**
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- **Drexel University College of Medicine**
  Master’s/Certificate Programs in Clinical Research Organization and Management
  Online
- **University of North Carolina at Wilmington**
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  Online

[ VIEW ACADEMIC PROGRAM DETAILS ]

### Upcoming Event Highlights

#### Conferences
- **SEPTEMBER 10-12, 2018**
  Mastering EU Medical Device Regulation
  Philadelphia, PA
- **SEPTEMBER 27, 2018**
  Emerging Biopharmaceutical Therapies
  Washington, DC
- **OCTOBER 23-25, 2018**
  FDA Inspections Summit - 13th Annual
  Bethesda, MD

[ VIEW ALL CONFERENCES ]

#### Training Programs
- **SEPTEMBER 1-31, 2018**
  Program Phlebotomy Training — Two Day Training
  Various locations

[ VIEW ALL TRAINING PROGRAMS ]

#### Webinars
- **AUGUST 14, 2018**
  MDR Adverse Event Codes for Devicemakers
  New challenges arising to completion of Form 3500A. Dan O’Leary, one of our top-rated presenters, introduces you to the new coding regimen and walks you through eSubmitter’s twists, turns and tricks.

- **AUGUST 15, 2018**
  Getting Real About Real World Evidence: Practical Next Steps for Drug and Device Manufacturers
  Sonali P. Gunawardhana Esq., one of the sharpest legal minds to emerge from the FDA in recent years, and Dr. Mary Jo Lambert, a faculty member at Tufts CSDD, will walk you through the fast-moving RWE changes currently affecting the agency and business decisions alike.

[ VIEW ALL WEBINARS ]